with paragraph (d)(1) in § 1-9.107-5 (f);

(3) An *irrevocable*, nonexclusive, royalty-free license in the inventions, in which case paragraph (d) of the Patent Rights clauses in § 1-9.107-5 shall be replaced with paragraph (d) in § 1-9.107-5(g); or

(4) An *irrevocable*, nonexclusive, royalty-free license in inventions constructively reduced to practice prior to the effective date of the contract, in which case paragraph (d)(4) of § 1-9.107-5(h) shall be added to the Patent Rights clauses in § 1-9.107-5.

(f) *Subcontracts.* (1) The policy expressed in § 1-9.107-3 is applicable to prime contracts and to subcontracts regardless of tier. The appropriate Patent Rights clause prescribed by this subpart shall be included in all subcontracts having as a purpose the conduct of experimental, developmental, or research work. In general, the Patent Rights clause in the prime contract, with the exception of the withholding provision, will be appropriate for inclusion in such subcontracts. Whenever the prime contractor or a subcontractor considers the inclusion of the Patent Rights clause of the prime contract in a subcontract to be inconsistent with the policy expressed in § 1-9.107-3, or a subcontractor refuses to accept a Patent Rights clause in his subcontract, the matter shall be referred to the agency contracting officer for resolution prior to the award of the subcontract. Upon such referral, the same considerations and procedures followed by the contracting officer in selecting the Patent Rights clause included in the prime contract shall be used in selecting the Patent Rights clause to be included in the subcontract.

(2) Contractors shall not use their ability to award subcontracts as economic leverage to acquire rights for themselves in the inventions resulting from subcontracts.

(g) *Publication of invention disclosures.* The Patent Rights clauses of § 1-9.107-5 and § 1-9.107-6 specify in paragraph (e)(4) and (b)(2), respectively, that the Government may duplicate and disclose invention disclosures reported under the contract. However, the publication of the information in an invention disclosure by any party before the filing of a patent application may create a bar to the filing of foreign patent applications. The agency may restrict the publication of such information by the contractor in order to protect the interests of the Government or the contractor in obtaining foreign patents by adding the paragraph prescribed by § 1-9.107-5(i)(2) as a consecutively-numbered paragraph after pargraph (e)(4) of the clauses of § 1-9.107-5, and after paragraph (b)(2) of the clauses of § 1-9.107-6. Where the contractor has been authorized to file foreign patent applications, the agency may desire to restrict its publication of the information in the related invention disclosure in order to protect the filing of such foreign applications by the contractor. In this event, the sentence in § 1-9.107-5(i)(1) should be added to paragraph (e)(4) of the Patent Rights clauses in § 1-9.107-5, and to paragraph (b)(2) of Patent Rights clauses in § 1-9.107-6.

(h) *Deviations.* Any departures from the policy, procedures, and clauses of this subpart shall be subject to the provisions of § 1-1.009.

§ 1-9.107-5 Clauses for domestic contracts (long form).

(a) *Patent Rights clause—Acquisition by the Government.* When the agency has determined that a contract falls within § 1-9.107-4(a)(2), the following clause shall be included in the contract.

PATENTS RIGHTS—ACQUISITION BY THE GOVERNMENT

(a) *Definitions.* (1) "Subject Invention" means any invention or discovery of the Contractor conceived or first actually reduced to practice in the course of or under this contract, and includes any art, method, process, machine, manufacture, design, or composition of matter, or any new and useful improvement thereof, or any variety of plant, which is or may be patentable under the Patent Laws of the United States of America or any foreign country.

(2) "Contract" means any contract, agreement, grant, or other arrangement, or subcontract entered into with or for the benefit of the Government where a purpose of the contract is the conduct of experimental, developmental, or research work.

(3) "States and domestic municipal governments" means the States of the United States, the District of Columbia, Puerto Rico, the Virgin Islands, American Samoa, Guam, the Trust Territory of the Pacific Islands, and any political subdivision and agencies thereof.

(4) "Government agency" includes an executive department, independent commission, board, office, agency, administration, authority, Government corporation, or other Government establishment of the executive branch of the Government of the United States of America.

(5) "To the point of practical ... means to manufacture in the ca... position or product, to practice ... of a process, or to operate in t... machine and under such cond... establish that the invention is ... and that its benefits are reasona... ble to the public.

(b) *Allocation of principal ri... signment to the Government.* Th... agrees to assign to the Governm... tire right, title, and interest thr... world in and to each Subject In... cept to the extent that rights ... by the Contractor under paragra... and (d) of this clause.

(2) *Greater rights determi...* Contractor or the employee-in... authorization of the Contractor ... greater rights than the nonexcl... provided in paragraph (d) of ... in accordance with the procedure... of 41 CFR 1-9.109-6. A request ... nation whether the Contractor ... ployee-inventor is entitled to ... greater rights must be submi... Contracting Officer at the time ... disclosure of the invention purs... graph (e)(2)(i) of this clause, ... than 3 months thereafter, or ... period as may be authorized by t... ing Officer for good cause show... by the Contractor. The inform... submitted for a greater rights ... is specified in 41 CFR 1-9.109... mination of greater rights un... tract normally shall be subject ... (c) of this clause and to the re... conditions deemed to be appro... agency.

(c) *Minimum rights acquired ... ernment.* With respect to each ... vention to which the Contractor ... cipal or exclusive rights, the Co...

(1) Hereby grants to the G... nonexclusive, nontransferable, ... cense to make, use, and sell each ... vention throughout the world by ... of the Government of the United ... cluding any Government agency ... and domestic municipal governm...

(2) Agrees to grant to respo... cants, upon request of the Gov... cense on terms that are reasona... circumstances:

(i) Unless the Contractor, h... his assignee demonstrates to the ... that effective steps have been ... 3 years after a patent issues on ... tion to bring the invention to ... practical application, or that it ... has been made available for licen... free or on terms that are reas... circumstances, or can show cau... principal or exclusive rights ob... tained for a further period of tim...

(ii) To the extent that the ... required for public use by gover... ulations or as may be necessary to ... lic health, safety or welfare ne...

ntractor in order to pro-
erests of the Government or
or in obtaining foreign pat-
ng the paragraph prescribed
-5(i)(2) as a consecutively-
aragraph after paragraph (e)
clauses of § 1-9.107-5, and
raph (b)(2) of the clauses
-6. Where the contractor has
rized to file foreign patent
, the agency may desire to
publication of the informa-
related invention disclosure
protect the filing of such
lications by the contractor.
t, the sentence in § 1-9.107-5
ld be added to paragraph (e)
atent Rights clauses in § 1-9.
o paragraph (b)(2) of Patent
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Clauses for domestic con-
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be included in the contract.

