FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING, AND TECHNOLOGY
COMMITTEE ON INTELLECTUAL PROPERTY AND INFORMATION

~~FEDERAL COUNCIL FOR SCIENCE AND TECHNOLOGY~~
~~COMMITTEE ON GOVERNMENT PATENT POLICY~~
U.S. DEPARTMENT OF COMMERCE BUILDING
WASHINGTON, D.C. 20230

PATENT BRANCH, OGC
DHEW

APR 15 1977

April 13, 1977

MEMORANDUM FOR Members of the Subcommittee on Intellectual Property

From: for James E. Denny R. A. Keimann
Chairman

Meeting: Thursday, April 21, 1977, 9:30 a.m.
Room 5141A, Main GSA Building
18th & F Streets, N.W.
Washington, D. C.

No action taken deferred to MAY 19

AGENDA

1. Review of the reports on Recommendations 10 and 12 of Part I, Volume IV, of the Commission's Report. Mr. Postman is to make the presentation.

2. Review of Ad Hoc Group report on the amendment to the FPR regarding the Institutional Patent Agreement. Mr. Latker is to make materials available to the members.

3. Discussion of H.R. 6249, a copy of which is enclosed.

Also enclosed is a copy of the minutes of the March 11, 1977 meeting of the Subcommittee.

Labassy Rm. 722A
Friday 2:00

2 Enclosures
1. Cy of H.R. 6249
2. Cy of 3/11/77 Mins.

ADDRESSEES

Members

M. Howard Silverstein, USDA
Robert B. Ellert, DOC
Barry L. Grossman, DOC Alternate
Joseph E. Rusz, AF
William G. Gapcynski, Army
William O. Quesenberry, Navy
Norman J. Latker, HEW
Donald A. Gardiner, DOI
Miles F. Ryan, Jr., DOJ
Joseph A. Hill, DOJ Alternate
Harold P. Deeley, Jr., DOT
Benjamin Bochenek, EPA
Philip G. Read, GSA

FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING, AND TECHNOLOGY
COMMITTEE ON INTELLECTUAL PROPERTY AND INFORMATION
U.S. Department of Commerce Building
Washington, D. C. 20230

SUBCOMMITTEE ON INTELLECTUAL PROPERTY

Minutes of Meeting - March 11, 1977

The meeting convened at 9:40 a.m. in Room 5141A, GSA Headquarters Building, Washington, D. C.

Attendees

Members Present	
James E. Denny, Chairman	ERDA
M. Howard Silverstein	USDA
Robert B. Ellert	DOC
Barry L. Grossman	DOC Alternate
Joseph E. Rusz	Air Force
William G. Gapcynski	Army
William O. Quesenberry	Navy
Norman J. Latker	HEW
Donald A. Gardiner	DOI
Joseph A. Hill for Miles F. Ryan, Jr.	DOJ
Harold P. Deeley, Jr.	DOT
Benjamin Bochenek	EPA
Philip G. Read	GSA
Robert F. Kempf	NASA
Jesse Lasken for John H. Raubitschek	NSF
Observers Present	
Maxwell C. Freudenberg	DLA
Charles Goodwin	OFPP
Executive Secretary	
O. A. Neumann	DOC
Guests Present	
Martin S. Postman	Air Force
George T. Mann	DOC
Members Absent	
Jerry A. Cooke	NRC
Jay W. Maynard	NRC Alternate
Observers Absent	
Ralph C. Oser	AID
Abraham R. Richstein	AID Alternate
Robert J. Bladergroen	CIA
Robert L. Malech	HUD
Harvey J. Winter	DOS
Walter B. Lockwood	DOS Alternate
Forest D. Montgomery	Treasury
Luther A. Marsh	Postal Service
Lewis E. Wallace	TVA
Ex-Officio Absent	
Dr. Betsy Ancker-Johnson	DOC
William C. Bartley	FCCSET

Members continued
Robert F. Kempf, NASA
Jerry A. Cooke, NRC
Jay W. Maynard, NRC Alternate
John H. Raubitschek, NSF
Jesse Lasken, NSF Alternate

Observers
Ralph C. Oser, AID
Abraham R. Richstein, AID Alternate
Robert J. Bladergroen, CIA
Robert L. Malech, HUD
Maxwell C. Freudenberg, DLA
Harvey J. Winter, DOS
Walter B. Lockwood, DOS Alternate
Forest D. Montgomery, Treasury
Charles Goodwin, OFPP
Luther A. Marsh, Postal Service
Lewis E. Wallace, TVA

Ex-Officio
Dr. Jordan J. Baruch, DOC
William C. Bartley, FCCSET

Executive Secretary
O. A. Neumann, DOC

cc: William T. Knox, NTIS
Martin S. Postman, AF

(3) Following publication of the Combined Report, Mr. Denny noted that the suggested "questionnaire" set forth in the report implementing Recommendation 3 should be implemented. Mr. Denny stated that once FCCSET approves the report on Recommendation 3, action of the Subcommittee is completed. To finally complete action by the Executive Branch, however, it would be up to the Director of OSTP to request the Heads of the Federal agencies to implement the use of the questionnaire. Target date was set for June 1, 1977.

(4) It was agreed that a letter to OFPP is not necessary regarding Recommendation 4 since it was officially rejected. Mr. Read advised that comments are still being compiled by GSA for submission to the Subcommittee.

(5) With respect to Recommendation 5, Mr. Read noted that comments are also being compiled by GSA and material would be forwarded to the Subcommittee for its consideration.

Mr. Denny advised that OFPP should be looking to GSA for action on Recommendations 4 and 5. Mr. Read agreed and would advise OFPP as to the new target date for these recommendations and would include three months or so to permit time for Subcommittee consideration. Mr. Read noted that he believed September 1, 1977 might be a reasonable target date.

(6) Mr. Denny noted that in view of the I.T.T. decision it may be advisable to reopen the need for legislation to implement Recommendation 6. Mr. Kempf stated that he would be willing to chair a reactivated Legislation Working Group, and advised that he would try to get a report to the Working Group by June 1, 1977, and the Subcommittee would get a complete report by August 1, 1977.

(7) It was agreed that Mr. Kempf's group would provide a report on Recommendation 7 together with its report on Recommendation 6.

