H-E-W's RESPONSE TO GENERAL ACCOUNTING OFFICE's FIRST DRAFT OF REPORT, REVEALS STRUGGLE TO ERECT PATENT APPARATUS DESPITE POOR POLICY BASE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
WASHINGTON, D.C. 20201

OFFICE OF THE SECRETARY

MAR 20 1968

Dear Mr. Rabel:

The Secretary has asked that I reply to your draft report to the Congress entitled, "Review of Grants for Research in Medicinal Chemistry, National Institutes of Health, Public Health Service, Department of Health, Education, and Welfare."

The effective utilization of the results of Department-sponsored research, including any compounds that may be synthesized or identified, is considered to be an essential part of the Department's program goals. The problems relating to the screening and testing of such compounds have been under continuing review within the Department. Some changes have been made in our administrative practices and procedures to encourage such screening, and additional changes will be made where found to be appropriate.

We would like to comment briefly on some significant aspects of the draft report and to bring you up to date on the status of pertinent activities within the Department. The report indicates that investigators have alleged that their collaboration with the pharmaceutical industry for screening and testing generally ended in early 1962 when the PHS required that the screening organization and the grantee institution execute a formal patent agreement. We wish to point out that this patent agreement did not involve any change in PHS policy. It merely formalized in writing the relationship and respective rights of the parties in light of the investigator's obligations to the PHS under his grant agreement.

As noted in the Report, HEW has considered a number of changes in the patent agreement required to be signed for screening. During 1967, a revised form of agreement was put into effect, a copy of which is attached.[1] The form of the agreement currently in use differs significantly from that originally required in 1962. It does not restrict the tester's rights of ownership to new uses of compounds which it may discover at its own expense without the participation or suggestion of the PHS investigator even "where such new use is within the field of research work supported by the grant." We understand that restrictions of this type in agreements formerly in use were unacceptable to a number of pharmaceutical companies.

Our records indicate that the revised agreement is acceptable to some members of the pharmaceutical industry who are interested in providing screening and testing services, and that PHS investigators and pharmaceutical companies entered into 53 agreements using the revised form during calendar year 1967. The form of the required patent agreement will undergo further review, and additional changes will be made where appropriate to assure recognition of the respective rights and interests of the PHS, its investigators and organizations performing screening and testing services.

As noted in the Report, it is the general policy of this Department that the results of Department research should be widely, promptly, and freely available to other research workers and the public. At the same time, the policy recognizes that in some situations, and particularly where commercial development of inventions will be costly, the public interest can best be served if a developer is granted some exclusivity for a limited period of time.

Section 8.1(b) of the Department Patent Regulations provides that ownership of inventions made under Department-sponsored research may be left to a grantee institution for administration in accordance with the grantee's

[1] GAO note: Attachment not included.

established policies and procedures with such modifications as may be agreed upon, provided that the Assistant Secretary, Health and Scientific Affairs, finds that the policies and procedures, as modified, are such as to assure that the invention will be made available without unreasonable restrictions or excessive royalties. This aspect of Department patent policy has been undergoing review, and it was recently reaffirmed that the policy serves the public interest and should be continued.

At the present time, a revised standard basic Institutional Patent Agreement, to be utilized under Section 8.1(b), is under preparation. This Agreement will permit the grantee institution to retain and to administer the principal ownership rights in inventions made under Department grants and awards, will clearly define the rights of the parties with respect to such inventions, and will set forth general guidelines governing the licensing of inventions, including limitations on the duration of exclusive licenses that may be granted. It will also include the reservation of a royalty-free license to the Government and other appropriate safeguards to protect the public interest, including all of those specified in the 1963 Presidential Statement of Government Patent Policy. These latter safeguards will include a reservation to the Government of the right to require the granting of additional licenses royalty-free or on terms that are reasonable under the circumstances where such licenses are necessary to fulfill public health, welfare or safety requirements. As soon as the terms of this basic agreement can be fully developed, the existing agreements will be terminated and standard agreements will be entered into with qualified grantee institutions.

We consider that the Institutional Patent Agreements will go far towards solving the problems encountered by investigators in connection with the screening and testing of compounds synthesized or identified under Department-sponsored research and will, at the same time, fully protect the public interest. An Institutional Patent Agreement will

authorize a grantee institution to enter into agreements with pharmaceutical companies for the screening and testing of compounds and to agree to grant limited exclusive licenses to any inventions that may result from the screening. All such licenses will be required to include the conditions and safeguards specified in the Institutional Patent Agreement.

Section 8.2(b) of the Department Patent Regulations authorizes the Assistant Secretary, Health and Scientific Affairs, to permit assignment of an invention by the inventor to a competent organization on a case-by-case basis where he finds that the invention will thereby be more adequately and quickly developed for widest use, and that there are satisfactory safeguards against unreasonable royalties and repressive practices. During 1967, efforts were made to expedite the issuance of determinations pursuant to this provision. Since April 1, 1967, fifteen determinations have been issued pursuant to Section 8.2(b) permitting assignment of inventions to grantee institutions. A number of requests are pending, and it is our intent to continue to act on such requests as expeditiously as possible. We intend to continue to utilize this provision of the Regulations where an Institutional Patent Agreement is not in effect.

During our review of the problems associated with screening and testing of compounds arising out of Department-sponsored research, it has become apparent that there is a clear-cut need for a comprehensive statement of the Department's policies and requirements regarding this subject. Therefore, it is our intent to issue a statement outlining the Department's policies regarding screening and testing of compounds and clearly setting forth the alternative methods of obtaining screening and testing services that are available to investigators supported by the Department. This statement will encourage the utilization of Government facilities, including the Cancer Chemotherapy National Service Center (CCNSC) and the Walter Reed Army Institute of Research for screening whenever appropriate.

In summary, we consider that the results of Department-sponsored research, including newly synthesized or identified compounds, constitute a valuable national resource, and that the effective utilization of such compounds is an essential part of the Department's program goals. We intend to continue to make such changes in our practices as are necessary to foster the fullest utilization of all compounds synthesized or identified during the course of research supported by the Department in such a manner as to recognize and protect the legitimate interests of the public, the investigator, and the screening organizations.

Sincerely yours,

James F. Kelly
Assistant Secretary,
Comptroller

Mr. Frederick K. Rabel
Assistant Director
Civil Accounting and
Auditing Division
United States General Accounting Office
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Attachment [1]

[1]GAO note: Attachment not included.