RIGHTS—ACQUISITION BY THE GOVERNMENT

tions. (1) "Subject Invention"
vention or discovery of the
eived or first actually reduced
the course of or under this
includes any art, method, proc-
, manufacture, design, or com-
matter, or any new and useful
t thereof, or any variety of plant,
may be patentable under the
of the United States of America
n country.
ract" means any contract, agree-
, or other arrangement, or sub-
ered into with or for the benefit
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he conduct of experimental, de-
, or research work.
s and domestic municipal gov-
neans the States of the United
District of Columbia, Puerto Rico,
slands, American Samoa, Guam,
Territory of the Pacific Islands,
litical subdivision and agencies

rnment agency" includes an ex-
artment, independent commis-
, office, agency, administration,
overnment corporation, or other
establishment of the executive
the Government of the United
erica.

(5) "To the point of practical application" means to manufacture in the case of a composition or product, to practice in the case of a process, or to operate in the case of a machine and under such conditions as to establish that the invention is being worked and that its benefits are reasonably accessible to the public.

(b) *Allocation of principal rights.* (1) *Assignment to the Government.* The Contractor agrees to assign to the Government the entire right, title, and interest throughout the world in and to each Subject Invention, except to the extent that rights are retained by the Contractor under paragraphs (b)(2) and (d) of this clause.

(2) *Greater rights determinations.* The Contractor or the employee-inventor with authorization of the Contractor may retain greater rights than the nonexclusive license provided in paragraph (d) of this clause in accordance with the procedure and criteria of 41 CFR 1-9.109-6. A request for determination whether the Contractor or the employee-inventor is entitled to retain such greater rights must be submitted to the Contracting Officer at the time of the first disclosure of the invention pursuant to paragraph (e)(2)(i) of this clause, or not later than 3 months thereafter, or such longer period as may be authorized by the Contracting Officer for good cause shown in writing by the Contractor. The information to be submitted for a greater rights determination is specified in 41 CFR 1-9.109-6. Each determination of greater rights under this contract normally shall be subject to paragraph (c) of this clause and to the reservations and conditions deemed to be appropriate by the agency.

(c) *Minimum rights acquired by the Government.* With respect to each Subject Invention to which the Contractor retains principal or exclusive rights, the Contractor:

(1) Hereby grants to the Government a nonexclusive, nontransferable, paid-up license to make, use, and sell each Subject Invention throughout the world by or on behalf of the Government of the United States (including any Government agency) and States and domestic municipal governments;

(2) Agrees to grant to responsible applicants, upon request of the Government, a license on terms that are reasonable under the circumstances:

(i) Unless the Contractor, his licensee, or his assignee demonstrates to the Government that effective steps have been taken within 3 years after a patent issues on such invention to bring the invention to the point of practical application, or that the invention has been made available for licensing royalty-free or on terms that are reasonable in the circumstances, or can show cause why the principal or exclusive rights should be retained for a further period of time; or

(ii) To the extent that the invention is required for public use by governmental regulations or as may be necessary to fulfill public health, safety or welfare needs, or for other public purposes stipulated in this contract;

(3) Shall submit written reports at reasonable intervals upon request of the Government during the term of the patent on the Subject Invention regarding:

(i) The commercial use that is being made or is intended to be made of the invention; and

(ii) The steps taken by the Contractor or his transferee to bring the invention to the point of practical application or to make the invention available for licensing;

(4) Agrees to refund any amounts received as royalty charges on any Subject Invention in procurements for or on behalf of the Government and to provide for that refund in any instrument transferring rights to any party in the invention; and

(5) Agrees to provide for the Government's paid-up license pursuant to paragraph (c)(1) of this clause in any instrument transferring rights in a Subject Invention and to provide for the granting of licenses as required by (2) of this clause, and for the reporting of utilization information as required by paragraph (c)(3) of this clause whenever the instrument transfers principal or exclusive rights in any Subject Invention.

Nothing contained in this paragraph (c) shall be deemed to grant to the Government any rights with respect to any invention other than a Subject Invention.

(d) *Minimum rights to the Contractor.* (1) The Contractor reserves a *revocable*, nonexclusive, royalty-free license in each patent application filed in any country on a Subject Invention and any resulting patent in which the Government acquires title. The license shall extend to the Contractor's domestic subsidiaries and affiliates, if any, within the corporate structure of which the Contractor is a part and shall include the right to grant sublicenses of the same scope to the extent the Contractor was legally obligated to do so at the time the contract was awarded. The license shall be transferable only with approval of the agency except when transferred to the successor of that part of the Contractor's business to which the invention pertains.

(2) The Contractor's nonexclusive domestic license retained pursuant to paragraph (d)(1) of this clause may be revoked or modified by the agency to the extent necessary to achieve expeditious practical application of the Subject Invention under 41 CFR 101-4.103-3 pursuant to an application for exclusive license submitted in accordance with 41 CFR 101-4.104-3. This license shall not be revoked in that field of use and/or the geographical areas in which the Contractor has brought the invention to the point of practical application and continues to make the benefits of the invention reasonably accessible to the public. The Contractor's nonexclusive license in any foreign country reserved pursuant to paragraph

(d) (1) of this clause may be revoked or modified at the discretion of the agency to the extent the Contractor or his domestic subsidiaries or affiliates have failed to achieve the practical application of the invention in that foreign country.

(3) Before modification or revocation of the license, pursuant to paragraph (d) (2) of this clause, the agency shall furnish the Contractor a written notice of its intention to modify or revoke the license, and the Contractor shall be allowed 30 days (or such longer period as may be authorized by the agency for good cause shown in writing by the Contractor) after the notice to show cause why the license should not be modified or revoked. The Contractor shall have the right to appeal, in accordance with procedures prescribed by the agency, any decision concerning the modification or revocation of his license.

(e) *Invention, identification, disclosures, and reports.* (1) The Contractor shall establish and maintain active and effective procedures to ensure that Subject Inventions are promptly identified and timely disclosed. These procedures shall include the maintenance of laboratory notebooks or equivalent records and any other records that are reasonably necessary to document the conception and/or the first actual reduction to practice of Subject Inventions, and records which show that the procedures for identifying and disclosing the inventions are followed. Upon request, the Contractor shall furnish the Contracting Officer a description of these procedures so that he may evaluate and determine their effectiveness.

(2) The Contractor shall furnish the Contracting Officer:

(i) A complete technical disclosure for each Subject Invention within 6 months after conception or first actual reduction to practice whichever occurs first in the course of or under the contract, but in any event prior to any on sale, public use, or publication of such invention known to the Contractor. The disclosure shall identify the contract and inventor and shall be sufficiently complete in technical detail and appropriately illustrated by sketch or diagram to convey to one skilled in the art to which the invention pertains a clear understanding of the nature, purpose, operation, and, to the extent known, the physical, chemical, biological, or electrical characteristics of the invention;

(ii) Interim reports[1] at least every 12 months from the date of the contract listing Subject Inventions for that period and certifying that:

(A) The Contractor's procedures for identifying and disclosing Subject Inventions as required by this paragraph (e) have been followed throughout the reporting period; and

(B) All Subject Inventions have been disclosed or that there are no such inventions; and

(iii) A final report[1] within 3 months after completion of the contract work, listing all Subject Inventions or certifying that there were no such inventions.