Mr. Denny advised that [illegible]

Mr. Denny opened the meeting by suggesting that the Subcommittee review the various action items presented in Mr. Neumann's March 2, 1977 draft memorandum.

GENERAL OVERVIEW OF THE ACTION ITEMS LISTED

Action Item No. 1. The Executive Secretary was asked to make the completion of the Combined Report on Government Patent Policy a priority item. Mr. Neumann advised that Messrs. Kempf and Postman still are to provide inputs.

Action Item No. 2. Mr. Denny noted that an informal group met to discuss the comments received by OMB following the circulation of the draft legislation to the Federal agencies, but nothing has been done by the Subcommittee to date.

Mr. Latker noted that he believes the work of the Subcommittee has been taken over by events, and any efforts of the Congress at this point are out of the hands of the Subcommittee. Mr. Neumann suggested a review of the comments so agencies would have a better fix on the problems if and when legislation is introduced. Mr. Denny concluded the discussion by stating he would entertain a motion for the Subcommittee to take further action on the legislative proposal. No motion was made and it was struck from the record as an agenda item.

Action Item No. 3. (Intellectual Property - Commission Recommendations)

(1) Mr. Denny noted that the remaining work on Recommendation 1 was that of the University Ad Hoc Group with respect to the drafting of an amendment to the FPR concerning the Institutional Patent Agreement. Mr. Latker advised that the Ad Hoc Group would present the material to the Subcommittee for its April meeting. The new target date for completing the work on the implementation of the Executive Branch position on the recommendation was established for June 1, 1977.

(2) Mr. Denny stated that he believed no further work by the Subcommittee is necessary on Recommendation 2.

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to take further action on the legislative proposal. No

(8) No action necessary - rejected.

(9) Mr. Kempf, Chairman of the Legislation Working Group, would also provide a report to the Subcommittee three months after Recommendations 10 and 12 have been approved by the Subcommittee.

(10) It was decided to suspend Subcommittee action on the report on Recommendation 10, and to consider it later during this meeting, or during the next meeting. A new target date would be established then.

(11) Mr. Kempf's Legislation Working Group would consider Recommendation 11 along with Recommendations 6 and 7.

(12) The report on Recommendation 12 would be considered along with Recommendation 10.

(13) With respect to Recommendation 13, Mr. Kempf, Chairman of the Legislation Working Group, agreed to provide a report to the Subcommittee three months after Recommendations 10 and 12 have been approved by the Subcommittee.

(14) Mr. Kempf, Chairman of the Legislation Working Group, agreed to provide a report to the Subcommittee three months after the report on Recommendation 16 has been approved by the Subcommittee.

(15) Mr. Kempf, Chairman of the Legislation Working Group, advised that he would try to get a report to the Subcommittee by June 1, 1977, and the Subcommittee should receive a complete report by August 1, 1977.

(16) The report on Recommendation 16 was deferred until later in the meeting.

Following the discussion of the recommendations, Mr. Denny asked Mr. Neumann to prepare a letter for his signature addressed to Mr. Goodwin of OFPP noting the status and expected completion dates for Recommendations 1 through 3, 6, 7, and 9 through 16.

Action Item No. 4. No action necessary inasmuch as the development of alternatives are not necessary in light of the action taken.

Action Item No. 5. The amendment to the FPR on the IPA was discussed under Action Item 3.(1).

Action Items Nos. 6 & 7. New Business. It was agreed that if any problems raised by the current and proposed legislation are not taken care of by Subcommittee action on Action Item No. 3.(1) through (16), examination of current and proposed legislation would be considered new business.

REPORT OF COPYRIGHT WORKING GROUP

Mr. Lasken briefly discussed the report of the Copyright Working Group intended to implementat Recommendation 16.

General Discussion

Mr. Denny noted that he believed that this report might be the type of report which also should be reviewed by the Subcommittee's counterpart of CIPI, if in fact the two groups stay together as proposed. Mr. Lasken noted that the group which developed the report did have "information type" representatives on the Copyright Working Group; namely, Messrs. Bachrach (NIE), Gratton (ERDA), and Mann (NTIS).

Mr. Postman noted that under the new copyright law, everything is given copyright protection upon its creation, and therefore, would appear to cover technical data.

Mr. Freudenberg noted that since the passage of the Copyright Act, there are going to be hearings during which time NTIS's concern will be aired. He also noted that the new Act provides that the copyright of a work reverts back to the author after 35 years, and normally the Government contracts "work for hire" so that the Government rights may be lost after 35 years unless the contract agreement provides for a dedication to the public.

Mr. Latker noted the term "Governmental purposes" is being interpreted differently by the Federal agencies, and perhaps action should be taken to correct this situation. He also suggested that the problem of approving publications might better be decided at the time of contracting. He noted that DHEW has advised the Joint Committee on Government Printing that some 38,000 publications are generated by its grants, and wondered if the Joint Committee wanted to see all of

these items prior to publication. He also noted the problem of covering computer programs. Mr. Latker further noted the widespread infringement of copyrights. He advised that NTIS is attempting to reserve its right to copyright in foreign countries and the Policy Statement does not cover this point, and probably should.

Mr. Rusz had problems with respect to the general policy statement set forth on page 5 because of security problems, and suggested that the policy statement be restated to avoid any problems.

Mr. Postman believed that perhaps the Employee Works section ought to be expanded and agreed to do so if desirable.

Mr. Denny noted that the Copyright Policy Statement seems to be less definitive than the Presidential Statements on Government Patent Policy. Mr. Read asked if this is the intent of Recommendation 16. Mr. Denny queried if there ought to be 1(a), 1(b), and 1(c)-type categories. He stated he did not believe the Statement would produce consistency or unformity which the Commission on Government Procurement was looking for. He added perhaps the Subcommittee should go back and state that the report is the best it can do with the guidance provided. Query, Is the Subcommittee stating that the Federal agencies do not need and should not have a Federal copyright policy? Mr. Denny concluded by stating that the report does not give the type of guidance he thought the Commission was looking for.

Action Taken

Mr. Lasken suggested that the Subcommittee determine whether the work product ought to be made specific with respect to providing guidance. The Chairman took a poll of the members who virtually unanimously agreed to keep the style of the report as presented. Areas of concern were:

Governmental purpose;
Security;
Dedication to Public;
Assignment to Government; and
Reserving the right to obtain copyrights in foreign countries.

