MEMORANDUM

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

TO : James Hinchman
Assistant General Counsel

DATE: January 9, 1977

PATENT BRANCH, OGC
DHEW

JAN 17 1978

FROM : Senior Fellow, NCHSR

SUBJECT: Patent Policy Study

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

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

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

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

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

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

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

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

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

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

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

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

Sherry Arnstein

cc: David Cooper
Chris Bladen
Norman Latker