(3) The Contractor shall obtain patent agreements to effectuate the provisions of this clause from all persons in his employ who perform any part of the work under this contract except nontechnical personnel, such as clerical employees and manual laborers.

(4) The Contractor agrees that the Government may duplicate and disclose Subject Invention disclosures and all other reports and papers furnished or required to be furnished pursuant to this clause.

(f) *Forfeiture of rights in unreported Subject Inventions.* (1) The Contractor shall forfeit to the Government all rights in any Subject Invention which he fails to disclose to the Contracting Officer within 6 months after the time he:

(i) Files or causes to be filed a United States or foreign application thereon; or

(ii) Submits the final report required by paragraph (e) (2) (iii) of this clause, whichever is later.

(2) However, the Contractor shall not forfeit rights in a Subject Invention if, within the time specified in (1) (i) or (1) (ii) of this paragraph (f), the Contractor:

(i) Prepared a written decision based upon a review of the record that the invention was neither conceived nor first actually reduced to practice in the course of or under the contract; or

(ii) Contending that the invention is not a Subject Invention, he nevertheless discloses the invention and all facts pertinent to his contention to the Contracting Officer; or

(iii) Establishes that the failure to disclose did not result from his fault or negligence.

(3) Pending written assignment of the patent applications and patents on a Subject Invention determined by the Contracting Officer to be forfeited (such determination to be a final decision under the Disputes Clause), the Contractor shall be deemed to hold the invention and the patent applications and patents pertaining thereto in trust for the Government. The forfeiture provision of this paragraph (f) shall be in addition to and shall not supersede other rights and remedies which the Government may have with respect to Subject Inventions.

(g) *Examination of records relating to inventions.* (1) The Contracting Officer or his authorized representative until the expiration of 3 years after final payment under this contract shall have the right to examine any books (including laboratory notebooks), records, documents, and other supporting data of the Contractor which the Contracting Officer reasonably deems pertinent to the discovery or identification of Subject Inventions to determine compliance with the requirements of this clause.

(2) The Contracting Officer shall have the right to review all books (including laboratory notebooks), records and ... the Contractor relating to the ... first actual reduction to prac... tions in the same field of tech... work under this contract ... whether any such invention... Inventions if the Contractor re... to:

(i) Establish the procedures ... (e) (1) of this clause; or

(ii) Maintain and follow such ... or

(iii) Correct or eliminate ... deficiency in the procedures ... (30) days after the Contracting ... fies the Contractor of such a d...

(h) *Withholding of payments ... cable to Subcontracts).* (1) A... final payment of the amount ... tract, the Contracting Officer ... deems such action warranted, ... ment until a reserve not exc... or 5 percent of the amount of ... whichever is less, shall have ... if in his opinion the Contract...

(i) Establish, maintain, an... tive procedures for identifyi... ing Subject Inventions pur... graph (e) (1) of this clause; ...

(ii) Disclose any Subject I... suant to paragraph (e) (2) (i) ... or

(iii) Deliver acceptable f... pursuant to paragraph (e) ... clause; or

(iv) Provide the inform... subcontracts pursuant to par... this clause.

The reserve or balance sh... until the Contracting Officer ... that the Contractor has re... deficiencies exist and has ... ports, disclosures, and other ... quired by this clause.

(2) Final payment under ... shall not be made before the ... livers to the Contracting O... sures of Subject Inventio... paragraph (e) (2) (i) of this ... acceptable final report purs... (iii) of this clause.

(3) The Contracting Offi... discretion, decrease or incr... withheld up to the maxim... above. If the Contractor is ... ganization the maximum am... be withheld under this para... exceed $50,000 or 1 percent ... this contract whichever is ... shall be withheld under this ... the amount specified by th... being withheld under other ... contract. The withholding ... or subsequent payment there... construed as a waiver of any ... to the Government under th...

(i) *Subcontracts.* (1) For ... this paragraph the term ... means the party awarding a ... the term "Subcontractor" ...

[1] Agency may specify form.

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determine compliance with
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ntracting Officer shall have the
w all books (including labora-

tory notebooks), records and documents of the Contractor relating to the conception or first actual reduction to practice of inventions in the same field of technology as the work under this contract to determine whether any such inventions are Subject Inventions if the Contractor refuses or fails to:

(i) Establish the procedures of paragraph (e) (1) of this clause; or

(ii) Maintain and follow such procedures; or

(iii) Correct or eliminate any material deficiency in the procedures within thirty (30) days after the Contracting Officer notifies the Contractor of such a deficiency.

(h) *Withholding of payment (Not applicable to Subcontracts).* (1) Any time before final payment of the amount of this contract, the Contracting Officer may, if he deems such action warranted, withhold payment until a reserve not exceeding $50,000 or 5 percent of the amount of this contract, whichever is less, shall have been set aside if in his opinion the Contractor fails to:

(i) Establish, maintain, and follow effective procedures for identifying and disclosing Subject Inventions pursuant to paragraph (e) (1) of this clause; or

(ii) Disclose any Subject Invention pursuant to paragraph (e) (2) (i) of this clause; or

(iii) Deliver acceptable interim reports pursuant to paragraph (e) (2) (ii) of this clause; or

(iv) Provide the information regarding subcontracts pursuant to paragraph (i) (5) of this clause.

The reserve or balance shall be withheld until the Contracting Officer has determined that the Contractor has rectified whatever deficiencies exist and has delivered all reports, disclosures, and other information required by this clause.

(2) Final payment under this contract shall not be made before the Contractor delivers to the Contracting Officer all disclosures of Subject Inventions required by paragraph (e) (2) (i) of this clause, and an acceptable final report pursuant to (e) (2) (iii) of this clause.

(3) The Contracting Officer may, in his discretion, decrease or increase the sums withheld up to the maximum authorized above. If the Contractor is a nonprofit organization the maximum amount that may be withheld under this paragraph shall not exceed $50,000 or 1 percent of the amount of this contract whichever is less. No amount shall be withheld under this paragraph while the amount specified by this paragraph is being withheld under other provisions of the contract. The withholding of any amount or subsequent payment thereof shall not be construed as a waiver of any rights accruing to the Government under this contract.

(i) *Subcontracts.* (1) For the purpose of this paragraph the term "Contractor" means the party awarding a subcontract and the term "Subcontractor" means the party being awarded a subcontract, regardless of tier.

(2) Unless otherwise authorized or directed by the Government Contracting Officer, the Contractor shall include this Patent Rights clause modified to identify the parties in any subcontract hereunder if a purpose of the subcontract is the conduct of experimental, developmental, or research work. In the event of refusal by a Subcontractor to accept this clause, or if in the opinion of the Contractor this clause is inconsistent with the policy set forth in 41 CFR 1-9.107-3, the Contractor:

(i) Shall promptly submit a written notice to the Government Contracting Officer setting forth reasons for the Subcontractor's refusal and other pertinent information which may expedite disposition of the matter; and

(ii) Shall not proceed with the subcontract without the written authorization of the Government Contracting Officer.