Mr. Lasken agreed to revise the report on Recommendation 16 and present it to the Subcommittee at a later meeting. No target date for OFPP was established, especially since it may be desirable to coordinate the contents of the report with the Information Subcommittee.

NEXT MEETING

The next meeting of the Subcommittee was scheduled for Thursday, April 21, 1977 at 9:30 a.m. During this meeting, Mr. Postman will be asked to brief the Subcommittee on the reports on Recommendations 10 and 12, at which time target dates for presentation to OFPP also will be established.

The meeting adjourned at 2:30 p.m.

O. A. Neumann
Executive Secretary

FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING, AND TECHNOLOGY
COMMITTEE ON INTELLECTUAL PROPERTY AND INFORMATION
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U.S. DEPARTMENT OF COMMERCE BUILDING
WASHINGTON, D.C. 20230

PATENT BRANCH, OGC
DHEW

MAY 1 ? 1977

May 12, 1977

MEMORANDUM FOR Members of the Subcommittee on Intellectual Property

From: for D. J. Neumann at
James E. Denny, Chairman
Subcommittee on Intellectual Property

Meeting: Thursday, May 19, 1977, 9:30 a.m.
Room 5141A, Main GSA Building
18th & F Streets, N.W.
Washington, D. C.

AGENDA

Review of the Ad Hoc Group report on the amendment to the FPR regarding the Institutional Patent Agreement.

A copy of the report was attached to Mr. Latker's letter to Mr. Denny dated April 12, 1977.

Enclosed is a copy of the minutes of the April 21, 1977 meeting of the Subcommittee.

Enclosure

ADDRESSEES
Members
M. Howard Silverstein, USDA
Robert B. Ellert, DOC
Barry L. Grossman, DOC Alternate
Joseph E. Rusz, AF
William G. Gapcynski, Army
William O. Quesenberry, Navy
Norman J. Latker, HEW
Donald A. Gardiner, DOI
Miles F. Ryan, Jr., DOJ
Joseph A. Hill, DOJ Alternate
Harold P. Deeley, Jr., DOT
Benjamin Bochenek, EPA
Philip G. Read, GSA
Robert F. Kempf, NASA
Jay W. Maynard, NRC Alternate
Jerry A. Cooke, NRC
Jesse Lasken, NSF

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U.S. DEPARTMENT OF COMMERCE BUILDING
WASHINGTON, D.C. 20230

SUBCOMMITTEE ON INTELLECTUAL PROPERTY

Minutes of Meeting - April 21, 1977

The meeting convened at 9:35 a.m. in Room 5141A of the GSA Building, 18th and F Streets, N.W., Washington, D. C.

Attendees

Members Present	
James E. Denny, Chairman	ERDA
Eugene Pawlikowski for Robert B. Ellert	DOC
Joseph E. Rusz	Air Force
William Gapcynski	Army
William O. Quesenberry	Navy
Norman J. Latker	HEW
Donald A. Gardiner	DOI
Harold P. Deeley, Jr.	DOT
Robert F. Kempf	NASA
Jerry A. Cooke	NRC
Jesse Lasken	NSF
Executive Secretary	
O. A. Neumann	DOC
Guests Present	
Frank Lukasik	Air Force
Martin Postman	Air Force
Albert Sopp	ERDA
LTC H. M. Hougen	Army
Members Absent	
M. Howard Silverstein	USDA
Miles F. Ryan, Jr.	DOJ
Joseph A. Hill, Alternate	DOJ
Benjamin Bochenek	EPA
Philip G. Read	GSA
Observers Absent	
Ralph C. Oser	AID
Abraham R. Richstein, Alternate	AID
Robert J. Bladergroen	CIA
Robert L. Malech	HUD
Maxwell C. Freudenberg	DLA
Harvey J. Winter	DOS
Walter B. Lockwood, Alternate	DOS
Forest D. Montgomery	Treasury
Charles Goodwin	OFPP
Luther A. Marsh	Postal Service
Lewis E. Wallace	TVA
Ex-Officio Absent	
Dr. Jordan J. Baruch	DOC
William C. Bartley	FCCSET

Mr. Denny noted the move to take "computer software" outside of technical data. DOD did so and GSA is making an attempt to do so. Mr. Postman advised that the reason for switching to the term "data" from "technical data" was that sometimes "data" was not actually "technical data". However, the Working Group believed all data should be covered by the Policy Statements.

Mr. Denny MOVED that the report adopt NASA's definition of "data" instead of the one used in the report. [This motion was withheld pending a discussion.] Mr. Kempf read the NASA definition and noted that the term does not include financial, administrative, cost and pricing, management data, and other information incidental to contract administration.

Mr. Cooke suggested that the report be returned to the Working Group asking that the deliberations of the Subcommittee be taken into consideration. Mr. Denny suggested that the term "protectable data" be redefined bringing in the FOIA concepts using the language of the FOIA.

With respect to the report on I-10, under Part III entitled, Considerations, Mr. Denny stated he believed item 2 entitled, Government Financed Work, should be redrafted. He noted that in drafting the ERDA technical data regulation, ERDA became more sensitive to problems as knowledge and experience weregained. Mr. Neumann suggested that this is precisely why it appears that Mr. Goodwin's idea of writing regulations rather than a policy statement may make sense. He advised that a policy statement is difficult to change, and we could easily get boxed-in in writing implementing regulations. A regulation, however, may be readily revised. He also noted that in all probability, OFPP would return the statement with the added direction that regulations be drafted to implement it.

Mr. Kempf noted that it would take a real concentrated effort to draft regulations. He suggested that he would prefer that the policy statement go to OFPP and that OFPP advise whether regulations should be drafted so that a concentrated effort may then be made.

It was decided that further consideration of the report be deferred to the next meeting.

NEXT MEETING

The next meeting was scheduled for Thursday, May 19, 1977, at 9:30 a.m. during which time the report on the amendment to the FPR regarding IPA's would be considered.

The meeting adjourned at 3 p.m.