(3) The Contractor shall not, in any subcontract or by using a subcontract as consideration therefor, acquire any rights in his Subcontractor's Subject Invention for his own use (as distinguished from such rights as may be required solely to fulfill his contract obligations to the Government in the performance of this contract).

(4) All invention disclosures, reports, instruments, and other information required to be furnished by the Subcontractor to the Government Contracting Officer under the provisions of a Patent Rights clause in any subcontract hereunder may, in the discretion of the Government Contracting Officer, be furnished to the Contractor for transmission to the Government Contracting Officer.

(5) The Contractor shall promptly notify the Government Contracting Officer in writing upon the award of any subcontract containing a Patent Rights clause by identifying the Subcontractor, the work to be performed under the subcontract, and the dates of award and estimated completion. Upon request of the Government Contracting Officer, the Contractor shall furnish a copy of the subcontract. If there are no subcontracts containing Patent Rights Clauses, a negative report shall be included in the final report submitted pursuant to paragraph (e) (2) (iii) of this clause.

(6) The Contractor shall identify all Subject Inventions of the Subcontractor of which he acquires knowledge in the performance of this contract and shall notify the Government Contracting Officer promptly upon the identification of the inventions.

(7) It is understood that the Government is a third party beneficiary of any subcontract clause granting rights to the Government in Subject Inventions, and the Contractor hereby assigns to the Government all rights that he would have to enforce the Subcontractor's obligations for the benefit of the Government with respect to Subject Inventions. The Contractor shall not

66-007 O—76——30

...e obligated to enforce the agreements of ...ny Subcontractor hereunder relating to the ...bligations of the Subcontractor to the Gov...rnment in regard to Subject Inventions.

(b) *Patent Rights clause—Retention by the Contractor.* When the agency has determined that a contract falls within § 1-9.107-4(a)(3), the Patent Rights clause in § 1-9.107-5(a) shall be included in the contract, except that the name of the clause shall be changed to "Patent Rights—Retention by the Contractor", paragraph (b) of that clause shall be replaced by the following paragraph (b), and the following paragraphs (j) and (k) shall be added:

(b) *Allocation of principal rights.* (1) The Contractor may retain the entire right, title, and interest throughout the world or in any country thereof in and to each Subject Invention disclosed pursuant to paragraph (e)(2)(i) of this clause, subject to the rights obtained by the Government in paragraph (c) of this clause. The Contractor shall include with each Subject Invention disclosure an election as to whether he will retain the entire right, title, and interest in the invention throughout the world or any country thereof.

(2) Subject to the license specified in paragraph (d) of this clause, the Contractor agrees to convey to the Government, upon request, the entire domestic right, title, and interest in any Subject Invention when the Contractor:

(i) Does not elect under paragraph (b)(1) of this clause to retain such rights; or

(ii) Fails to have a United States patent application filed on the invention in accordance with paragraph (j) of this clause, or decides not to continue prosecution of such application; or

(iii) At any time, no longer desires to retain title.

(3) Subject to the license specified in paragraph (d) of this clause, the Contractor agrees to convey to the Government upon request the entire right, title, and interest in any Subject Invention in any foreign country if the Contractor:

(i) Does not elect under paragraph (b)(1) of this clause to retain such rights in the country; or

(ii) Fails to have a patent application filed in the country on the invention in accordance with paragraph (k) of this clause, or decides not to continue prosecution or to pay any maintenance fees covering the invention. To avoid forfeiture of the patent application or patent, the Contractor shall notify the Contracting Officer not less than 60 days before the expiration period for any action required by the foreign patent office.

(4) A conveyance requested pursuant to paragraph (b)(2) or (3) of this clause shall be made by delivering to the Contracting Officer duly executed instruments (prepared by the Government) and such other papers as are deemed necessary to vest in the Government the entire right, title, and interest to enable the Government to apply for and prosecute patent applications covering the invention in this or the foreign country, respectively, or otherwise establish its ownership of the invention.

(j) *Filing of domestic patent applications.*

(1) With respect to each Subject Invention in which the Contractor elects to retain domestic rights pursuant to paragraph (b) of this clause, the Contractor shall have a domestic patent application filed within 6 months after submission of the invention disclosure pursuant to paragraph (e)(2)(i) of this clause or such longer period as may be approved by the Contracting Officer for good cause shown in writing by the Contractor. With respect to the invention, the Contractor shall promptly notify the Contracting Officer of any decision not to file an application.

(2) For each Subject Invention on which a patent application is filed by or on behalf of the Contractor, the Contractor shall:

(i) Within 2 months after the filing or within 2 months after submission of the invention disclosure if the patent application previously has been filed, deliver to the Contracting Officer a copy of the application as filed including the filing date and serial number;

(ii) Include the following statement in the second paragraph of the specification of the application and any patents issued on a Subject Invention, "The Government has rights in this invention pursuant to Contract No. ------- (or Grant No. -------) awarded by (identify the agency).";

(iii) Within 6 months after filing the application or within 6 months after submitting the invention disclosure if the application has been filed previously, deliver to the Contracting Officer a duly executed and approved instrument on a form specified by the Government fully confirmatory of all rights to which the Government is entitled, and provide the agency an irrevocable power to inspect and make copies of the patent application filed;

(iv) Provide the Contracting Officer with a copy of the patent within 2 months after a patent is issued on the application; and

(v) Not less than 30 days before the expiration of the response period for any action required by the Patent and Trademark Office, notify the agency of any decision not to continue prosecution of the application and deliver to the agency executed instruments granting the Government a power of attorney.

(3) For each Subject Invention in which the Contractor initially elects not to retain principal domestic rights, the Contractor shall inform the Contracting Officer promptly in writing of the date and identity of any on sale, public use, or publication of the invention which may constitute a statutory bar under 35 U.S.C. 102, which w... ized by or known to the Contra... contemplated action of this natu...

(k) *Filing of foreign patent ...*

(1) With respect to each Subje... in which the Contractor elects to ... cipal rights in a foreign count... to paragraph (b)(1) of this cla... tractor shall have a patent appl... on the invention in that country, ance with applicable statutes ... tions, and within one of th... periods:

(i) Eight months from the da... responding United States appl... by or on behalf of the Contracto... an application is not filed, 6 m... the date the invention is submi... closure pursuant to paragraph ... this clause;

(ii) Six months from the date ... granted by the Commissioner of ... Trademarks to file foreign ... where such filing has been pr... security reasons; or

(iii) Such longer period as ... proved by the Contracting Of...

(2) The Contractor shall no... tracting Officer promptly of e... plication filed and upon writte... furnish an English version o... application without additional ...

(c) *Patent Rights clau...* When the agency has de... a contract falls within § 1-9... the Patent Rights clause ... (a) shall be included in the ... cept that the name of the ... changed to "Patent Right... and paragraph (b) of th... be replaced with the follow... (b):

(b) *Allocation of principal ... signment to the Government.* ... ject Invention is identified, ... agrees to assign to the Gove... tire right, title, and interest t... out the world except to t... greater rights are retained b... under paragraphs (b)(2) ... clause.

(2) *Greater rights dete...* Contractor, or the employe... authorization of the Contra... greater rights than the non... provided in paragraph (d) ... accordance with the proce... of 41 CFR 1-9.109-6. A req... mination of whether the C... employee-inventor is entitle... greater rights must be subm... tracting Officer at the time o... of the invention pursuant t... (2)(i) of this clause, or ... months thereafter or such ... may be authorized by the C... cer for good cause shown in ...

NEXT

Grantee investigators may also obtain screening and testing services from academic colleagues in other health-related disciplines, such as pharmacology and physiology. However, 10 of the investigators contacted told us that these services were limited in scope and that there were delays in receiving the results; limitations result from the fact that their testing needs do not always correspond to the independent research programs of their colleagues. We also have been informed that academic testing services do not provide the screening and testing necessary to develop promising compounds because their emphasis is on scientific knowledge and not on utilization.

Examples of inadequate screening and testing services

The following examples illustrate some of the adverse effects upon the medicinal chemistry research program brought about by the lack of appropriate screening and testing services for the compounds prepared by the research investigators.

1. An experienced investigator credited with the discovery of at least two drugs received a grant amounting to about $123,000 during the period 1954 to 1964 from the National Heart Institute for the study of hypotensive compounds. During the initial period of the grant, at least one highly active clinical drug resulted from this research.

   Six pharmaceutical companies expressed interest in testing compounds for the investigator, and a working relationship was established with one of these companies that promised to provide biological testing to the point of clinical investigation. The investigator informed us that, subsequent to adoption of the 1962 patent agreement, the company withdrew its testing services and that generally all companies now decline to test compounds prepared with Federal support.

   The investigator stated that adequate screening and testing had not been received on 21 compounds synthesized by him during the period 1963 to 1966 and

that he had been unable to obtain any screening for 14 other compounds. He said that some testing was available at a university medical school on an irregular basis and that CCNSC cancer test results were only indirectly related to his heart research. An article published in 1966 in the Journal of Pharmaceutical Sciences discussing potential antihypertensive agents specifically mentioned the problem of inadequate screening in this area of research and contained the following comment concerning this grant:

> "Owing to the difficulty of obtaining screening of compounds obtained under a grant from the National Institutes of Health, no data are available pertaining to the possible antihypertensive activity of the amino acid."

The investigator told us that, because he could not obtain proper screening for his compounds, he decided not to request a renewal of his heart research grant.

2. During the period 1963-65, grant awards totaling about $37,000 were made to an investigator for research in the mental health area. According to files made available to us, the investigator attempted to make testing arrangements with two pharmaceutical firms; however, both firms declined to sign the patent agreement required by PHS. Arrangements for testing were finally made with the Psychopharmacology Service Center of the National Institute of Mental Health.

Two weeks after the investigator submitted his compounds to the Center for testing, he was notified by the Center that, due to reductions in its programs, additional compounds would not be accepted. He informed us that PHS did not suggest any alternative testing facilities and that other arrangements were not made. He also stated that, following the 1962 PHS requirements for a patent agreement, scientific information formerly provided by industry

no longer made available to him. He explained that the inadequacy of available testing facilities contributed to his decision not to request a renewal of his grant after 1965.

3. Another investigator received grants totaling about $71,000 during the period 1964-66 from the National Institute of General Medical Sciences (NIGMS). About the time of the first award an official at NIGMS suggested that the investigator have his compounds tested for biological activity and especially for antiviral, anticancer, and anticonvulsant activities.

The investigator explained to us that his compounds were of the type that should receive broad biological screening. However, the only screening and testing arrangements made were with CCNSC and they did not provide for anticonvulsant screening. The investigator stated that no Government testing facility offered broad screening and that no such testing was available at any of the institutions listed in the NIH booklet "Biological Testing Facilities." He stated that he was particularly concerned about his inability to obtain anticonvulsant testing and that PHS had not assisted him.

Prior to 1962 the investigator had sent compounds to pharmaceutical companies for testing. Test results from one company showed that a compound, submitted for testing in 1955, had been subjected to at least 20 different test systems, including several in the area of anticonvulsants the latest test occurring in March 1966. The investigator stated that the inadequacy of his current arrangements influenced his decision not to request a renewal of his grant.

4. Since 1959, awards totaling about $141,000 have been made to an investigator by the National Cancer Institute (NCI). In connection with compounds produced under the grant, the investigator has made arrangements with CCNSC for anticancer testing and since 1962 has submitted over 100 compounds. His

correspondence with CCNSC indicates that his compounds might also show activity in the treatment of mental disease; he informed us that, in his opinion, the compounds should also be tested for blood pressure activity.

He advised us that attempts to make testing arrangements through the National Institute of Mental Healt were unsuccessful, and he expressed doubts to us whether adequate testing arrangements could be made with medical school facilities. The only regular testing arrangements made by him were with CCNSC, although a pharmaceutical company had provided some tests in mental chemistry prior to 1962. The investigator stated that, although anticancer activity is the main concern of the NCI, he would like to obtain broader screening of his compounds.

Change in direction of research

We found that, within the broad terms of the grants, several grantee investigators have redirected their researc efforts away from the objective of developing compounds hav ing potential new medicinal value in the prevention and tre ment of human disorders. Some investigators are concentrat on basic chemistry studies even though they had originally proposed to prepare compounds with potential medicinal valu in several areas of health. We were advised by other inve tigators that, because of their awareness of testing proble encountered by others, they intentionally directed their re search around the need for testing. The following cases il lustrate the changes being made in the direction of the research effort in certain medicinal chemistry grants as a re sult of the difficulties being encountered in obtaining ade quate screening and testing services.

1. At one university an investigator received grants o about $49,000 during the period 1962-66 from NIGMS. The investigator was preparing various kinds of potential medicinal agents when he applied for the P grant. In his application the investigator stated that he planned to obtain screening and testing fro a pharmaceutical firm.

Subsequently, he received a commitment from the firm for these services. However, in May 1962, the firm advised him that it was opposed to the signing of the patent agreement required by PHS. The investigator made alternate testing arrangements with a commercial testing laboratory and later with a university pharmacologist for specific types of tests, but not for broad screening. The investigator has informed us that he is currently interested in the study of how drugs work and that he is studying specific drugs whose medicinal value is already known, rather than concerning himself with developing new drugs.

2. Another investigator, who received grants of about $66,000 for the period 1962-66, proposed in his initial grant application to submit his compounds to routine screening in order to obtain as broad an evaluation as possible.

The investigator stated that his attempts to obtain screening and testing from the pharmaceutical industry were unsuccessful and that he finally made arrangements with a university pharmacologist who provided limited services. The investigator informed us that his current research goals were limited and that his testing needs were also limited. He said that the broad testing proposed in the original grant application was still valuable and that, if it had been obtained from industry, the direction of his research might not have changed.