O. A. Neumann
Executive Secretary

FEDERAL COORDINATING COUNCIL FOR SCIENCE, ENGINEERING, AND TECHNOLOGY
COMMITTEE ON INTELLECTUAL PROPERTY AND INFORMATION

U.S. DEPARTMENT OF COMMERCE BUILDING
WASHINGTON, D.C. 20230

PATENT DIV, OGC
JUN 1977

SUBCOMMITTEE ON INTELLECTUAL PROPERTY

Minutes of Meeting - May 19, 1977

The meeting convened at 9:35 a.m. in Room 5141A, General Services Building, 18th and F Streets, N.W., Washington, D. C.

Attendees

Members Present	
James E. Denny, Chairman	ERDA
Eugene Pawlikowski for Robert B. Ellert	DOC
Barry L. Grossman, Alternate	DOC
Joseph E. Rusz	AF
William G. Gapcynski	Army
William O. Quesenberry	Navy
Norman J. Latker	HEW
Miles F. Ryan, Jr.	DOJ
Harold P. Deeley, Jr.	DOT
Benjamin Bochenek	EPA
Robert F. Kempf	NASA
Jesse Lasken	NSF
Observers Present	
Maxwell C. Freudenberg	DLA
Charles Goodwin	OFPP
Executive Secretary	
O. A. Neumann	DOC
Guest Present	
Albert Sopp	ERDA
Members Absent	
M. Howard Silverstein	USDA
Donald A. Gardiner	DOI
Philip G. Read	GSA
Jerry A. Cooke	NRC
Jay W. Maynard, Alternate	NRC
Observers Absent	
Ralph C. Oser	AID
Abraham R. Richstein, Alternate	AID
Robert J. Bladergroen	CIA
Robert L. Malech	HUD
Harvey J. Winter	DOS
Walter B. Lockwood, Alternate	DOS
Forest D. Montgomery	Treasury
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Lewis E. Wallace	TVA
Ex-Officio	
Dr. Jordan J. Baruch	DOC
William C. Bartley	FCCSET

EXECUTIVE SECRETARY

ROYALTY ADJUSTMENT ACT

Mr. Kempf advised he called a meeting of the reestablished Legislation Working Group and reported that the group was desirous of obtaining information on the Royalty Adjustment Act insofar as the Act has been resurrected by the Court of Claims decision in the I.T.T. case.

Mr. Deeley noted that LTC. Hougen has written an article relating to this subject which appeared in a recent issue of IDEA.

Mr. Denny reviewed where we are by stating that the Subcommittee has been asked to develop legislation, and the members of the Subcommittee agreed it was a good idea. However, in view of the I.T.T. case, the Subcommittee is reviewing the decision to go ahead.

It was noted that related legislative authority already is provided under 10 U.S.C. 2386. Therefore, drafting legislative authority would be relatively simple. Mr. Kempf advised he is biased toward going for legislation, but still would like to see where the remaining holes are in the Royalty Adjustment Act.

H. R. 6249

Mr. Denny advised that Dr. Jordan Baruch is interested in H.R. 6249, especially since it was developed by a Committee which he undoubtedly would be asked to chair. He noted that Dr. Baruch has asked the Subcommittee to comment on the bill prior to its approval by the Committee for later submission to FCCSET. Mr. Denny believed that the review by the Subcommittee would be directed toward specific language changes which would take probably 2 or 3 meetings of the Subcommittee.

Mr. Quesenberry raised the question as to what the Administration may want with regard to such legislation.

Mr. Neumann advised that as of May 9, 1977, the House Judiciary Committee has requested the Department of Commerce and Justice to comment on the Thornton bill. Mr. Grossman advised that the Patent and Trademark Office has until May 24 to do so.

Mr. Denny suggested that the Subcommittee hold a meeting to discuss this topic, and give Dr. Baruch a chance to talk and meet with us.

Mr. Quesenberry MOVED that, notwithstanding the assignment to this Subcommittee, the IPA arrangement not be extended to the Section 1(a) "exceptional circumstances" provision of the 1971 Presidential Patent Policy Statement. Mr. Deeley seconded the motion.

Following a discussion of the motion, the motion failed to carry, with Air Force, Army, Navy and DOJ voting for the motion.

Substantive Discussion

Mr. Denny noted that it appeared that the amendment to the FPR on the IPA was developed by infusing the language of the NSF and DHEW IPA arrangement, rather than infusing the language of the FPR with the IPA concepts. Mr. Denny gave as an example, the words "granted a hearing" in Section IV.b as opposed to the FPR language of the "right to be heard."

Mr. Quesenberry noted five substantive problems -

1. substitution of "prompt" for "6-month period" (the statutory law problem was noted);
2. subcontract area (requirement to assign inventions to IPA holders - contrary to ASPR);
3. approved patent management organization (what does this consist of - who is to establish?);
4. royalty income utilized in education and research (isn't this so broad that it could encompass anything, for instance, is rasing salaries of professors contemplated?); and
5. is detailed information requested necessary (particularly relating to financial matters, personal information, gross royalties, etc.).

In discussing revisions to the proposed amendment to the FPR, Mr. Denny suggested that perhaps the Subcommittee ought to recommend that certain revisionsbe made to the FPR and ASPR.

With respect to item 1, it was agreed that the 6-month reporting period be maintained with a view that the revisions to the FPR and ASPR could be made later.

Mr. Quesenberry MOVED that the Subcommittee whittle down the information obtained from the universities. Mr. Rusz seconded the motion which did not carry.

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2. Subcontract area (requirement to assign inventions

NEXT MEETING

The next meeting for considering the IPA package was set for Tuesday, June 21, 1977, at 9:30 a.m.

The meeting adjourned at 3:30 p.m.

O. A. Neumann
Executive Secretary

Enclosure
WOQ Memo dtd 5/23/77 to
Exec Secty

DRAFT:JEL:5/20/77

To: Members of the Subcommittee on Intellectual Property

From: Jesse E. Lasken, NSF; Norm Latker, DHEW;
and Gene Pawlikowski, NBS

Subject: Revised IPA/FPR amendment draft

As requested at the SIP meeting of May 19, 1979, the attached redraft is submitted with those changes that were agreed to at that meeting. Some changes are also made to parts of the draft not discussed at SIP's last meeting in order to bring the proposed IPA in closer conformity with FPR language. At its last meeting, the SIP went through Article V(a) of the IPA. SIP concurred in §1-9.107-7(a) of the FPR.