On the basis of the several grants reviewed by us and of discussions with grantee investigators, it appears to us that the difficulties encountered by grantee investigators in obtaining adequate screening and testing of compounds have adversely affected the achievement of important objectives of research grants in medicinal chemistry. These difficulties, which many of the investigators attributed to the inability to obtain the cooperation of the pharmaceutical industry and the unavailability of adequate alternative sources of

screening and testing, also seem to be related to certain problems in the administration of HEW regulations concerning invention rights, which are discussed in the subsequent section of this report.

Difficulties in administration of regulations concerning invention rights

We noted certain difficulties in the administration of regulations concerning invention rights which needed resolution to facilitate the development of grantee investigators' discoveries of potential new drugs. These difficulties involved the determination of ownership and disposition of inventions conceived under PHS grants for research in medicinal chemistry, which we found was a factor contributing to the reluctance of the drug industry to provide screening and testing services to NIH-supported investigators.

It is the general policy of HEW that the results of Department-sponsored research should be made widely, promptly, and freely available to other research workers and to 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 time. However, we were advised by HEW officials that, in view of an opinion of the Attorney General (34 Op. Atty. Gen., 320,328 (1924)), HEW could not guarantee exclusive licensing of inventions. HEW officials told us that this opinion generally had been interpreted as holding that agencies may not grant exclusive licenses under Government-owned patents without specific statutory authority.

HEW regulations (45CFR8) require that all inventions arising out of activities supported by grants shall be promptly and fully reported to the agency. The regulations, as quoted on page 6 of this report, permit a utilization of the patent process in order to foster adequate commercial development to make new inventions widely available to the general public. The regulations specify that determination of ownership and disposition of invention rights may be made by either the responsible official on a case-by-case basis (sec. 8.1(a)) or, except for foreign rights, under blanket "institutional agreements" by grantee institutions whose policies and procedures have been approved by HEW (sec. 8.1(b)).

The regulations (sec. 8.2) provide four criteria for use by the responsible HEW official in determining disposition of rights under section 8.1(a). One of the criteria (sec. 8.2(b)) states that an invention may be assigned by HEW to a "competent" organization if it will be more adequately and quickly developed for widest use, providing there are adequate safeguards against unreasonable royalties and repressive practices.

In accordance with the general policy concerning publication or patenting of inventions, we found that HEW generally followed the practice of disseminating the results of PHS-sponsored research to other research workers and to the public through publication. Publication has the effect of making the results of research freely available to all interested parties and, subject to existing patents, permits nonexclusive exploitation of the discovery. However, we have been advised by representatives of the pharmaceutical industry that, since commercial development of new drugs is generally costly, the industry will not undertake this development unless some form of exclusivity can be obtained.

During our review, several grantee investigators informed us that, in their opinion, publication of the results of their research was not an adequate means to encourage development of promising compounds into new drugs. In addition, we noted that in April 1962 the Director of the National Cancer Institute advised the Surgeon General that he was doubtful that the policy of emphasizing dedication of inventions to the public through publication would make inventions available or that such a policy would always serve the public interest. He stated that a no-patent concept delayed the marketing of inventions because there was no protection for the investment of the developer.

Assignment of invention rights by HEW

Our review showed that HEW had not taken timely action to determine the disposition of rights to certain inventions and that only limited use had been made by HEW of the authority provided in the regulations to assign invention rights to "competent" organizations, such as grantee institutions. We found that, at the time of our fieldwork in January 1967, HEW had not acted upon several petitions

had been received from grantees for assignment of rights. We found also that, from 1962 through June 30, 1965, HEW had assigned invention rights to grantees in only one situation. NIH records showed that, during the 1962-65 period, grantees had reported a total of 682 inventions resulting from NIH-sponsored research and that numerous requests had been received for assignment of rights.

Subsequent to reporting inventions, grantee organizations may petition HEW for assignment of invention rights on an individual case basis. In such instances pursuant to section 8.1(a) the responsible HEW official, in accordance with section 8.2(b) of the regulations, may assign the invention rights to the grantee for a limited period.

HEW officials provided us with a list of nine petitions received by HEW from grantees that were pending determination as of January 1967. Two of these petitions had been submitted in 1963, one in early 1965, and three others were at least 6 months old.

University and industry officials advised us that they were dissatisfied with the determination of rights provisions by the agency because the provisions did not provide criteria and guidelines for determining rights; there were uncertainties as to the determinations to be made. The following case illustrates the delays and uncertainties involved in resolving a petition for patent rights made by a university we visited during our review:

In January 1966 a university petitioned PHS for assignment of domestic rights to inventions covering steroid compounds conceived under a PHS grant. Prior to the petition the Surgeon General had permitted the university to file six patent applications. At least 14 companies expressed interest in licenses for development of the university's inventions.

We were advised, however, by a university official that no company would develop the inventions without exclusive rights to protect its investment in the development of the inventions. He stated that, as of May 1967, no development work had been done on the inventions by any of the 14

companies. The investigator informed us that he had lost interest in development of the inventions, because of the long delay. In July 1967, 18 months after the petition, the Assistant Secretary for Health and Scientific Affairs assigned domestic rights to the university and stated that the public interest would best be served by expeditious development of the inventions.

Statements made in 1965 by two organizations representing university administrators stress the importance of assigning invention rights to universities at the time of awarding research grants or contracts. The Patent Policy Subcommittee of one organization[1] stated in a position paper that the public interest could best be served by encouraging educational institutions to assume the responsibility of furthering public use of the inventions of their faculties and recommended that universities be permitted to establish the licensing arrangements necessary to encourage private companies to invest in the development of pharmaceutical discoveries.

The Chairman of the Subcommittee in commenting on the position paper advised the organization's executive secretary that the necessity to petition the sponsoring agency for the right to patent an invention, and to justify each such petition on an individual basis, introduces substantial delay and a prolonged period of uncertainty.

In 1965 the other organization[2] submitted statements to the Senate Subcommittee on Patents, Trademarks, and Copyrights, Committee on the Judiciary, which stressed that granting invention rights to universities at the time of contracting would eliminate delays in the development of discoveries and the dissemination of research knowledge and would assist the sponsoring agency charged with the task of promoting the fruits of research. This organization also

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[1] Committee on Government Relations, The National Association of College and University Business Officers.

[2] American Council on Education.

recommended that universities be permitted to use licensing incentives to attract industry investment in product development. (Hearings on Government Patent Policy, pt. 2, p. 645.)

During our review, we requested HEW to provide us with information concerning the current status of its determinations under section 8.2(b), including the nine pending cases shown in its January 1967 listing. This information, provided to us in November 1967, showed a marked increase in departmental actions, inasmuch as HEW:

1. Had signed section 8.2(b) determinations, assigning invention rights to the grantee for a limited period, in seven cases.

2. Had decided to dedicate the invention to the public in one case.

3. Was evaluating additional information received on the remaining case.

The information provided to us also showed that, since January 1967, 17 other proposals had been submitted to HEW for 8.2(b) determinations; HEW had made determinations in four cases and was evaluating the proposals received in the other 13 cases.