We note, however, that the attached draft still contains certain variations from current FPR language in the following sections which were not reached by SIP at its last meeting:

1. Second sentence of Article IX(c) of the IPA.

2. Some of the time periods in Article VI(b) of the IPA. Otherwise the substance of this paragraph is the same as the FPR although the grammatical arrangement is an improvement.

3. The second sentence of Article V(c) of the IPA which is an attempt to deal with FOIA problems.

We urge SIP to retain the above provisions and to transmit to GSA, along with the IPA amendment, some additional amendments to the FPR to change the other FPR clauses to conform with the above cited language. We believe these changes should not be controversial and should be considered by SIP as part of its review of the draft. These were all changes recommended by some of the commentators on the draft sent out by GSA and are, we believe, eminently worthwhile changes.

To elaborate on these variations in language, we believe the changes to the time periods in Article VI(b) deal with routine administrative matters and merely extend slightly various time periods that are arbitrary in any case. These changes in no way affect the substantive rights of the Government.

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3. The second sentence of Article V(c) of the IPA which is an

The change in Article IX(c) dealing with royalty rebates is, perhaps, more substantive, but is a significant improvement and does not affect, except probably for the better, the Government's rights. We believe it makes more sense to bar a contractor from changing royalties on sales by his licensees to the Government than for the Government to allow him to charge them and then collect them back. It would seem that in this way the seller would have no reason to charge the Government for royalties in the first place. And if it did charge, clearly the Government would have an action against the seller either for fraud or under the Cost and Pricing Data/Truth in Negotiations procedures.

The second sentence of Article V(c) is an attempt to deal with the problem created by the interplay of the current FPR language and the FOIA. It should be noted that as written the FPR might have the effect of creating a statutory bar to patenting when a disclosure is made because of the availability of the disclosure under the FOIA. We urge SIP members to be prepared at the next meeting to discuss and either accept the proposed language or draft alternative language to deal with this problem.

We further recommend that SIP, either at its next meeting or at a meeting soon after review of the IPA amendment is completed, focus on the following items which represent language that was contained in the prior draft but that has been dropped from this draft:

1. The time for reporting of inventions.

2. The last paragraph in Article IV(b) dealing with march-in procedures.

3. The language of III(c)(ii) dealing with foreign filings prior to an agency request for transfer of rights. (This is a minor technical improvement which might possibly be reconsidered at the next meeting and treated in the same manner as suggested for the royalty, FOIA, and time period variations. It is not nearly as important as 1 and 2.)

Items 1 and 2 evoked considerable comment from persons commenting on the draft regulations and were discussed at length by the Subcommittee on University Patent Policy. It appears that SIP's action was based solely on the fact that the language in the draft is different from that of the FPR without any consideration of the fact that it may represent a substantial improvement. We believe it is important that in the near future these two items be taken up by SIP for discussion. We would prefer that this be done in conjunction with the IPA amendments, but agree that it could be deferred to a later meeting as long as there is a commitment by SIP to discuss these problems.

The other changes that have been dropped from this draft were intended to add to the rights of the Government, and we have no objection to leaving these out if the other agencies do not consider them necessary. Thus, this draft does not include the following items found in the prior draft:

1. The last sentence of Article III(a).

2. The last two sentences of Article VI(a).

JEL:DRAFT:5/23/77

L-3 Kent

PROPOSED FPR REVISION

Prepared by Ad Hoc Subcommittee on University Patent Policy

As Marked-up at SIP Meeting of May 19, 1977

1. Add the following subsection (6) to §1-9.107-4(a):

(6) In accordance with the exceptional circumstances language of §1-9.107-3(a) and/or the special situations language of §1-9.107-3(c), agencies may enter into Institutional Patent Agreements as set forth in §1-9.107-6(c)(2) with nonprofit organizations having a technology transfer program meeting the criteria of §1-9.109-7(b). Such agreements provide the organization the right to retain the entire right, title and interest in inventions made in the course of or under contracts subject to certain conditions. When such an agreement has been made with a nonprofit organization, it shall be made applicable to each contract with the organization in lieu of the Patent Rights clauses in §1-9.107-5 and §1-9.107-6 (unless a determination has been made to exclude the contract from the agreement.)

2. Retitle §1-9.107-6 as follows: "Clauses for domestic contracts (short form) and Institutional Patent Agreements."

3. Add the following new subsection (c) to §1-9.107-6:

(c) Patent Rights - Institutional Patent Agreement. (1) When an agency has determined in accordance with §1-9.109-7 that a nonprofit organization should receive an agreement as authorized under §1-9.107-4(a)(6), the Agreement set forth in paragraph (c)(2) of this section appropriately completed as indicated in the numbered notes appearing after the Agreement shall be used. Changes in the agreement should be limited to changes dictated by statutes applicable to the agency or by special administrative needs. In making any changes an agency shall seek to ensure that the agreement continues to include at least the following features:

(A) A requirement for the prompt reporting of all inventions to the applicable agency along with an election of rights;

(B) Reservation of all rights specified in §1-9.107-3(e)-(h);

(C) A requirement that the organization make such inventions available on a nonexclusive basis except where the desired practical or commercial application has not been achieved or is not likely to be expeditiously achieved through such licensing;

(D) A condition limiting any exclusive license to a period not substantially greater than necessary to provide the incentive for bringing the invention to the point of practical or commercial application and to permit the licensee to recoup its costs and a reasonable profit thereon;

(E) A restriction that royalty charges be limited to what is reasonable under the circumstances or reasonable within the industry involved;

(F) A requirement that the organization's royalty receipts, after payment of administrative costs and payments to inventors, be utilized for educational or research purposes;

(G) A provision permitting the agency to except individual contracts from the operation of the agreement;

(H) A requirement for progress reports after designated periods;

(I) A prohibition against assignment of inventions without Governmental approval to persons or organizations, other than assignments to approved patent management organizations subject to the above conditions; and

(J) A provision permitting termination for convenience by either party upon thirty days written notice.

(2) The following is the Institutional Patent Agreement:

INSTITUTIONAL PATENT AGREEMENT

This Agreement is made and entered into by and between the United States of America as represented by the _____ 1/ hereinafter referred to as the "Agency," and _____ hereinafter referred to as the "Institution."

WHEREAS, in accordance with the President's Memorandum and Statement of Government Patent Policy dated August 23, 1971, and the provisions of 41 CFR 1-9.107-4(a)(6), it has been determined that the Institution has a technology transfer program meeting the criteria of 41 CFR 1-9.109-7 in that the Institution's patent policy as set forth in _____ 2/ and its technology transfer practices have been reviewed and found acceptable; and

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1/ The following is the Institutional Patent Agreement:

WHEREAS, the Institution is desirous of entering into an agreement whereby it may retain the entire right, title, and interest in and administer inventions made in the course of or under research supported by the Agency, subject to certain rights acquired by the Government:

NOW, THEREFORE, in consideration of the foregoing, the parties hereto agree as follows:

I. Scope of Agreement

This Agreement defines the rights of the parties hereto regarding the allocation of rights in subject inventions made under contracts with the agency entered into after the execution of the Agreement ~~and prior to September 30, 19__,~~ 3/ except such contracts as may be specifically excluded by the Agency. 3/

II. Definitions

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

(b) "Contract" means any contract, (agreement, grant, or other arrangement) 4/ 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.

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

(d) "To bring 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.

(e) "Made," when used in relation to any invention or discovery, means the conception or first actual reduction to practice of such invention in the course of or under a contract.

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arrangement) 4/ or subcontract

III. Allocation of Principal Rights

(a) The Institution 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 Section V., below, subject to the provisions of this Agreement. The Institution shall include with each Subject Invention disclosure an election whether it will retain the entire right, title, and interest in the invention throughout the world or in any country thereof subject to the rights acquired by the Government in Section IV of the Agreement; provided that the Institution may request an extension of the time for election.

(b) The Institution agrees to convey to the Government, upon request, the entire domestic right, title, and interest in any Subject Invention when the Institution:

(i) does not elect under Section III(a) to retain such rights; or

(ii) fails to have a United States Patent Application filed on the invention in accordance with Section VI(a), or decides not to continue prosecution of such application; or

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

(c) The Institution agrees to convey to the Government, upon request, the entire right, title, and interest in any Subject Invention in any foreign country when the Institution:

(i) does not elect under Section III(a) 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 Section VII(a); or decides not to continue prosecution of such application or to pay any maintenance fees covering the invention. To avoid forfeiture of the patent application or patent, the Institution shall notify the Agency not less than sixty days before the expiration period for any action required by the foreign patent office.

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request, the entire right, title, and interest

(d) A conveyance, requested pursuant to Sections III(b) or (c) of this Agreement, shall be made by delivering to the Agency duly executed instruments (prepared by the Agency) 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 such invention.

IV. Minimum Rights Acquired by the Government

(a) With respect to each Subject Invention to which the Institution retains principal or exclusive rights, the Institution hereby grants to the Government of the United States 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, unless the Agency determines after the invention has been identified that it would not be in the public interest to acquire the license for States and domestic municipal governments;

~~(b) With respect to each Subject Invention to which the Institution retains principal or exclusive rights, the Institution~~ agrees to grant to responsible applicants, upon request of the Agency, a license on terms that are reasonable under the circumstances;

(i) unless the Institution, its licensee, or its assignee, demonstrates to the Government that effective steps have been taken within three 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 or safety needs, or for other public purposes stipulated in the applicable contract.

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

V. Invention Identification, Disclosures, and Reports

(a) The Institution shall furnish the Agency:

(i) a complete technical disclosure for each Subject Invention within six 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 ~~immediately upon~~ any on sale, public use, or publication of the invention known to the Institution. The disclosure shall identify the contract and inventor and shall be sufficiently complete in technical detail 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 5/ for each contract at least every twelve months from the date of the contract listing Subject Inventions for the period and certifying that all Subject Inventions have been disclosed or that there are no such inventions.

(iii) A final report within three months after completion of the work under any contract, listing all Subject Inventions or certifying that there were no such inventions. 6/

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

(c) The Institution agrees that the Government may duplicate and disclose Subject Invention disclosures and, subject to Section XI, all other reports and papers furnished or required to be furnished pursuant to this Agreement. However, if the Institution is to file a patent application on a Subject Invention, the Agency agrees, upon written request of the Institution, to use its best efforts to withhold publication of such invention disclosures until a patent application is filed theron, but in no event shall the Government or its employees be liable for any publication thereof.

(d) The Institution shall not bar or prohibit publication of disclosures of Subject Inventions on which patent applications have been filed. delete

VI. Filing of Domestic Patent Applications

(a) With respect to each Subject Invention in which the Institution elects to retain domestic rights pursuant to Section III(a) of this Agreement, the Institution shall have a domestic patent application filed within six months after an election has been made pursuant to Section III(a) of this Agreement or such longer period as may be approved in writing by the Agency.

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

(i) within six months after such filing, or within six months after submission of the invention disclosure if the patent application was filed prior to the contract, deliver to the Agency (A) a copy of the application as filed, including the filing date and serial number: (B) a copy of an assignment from the inventor or inventors to the Institution of all right, title, and interest in the invention properly recorded in the United States Patent and Trademark Office; and (C) a duly executed and approved instrument on the form specified in Exhibit A which is attached hereto and made a part hereof;

(ii) include the following statement, appropriately completed, in the second paragraph of the specification of the application and any patents issued on the Subject Invention, "The Government has rights in this invention pursuant to Contract(s) (or Grant(s)) No(s). _____ awarded by (identify the Agency or Agencies)";

(iii) not less than thirty days before the expiration of the response period for any action required by the United States Patent and Trademark Office, notify the Agency of any decision not to continue the prosecution of the application and deliver to the Agency ~~(upon request)~~ executed instruments granting the Government a power of attorney;

(iv) upon request, fully advise the Agency concerning all actions taken during the prosecution of any patent application and furnish copies of any relevant documents as requested; and

(v) provide the Agency with a copy of the patent within six months after a patent issues on the application.

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of the application and any

(c) For each Subject Invention in which the Institution initially elects not to retain rights or requests an extension of the election period, the Institution shall inform the Agency 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 USC 102, which was authorized by or known to the Institution or any contemplated action of this nature.