On the basis of our observations, we proposed to the Secretary that HEW, in line with its responsibility, should direct its efforts toward timely determination of rights to, and the appropriate disposition of, potentially patentable inventions resulting from research in medicinal chemistry reported by grantee investigators. We believe that such action would serve the public interest by reducing the uncertainties of the status of invention rights.

Use of institutional agreements

Our review showed that HEW had made only limited use of the regulation permitting the assigning of the determination of invention rights to grantee institutions whose patent policies had been approved by HEW (45 CFR. 8.1b). This regulation has been applied through the use of institutional

agreements between PHS and individual universities, and 18 such agreements, entered into between 1953 and 1958, are now in existence. At least 34 other universities have submitted requests for these agreements; however, in March 1967, we were advised by HEW officials that no additional agreements had been approved because opinions of responsible agency officials differed concerning the value of such agreements.

We found that HEW, in addition to placing limitation on the number of institutional agreements being approved, placed limitations on the institutions' administration of the agreements now in existence, because it required use of the PHS patent agreement. Some agency officials have expressed the opinion that the use of patent agreements should not be required at grantee institutions which are holding institutional agreements and that greater use of institutional agreements would help alleviate problems in obtaining screening and testing services by pharmaceutical companies.

Information obtained during our review shows that investigators from at least seven of the universities holding agreements with PHS encountered difficulties in making screening and testing arrangements with pharmaceutical companies, because of the required use of the PHS patent agreement. The following case illustrates problems encountered when screening and testing arrangements were sought:

> In November 1962 the chairman of the patent board at a university holding an institutional agreement advised an investigator, as well as university administrators, that PHS preferred to have investigators obtain screening and testing for their compounds from commercial laboratories not engaged in the manufacturing business. Testing fees were to be charged to the grant. The chairman pointed out that he had:
>
> > "*** protested this and other recent actions of the USPHS in issuing directives requiring compliance on matters contrary to established procedure within the university and the university's institutional agreement with that agency ***."

On two occasions the university advised the Deputy Surgeon General that fees for the required testing would amount from about $30,000 to $50,000 and would consume nearly all the funds of the grant. The university recommended action to permit the use of the free services of the pharmaceutical industry. The Deputy Surgeon General replied that although there was merit in this argument, PHS had no alternative but to use the amended patent agreement clause on screening compounds.

On the basis of our observations, we proposed to the Secretary that HEW clarify the intended use of institutional agreements and review the necessity for requiring the use of patent agreements by grantee institutions whose patent policies had already been approved by HEW.

Views of agency officials
and proposed actions

Recognition of problem area

We found that, prior to our review, various HEW officials had expressed their views on problems concerning the means needed to provide improved screening and testing of compounds resulting from PHS grants for research in medicinal chemistry. Cognizant HEW officials have been aware of the difficulties experienced by grantee investigators in arranging for adequate screening and testing of compounds. They also recognized that procedures implementing department policies had been unsatisfactory and had contributed to the loss of screening and testing services formerly provided by the pharmaceutical industry.

In March 1963 the Deputy Director of NIH stated in a letter to the Director that:

> "It is becoming increasingly apparent that our current patent policy does present a problem for grantees who depend upon industrial laboratories for biological testing of material produced with PHS support."

In August 1964 the Director NIH advised the Surgeon General, PHS, of the need for change in the HEW policy to permit effective collaboration with industry. He stated in the memorandum that, since early 1962, problems had increased to the point where a prompt review of the policy appeared necessary. The Director stated that investigators found the drug industry best able to accumulate the data necessary for the licensing of a new drug.

The Deputy Surgeon General, PHS, forwarded the August 1964 letter to the HEW Patent Officer and stated that:

> "*** it is preferable to create conditions that will attract private initiative rather than to undertake complete government financing of the cost of research and development of all inventions that grow out of the government's program."

In August 1965 the Director of NIH advised the Subcommittee on Patents, Trademarks, and Copyrights of the Senate Judiciary Committee that:

> "The uncertainties involved in after-the-fact determination have created barriers for collaboration by the drug industry with NIH-supported scientists in bringing potential therapeutic agents to the point of practical application."

and that:

> "Compounds which show some promise in early stages of investigation may be of no benefit to the public and may not serve the public interest unless clinical testing is undertaken and the resulting drug *** marketed. *** it seems sensible to be able to involve industry in the testing and marketing phases of drug development since these firms already possess capabilities in these areas that would have to be duplicated elsewhere to accomplish these necessary purposes."

HEW views of July 1967

In May 1967 we advised the Secretary HEW, by letter, of our findings concerning the problems in obtaining appropriate screening and testing for compounds prepared under Government-sponsored research. We inquired about the steps being taken or contemplated within the Department to provide improved means for screening and testing compounds resulting from the PHS-supported program for research in medicinal chemistry.

In his reply of July 1967, on behalf of the Secretary, the Assistant Secretary for Health and Scientific Affairs informed us that, since the responsibility for patent matters was assigned to his office in October 1966, the Department's patent policies and administrative practices, including the problems relating to screening and testing of compounds, had been under continuing review.

The Assistant Secretary mentioned that a private consulting firm was studying certain patent problems related to HEW operations in connection with a contract study being undertaken for the Committee on Government Patent Policy of the Federal Council for Science and Technology[1] and that the Department intended to use the study in the formulation of any changes in policy or administrative practices found to be in order.

The Assistant Secretary further stated that two steps were under consideration to promote screening and testing of compounds identified by grantees: (1) extension of the use of blanket institutional agreements and (2) entertainment of applications by other grantee institutions under section 8.2(b) of the regulations for assignment of principal rights by HEW to such institutions on a case-by-case basis where it was determined that such action would promote more adequate and wider utilization of the compounds, including screening and testing. However, HEW had reached no final decision regarding changes in patent policies or in the above administrative practices.

HEW comments of March 1968

After we brought the matters discussed in this report to the attention of the Secretary for review and comment, we were furnished with the Department's comments, by letter dated March 20, 1968, from the HEW Assistant Secretary, Comptroller. In this letter (see app. II), we were informed essentially of four principal actions taken or being taken by the Department to resolve the problems related to the screening and testing of compounds under HEW-sponsored research.

These actions include:

1. The use of a revised patent agreement between investigator and screening and testing organization.

[1]Established by Executive Order 10807, March 13, 1959, as an interagency body representing the principal agencies with scientific or technical missions.

2. The planned use of a revised standard institutional patent agreement.

3. The more expeditious issuance of determinations permitting assignment of an invention to a competent organization on a case-by-case basis.

4. The planned issue of a comprehensive statement of the Department's policies and requirements regarding the screening and testing of compounds.

The several actions as reported to us by the Department are summarized below.

1. During 1967, HEW put into effect a revised form of patent agreement which, as pointed out by the Department, differs significantly from that required in 1962 in that 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 of the NIH-supported investigator, even "where such new use is within the field of research work supported by the grant."