VII. Filing of Foreign Patent Applications

(a) With respect to each Subject Invention in which the Institution elects to retain principal rights in a foreign country pursuant to Section III(a) of this Agreement, the Institution shall have a patent application filed on the invention in ~~such~~ that country, in accordance with applicable statutes and regulations, and within one of the following periods:

(i) eight months from the date of a corresponding United States application filed by or on behalf of the Institution; or if such an application is not filed, ~~six months after an election is made pursuant to Section III(a)~~ from the date the invention is submitted pursuant to Section VI(a) of this Agreement;

(ii) six months from the date a license is granted by the Commissioner of Patents and Trademarks to file foreign applications when such filing has been prohibited by security reasons; or

(iii) such longer period as may be approved ~~in writing~~ by the Agency.

(b) The Institution shall notify the Agency of foreign applications filed and, upon request, shall furnish an English version of such application without additional compensation.

VIII. Subcontracts

(a) Except as provided in (b), below, or when the subcontractor holds an Institutional Patent Agreement with the Agency, the Institution shall include in any subcontract where a purpose of that subcontract is the conduct of experimental, developmental, or research work ~~either the "Patent Rights - Acquisition by the Government" clause found at 41 CFR 1-9.107-5(a) or~~ the following clause: use the following clause:

Patent Rights

(a) The Contractor hereby agrees to report fully and promptly to _____ (Institution) any invention conceived or first actually reduced to practice in the course of or under this contract (hereinafter referred to as "Subject Invention(s)," and, subject to (b), below, to assign all right, title, and interest in and to such invention to _____ (Institution) or its designee.

(b) At the time the Contractor reports any "Subject Invention" to _____ (Institution), the Contractor, at its option, may also report the invention to the agency with which the Institution holds the prime contract and request that the agency make a determination whether and on what terms the contractor may retain principal rights in the invention in lieu of assigning it to _____ (Institution). Such determinations by the agency shall be in accordance with the policies and procedures of Part 1-9 of the Federal Procurement Regulations and/or applicable agency regulations. Such determinations shall be final on both the Contractor and _____ (Institution), provided that Contractor may elect not to accept the Agency determination and instead assign all right, title, and interest in the invention to _____ (Institution) or its designee.

(c) In addition, the Contractor agrees to furnish the following materials, disclosures and reports:

(i) Upon request, such duly executed instruments (prepared by the _____ (Institution) or its designee) and such other papers as are deemed necessary to vest in the _____ (Institution) or its designee the rights granted under this clause and to enable the _____ (Institution) or its designee to apply for and prosecute any patent application, in any country, covering such invention.

(ii) Prior to final settlement of this contract, a final report listing all Subject Inventions or certifying that no inventions were conceived or first actually reduced to practice under the contract.

(d) The Contractor shall include in any subcontract either a clause identical to this clause or the "Patent Rights - Acquisition by the Government" clause found at 41 CFR 1-9.107-5(a) if a purpose of the subcontract is experimental, developmental, or research work. If a subcontractor refuses to accept either of these clauses or if, in the opinion of the Contractor, these clauses are inconsistent with the policy set forth in 41 CFR 1-9.107-3, the Contractor (i) shall promptly notify the Institution and (ii) shall not proceed with the subcontract without the written authorization of the Institution. It is understood that the Institution will seek direction from the _____ (insert name of appropriate Agency).

(e) The Contractor shall report any subcontracts containing a patent rights clause to the Institution. The Contractor shall not be obligated to enforce the agreements of any Subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to Subject Inventions.

[End of Clause]

(b) In the event of a refusal by a subcontractor to accept either of the clauses specified in (a), or if, in the opinion of the Institution, these clauses are inconsistent with the policy set forth in 41 CFR 1-9.107-3, the Institution (i) shall promptly submit a written notice to the Agency 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 Agency.

(c) 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 Institution hereby assigns to the Government all rights that it would have to enforce the Subcontractor's obligations for the benefit of the Government with respect to Subject Inventions. The Institution shall not be obligated to enforce the agreements of any subcontractor hereunder relating to the obligations of the Subcontractor to the Government in regard to Subject Invention.

(d) Nothing in this Agreement is intended to preclude the Institution from granting a subcontractor rights or an option to rights in any inventions made by the subcontractor to the extent such rights are consistent with the provisions of this Agreement.

1977

In the year of our Lord
and merciful Lord 1977

May 20, 1977

:

Attached are some additional interesting memos which are progenitors of present patent practices. Dr. Endicott's 1962 memo is the very first attempt to my knowledge to surface the need for review. Dr. Shannon's 1964 memo to the Surgeon General, and the Surgeon General's forwarding memo to Manny Hiller was the first attempt to resolve the deposition of rights question. You have Dr. Shannon's 1965 testimony before Congress and the 1968 GAO report which are probably the next relevant documents resulting in present practices.

Reading these documents together is very interesting and makes clear the long gestation period we moved through before reaching something that seems to be acceptable to most people. While things might be better, I feel we have moved nearly a light year from where we were when Dr. Endicott tried to spell out the problem in 1962.

Norman Latker

Attachments.

Attachments

prepared for
California

Health Tech
Migrant Study
'77

HEALTH TECHNOLOGY MANAGEMENT

AT THE

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

A Report for the Secretary

December 22, 1977

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INTRODUCTION

-- How many tonsillectomies performed in this country are necessary?

-- What are the health outcomes from coronary bypass surgery versus drug therapy ?

-- How can new laboratory findings be linked with bedside practice?

-- What institutional or professional qualifications should be required of those proposing tc perform open heart surgery?

-- What market incentive mechanisms can be used to stimulate development of lagging or absent beneficial and cost-saving health technologies?

The Problem

There is widespread agreement that twentieth century biomedical research and technological innovation have been responsible for profound improvements in human health. Some diseases have been eradicated; others can now be prevented; life itself has been extended; and much pain and suffering has been alleviated.

There is now emerging, however, a consensus that many technologies have been widely adopted into medical practice in the face of disturbingly scanty information about their health benefits, clinical risks, cost-effectiveness, and societal side-effects; that the use and overuse of other technologies has persisted long after it was evident that they were of marginal utility, outmoded, or even harmful; and that still other well-validated innovations have been inordinately slow in finding their way to patient care.

The consequences of such failures -- including spiraling costs with less than commensurate health improvements and iatrogenic health problems -- are now posing major dilemmas for providers, planners, patients and third party payers about the uses of existing and emerging technologies .

The Health Technology Environment

Evidence of a raised health technology consciousness is accumulating:

-- Dozens of articles about the use and abuse of technology have been written recently by prominent health officials and researchers;

-- Blue Shield has announced that it will no longer reimburse routinely for 28 medical and surgical procedures;

-- Two National commissions on biomedical research have been created in recent years one of which was Presidentially appointed;

-- Senator Kennedy has held a series of hearings, and Congressman Moss has proposed technology control-related legislation;

-- The Office of Technology Assessment has issued five reports on medical technology, and the Institute of Medicine will soon publish the results of a year-long study on the process of adoption and diffusion of hard technology;

-- Public interest groups are demanding increased consumer protection;

-- Private insurers and employers are searching for guidance on the relationship between the use of technology and soaring health care costs.

While there is increasing (though far from universal) advocacy for managing health technology toward serving the public more efficiently and effectively, there are divergent perspectives on who would take the lead role in integrating efforts toward that end and the means to be employed. For example:

-- Many research scientists view a stronger government role as a threat to beneficial technological innovation;

-- Many practicing physicians view such efforts as compromising the physician-patient relationship and their independence of professional judgement;

-- Many drug and device manufacturers are concerned about government interference with the marketplace and additional restrictions with which it is costly to comply;

-- Still others are concerned about overmanagement and its potential for increasing delays in the flow of beneficial innovations to bedside practice.

The multiple problems arising from technology development and utilization have not emerged overnight, and even the most carefully devised Department initiative is unlikely to provide a "quick fix" to the extraordinarily complex set of problems involved. This report proposes a major management initiative, but it is only one step toward a long-range solution that must take into account the complexities of technology development/transfer/utilization, and the divergent priorities, perspectives, and values of the various parties-at-interest.

The alternative to adopting a new strategy is to continue the current essentially laissez-faire approach which too frequently leaves development and adoption of technologies to the intellectual curiosity of researchers, the marketing strategies of manufacturers, the slowly evolving consensus of practitioners, the demands of usually uninformed consumers, and the incentives of the relatively unconstrained health market.

The Department of Health, Education, and Welfare

This report focuses on medical technologies (drugs, devices, and medical and surgical procedures) with which this Department is involved in three primary ways:

-- it develops technologies both intramurally through employee scientists and innovators, and extramurally through support of research and development activities;

-- it evaluates existing and emerging technologies to attempt to understand their value and their implications for health and society;

-- it recognizes technologies by regulating them, by buying them, by reimbursing for them, or by otherwise contributing to their use or non-use.

Yet for all of its involvement, the Department has no strategy for systematically linking the life cycle of technology development, evaluation, transfer, diffusion, utilization and phase-out. Nor has it either expected such a strategy of its agencies (with the exception of FDA) or provided resources to construct one. Consequently,

-- the "knowledge development" agencies (like NIH and NCHSR) each decide independently which technologies they will examine, how they will examine them, and how they will handle the results;

-- the "action agencies" (such as HSA, Medicare, Medicaid, and the PSRO program) lack both the technical information to carry out their responsibilities and the links to the knowledge development agencies through which to negotiate examination of the technologies for which they need action-supporting information;

-- results of technical evaluations appear in the research literature, but often do not come to the attention of practicing physicians or those officials responsible for making reimbursement decisions, and developing regulations, legislation and standards;

-- technology evaluation activities are extensive, but existing technologies (particularly medical and surgical procedures) receive too little attention;

-- considerable effort is focused on efficacy and safety evaluations, but little is done about the cost-benefit and cost-effectiveness implications and virtually nothing is done to examine general societal impacts;

-- the linkages between technology studies and action to impede or stimulate technology transfer and utilization are ad hoc and often fail.

What does this mean

As a result, DHEW is currently seeking a new strategy for handling medical technologies to assure that they are more carefully scrutinized for their efficacy and effect on health outcomes, more rapidly introduced or phased out of practice, more efficiently organized and equitably distributed, and more appropriately and effectively used. Such a strategy must be able to provide a balance between controlling costs of health care and over-controlling technological innovation at the expense of quality of health care.

From our past experience with drugs, it is known that expanding technology managment will place difficult and sensitive decisionmaking authorities in the hands of government. Although extensive intra-Departmental and extra-Departmental consultation is planned, in the final analysis DHEW officials will have to weigh uncertain evidence of scientific inquiry against their estimates of the value of quality of life and costs. Such decisions cannot be made without their inevitable risks and errors. Nevertheless, the Study Team believes that the systematization of currently fragmented processes and the rendering explicit of presently implicit decisions and actions sum to a justified and responsible step.

The Charge to the Study Team

On July 20, during his testimony before the Senate Subcommittee on Health and Scientific Research, Assistant Secretary for Health Dr. Julius Richmond was asked by Senator Kennedy if the Department could develop an outline for a DHEW

systems approach to technology management. At the same time, Assistant Secretary for Planning and Evaluation Henry Aaron had advised Secretary Califano that his staff was preparing a decision memorandum on technology management in the Department. As a result, the Office of the Assistant Secretary for Planning and Evaluation (P), in collaboration with the Office of the Assistant Secretary for Health (H), was asked to conduct a month-long Phase I study of this issue. P and H staff met jointly with representatives of the Department's health agencies and asked them to produce, within ten days, reports of their agencies' technology-related activities. (See Appendix Tab 2 for the Agency Report Outline.) The resulting reports (Appendix Tabs 3 through 11) were analyed and compared with the Study Team's conceptual framework for technology management to form the basis of this report.

Focus of the Phase I Study

The focus of this study is the development of a Departmental strategy for ensuring that emerging or existing health technologies are systematically evaluated and that results of those evaluations are linked to explicit actions -- using intervention mechanisms available to the Department -- to stimulate or retard development; encourage/discourage/or place constraints on utilization; or effect phase-out.

The Study Team examined current Departmental activities to discern (1) whether there exists in the Department structures and processes for systematically evaluating and acting to influence the development and use of technologies, and (2) whether technologies are in fact being systematically addressed. It was concluded that neither was the case. The Team then developed a linked,