HEW has informed us that its 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 investigators and pharmaceutical companies entered into 53 agreements, using the revised form during calendar year 1967. HEW has informed us also that the form of the required patent agreement will undergo further review and that additional changes will be made, where appropriate, to ensure recognition of the respective rights and interests of HEW, the investigators, and the organizations performing screening and testing services.

In commenting on the revised agreement the president of the Pharmaceutical Manufacturers Association advised us that it was a much needed improvement to the existing arrangements, and, although recognizing that certain problems would still exist, the association endorsed it as a progressive measure.

2. HEW has reaffirmed that the use of institutional agreements, as provided for under Department patent policy, serves the public interest and should be continued. HEW has informed us that a revised standard institutional patent agreement, now in preparation, will permit the grantee institution to retain and administer the principal ownership rights in inventions made under Department grants, will clearly define the rights of the parties with respect to such inventions, and will set forth general guidelines governing the licensing of inventions.

HEW considers that the revised agreements will go far toward solving the problems encountered by investigators in connection with screening and testing and will, at the same time, fully protect the public interest.

3. During 1967, HEW has made efforts to expedite the issuance of determinations pursuant to the provision in its patent regulations that permits assignment of an invention to a competent organization on a case-by-case basis. HEW stated that it was its intent to act as expeditiously as possible on a number of requests pending for such assignment, as well as on those determinations already made since April 1967. HEW intends to use this provision of the regulations where an institutional agreement is not in effect.

4. HEW has recognized the need for a comprehensive statement of the Department's policies and requirements regarding the screening and testing of compounds arising out of Department-sponsored research. HEW has informed us that it intends to issue a statement which will outline the Department's policies and clearly set forth alternative methods of obtaining screening and testing services and that it will encourage the utilization of Government facilities whenever appropriate.

In summary, HEW expressed its recognition that newly synthesized or identified compounds resulting from Department-sponsored research constitute a valuable national resource and that their effective utilization is a part of HEW's program goals. HEW has stated that it will continue to make such changes in its practices as are necessary to foster the fullest utilization of all such compounds, in a

manner that will protect the legitimate interests of the public, the investigator, and the screening organization.

Conclusions

On the basis of information obtained from grantee investigators and cognizant agency officials, it appears that the usefulness of the HEW grant program for research in medicinal chemistry has been adversely affected because of the difficulties encountered by grantees in arranging for adequate screening and testing services. Although the research efforts of grantee investigators provide useful scientific information in the area of health-related chemistry, optimum benefits are not obtainable if compounds which may have potential medicinal use do not receive adequate screening and testing.

We believe it is important to note that, in a meeting with agency officials in June 1966, the President of the United States expressed specific interest in medicinal research and in achieving increased practical results from drug research in the form of treatment of diseases. Agency officials have advised the President that a major impediment to these goals has been the patent policy which has made it extremely difficult to make use of the resources and services of the pharmaceutical industry.

Following this meeting, the President referred to the substantial amount of funds being spent annually by NIH on biochemical research and, after mentioning the role of medical research in control of polio and tuberculosis and in psychiatric treatment, stated:[1]

> "These examples provide dramatic proof of what can be achieved if we apply the lessons of research to detect, to deter and to cure disease. The Nation faces a heavy demand on its hospitals and health manpower. Medical research, effectively applied, can help reduce the load by preventing disease before it occurs, and by curing disease when it does strike.

[1] Weekly compilation of Presidential Documents, July 4, 1966, p. 837.

"But the greater reward is in the well-being of our citizens. We must make sure that no life-giving discovery is locked up in the laboratory."

It is apparent that HEW officials have, for some time, recognized the problems discussed in this report, and we have since been informed that remedial measures are under way or under consideration, including changes in the patent agreement for screening and testing purposes, increased use of institutional agreements, and more expeditious assignment of invention rights at the time of grant award. However, until such time as the contemplated actions have been fully implemented, it is not practicable for us to assess the effectiveness of those various measures and to determine whether they will enable investigators to obtain adequate screening and testing services in connection with their HEW-supported research activities.

Recommendation to the Secretary of Health, Education, and Welfare

We recommend that the Secretary of Health, Education, and Welfare develop and put into effect such policies and procedures as are necessary to provide adequate screening and testing of compounds resulting from HEW-supported research in medicinal chemistry to facilitate the development of potential drugs for the prevention and treatment of diseases and disabilities of man.

SCOPE

Our review of the administration of HEW grants for research in medicinal chemistry included an examination into the pertinent legislation and the regulations, policies, procedures, and practices of HEW and its constituent organizations, to the extent applicable. Our work was performed at the headquarters of HEW, PHS, and NIH, and at selected educational institutions, which were recipients of PHS grants, in the States of California, Michigan, Minnesota, and Wisconsin.

We reviewed selected grants, totaling about $4.6 million, awarded during the period 1962 to 1967 to 38 research investigators at 10 educational institutions. We examined the grantees' research programs and obtained information from the investigators and university officials as to the arrangements made or available for screening and testing new compounds to determine their usefulness. Our review did not include an examination of the manner in which the funds were expended under the grants.

We met with representatives of two pharmaceutical firms and of the Pharmaceutical Manufacturers Association to determine the basis of the industry's actions discussed in this report.

We discussed with responsible agency officials pertinent aspects of the Department's policies affecting the administration of the grants and possible changes contemplated in such policies or implementing procedures.

APPENDIXES

APPENDIX I

PRINCIPAL OFFICIALS
OF
THE DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
RESPONSIBLE FOR THE ACTIVITIES
DISCUSSED IN THIS REPORT

	Tenure of office			
	From		To	
SECRETARY OF HEALTH, EDUCATION, AND WELFARE:				
Abraham A. Ribicoff	Jan.	1961	July	1962
Anthony J. Celebrezze	July	1962	Aug.	1965
John W. Gardner	Aug.	1965	Mar.	1968
Wilbur J. Cohen	Mar.	1968	Present	
ASSISTANT SECRETARY FOR HEALTH AND SCIENTIFIC AFFAIRS (note a):				
Philip R. Lee	Nov.	1965	Present	
SURGEON GENERAL, PUBLIC HEALTH SERVICE:				
Luther L. Terry	Mar.	1961	Oct.	1965
William H. Stewart	Oct.	1965	Present	
DIRECTOR, NATIONAL INSTITUTES OF HEALTH:				
James A. Shannon	Aug.	1955	Present	

[a]Effective March 13, 1968, the Assistant Secretary was given direct authority over PHS and FDA. Effective April 1, 1968, the functions previously assigned to PHS were assigned to two new operating agencies--the National Institutes of Health (including the former NIH and certain additional functions) and the Health Services and Mental Health Administration (comprising all other functions previously assigned to PHS). The Surgeon General was made the principal deputy to the Assistant Secretary.

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.

Mr. Frederick K. Rabel

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

Mr. Frederick K. Rabel

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.

Mr. Frederick K. Rabel

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
Washington, D. C. 20548

Attachment [1]

[1]GAO note: Attachment not included.

U.S. GAO Wash., D.C.