DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Office of the Assistant Secretary
for Health
Washington DC 20201

NOV 24 1987

TO: Heads of PHS Agencies, Centers and Institutes
(Delegatees of October 14 Memorandum)

From: Assistant Secretary for Health

Under my authorities under Chapter 1-901-10 of the department Organization Manual, I am delegating to the delegatees indicated in my October 14, 1987 memorandum implementing the Federal Technology Transfer Act of 1986, the following agency responsibilities under P. L. 96-517 as amended and as implemented under the Department of Commerce regulations found at 37 CFR, Part 401 (Attached):

a) The authority as provided to the agency under 35 USC 202(c)(7), to grant approval of the assignment of a subject invention to organizations who do not have as one of its primary junctions the management of inventions.

b) The authority, as provided to the agency under 35 USC 202(c) (7) (B) prior to its amendment by P.L. 98-620, to on a case-by-case basis approve longer exclusive licenses than specified by 202(c) (7) (B) to organizations other than small business firms.

c) The authority as provided to the agency under 35 USC 204, to waive the requirement that when a small business firm or nonprofit organization grants an exclusive license the licensee must agree that any products embodying the subject invention or produced through the use of the subject invention will be manufactured substantially in the United States.

d) The authority, as provided to the agency by 35 USC 205, to withhold from disclosure to the public information , 1) disclosing any invention in which the government may own an interest for a reasonable time in order for a patent application to be filed, and 2) copies of documents which are part of foreign or domestic patent applications.

e) The authorities provided to the agency under 35 USC 207 and 209 where delegated to you by my October 14, 1987 memorandum. (35 US 209 sets out the procedures and conditions that must be undertaken when exercising the licensing authority of 35 US 207).

All other agency responsibilities specified by P.L. 96-517, as amended, will be retained by ASH. As necessary, the delegatee shall discuss the exercise of these authorities with the Department of Commerce, who is responsible for implementation of P.L. 96-517, as amended, through their regulation as 37 CFR, Part 401, copies attached herewith.

Robert E. Windom, M.D.

Dr. Ortner

UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Economic Affairs
Washington, D.C. 20230

2 NOV 1987

MEMORANDUM FOR Douglas A. Riggs
General Counsel

FROM: Robert Ortner
Under Secretary for Economic Affairs

SUBJECT: Preparation of Materials Explaining the Application of the Employee Standards of Conduct to Activities Under the Technology Transfer Act of 1986

In your memorandum of February 11, 1987, you reviewed this Department's Employee Standards of Conduct for the purposes of the Federal Technology Transfer Act of 1986, and concluded that "our regulations establish adequate guidelines to cover situations under the law and do not require changes at this time." My office is now beginning to prepare materials for use in the Department's laboratories that will establish guidelines for employees in situations likely to arise under the Act. The purpose of this memorandum is to ask you to assign a member of your staff to work with Norm Latker, Director, Office of Federal Technology Management, in the preparation of these guidelines.

These guidelines would address problems that might arise in the course of this Department's implementation of the Act. Some examples of specific questions that should be discussed include:

- Could a Federal employee/inventor accept compensation as a consultant from a firm which is licensing that employee's invention from the Federal government?
- Could a Federal employee/inventor or co-inventor accept compensation for giving technical advice to a private firm on developing an invention that these employees made under a cooperative agreement with the laboratory?
- Could a Federal employee/inventor invest or become a stockholder in a firm which is licensing that employee's invention from the Federal government?
- Could a Federal employee/inventor become an officer in a firm which is licensing that employee's invention from the Federal government?

- Could a Federal employee/inventor remain an employee and become an officer in a firm which, as a result of a cooperative agreement, has been granted in advance a patent license for all that employee's inventions arising under the agreement?

- Would a Federal employee/inventor who obtains a license from the government to use his or her own invention receive 15 percent of the royalties back from the government that he or she paid to the government for the right to use the invention?

- What restrictions are there on a former employee of a Federal laboratory negotiating a cooperative R&D agreement with that Federal laboratory?

- Under what circumstances can an employee of a laboratory leave the laboratory and become an employee of a company which has a cooperative agreement with the laboratory?

Ch.C/EA/re 9/21/87
bc: Dr. Ortner
Bob Ellert 9/15
Chron
Read

UNITED STATES DEPARTMENT OF COMMERCE
The Under Secretary for Economic Affairs
Washington, D.C. 20230

2 NOV 1987

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General Counsel

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- Under what circumstances can an employee of a laboratory leave the laboratory and become an employee of a company which has a cooperative agreement with the laboratory?

GENERAL COUNSEL OF THE
UNITED STATES DEPARTMENT OF COMMERCE
Washington, D C 20230

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see 86-121

MEMORANDUM FOR: Robert Ortner
Under Secretary for Economic Affairs

FROM: Douglas A. Riggs Douglas A. Riggs

SUBJECT: Review of Employee Standards of Conduct Under P. L. 99-502

Under the provisions of subsection 11(c)(3)(A) of the Stevenson-Wydler Technology Innovation Act of 1980 (Pub. L. 96-480), as amended by section 2 of the Federal Technology Transfer Act of 1986 (Pub. L. 99-502), and at your request, my office has reviewed the Department's employee standards of conduct (15 CFR Part 0). The statutory purpose of the review was to ensure that the standards of conduct contain adequate guidelines to deal with situations likely to arise using the authority of section 11(a) of this legislation. Briefly, section 11(a) authorizes Federal agencies to enter into cooperative research and development agreements with other parties, including licensees of inventions owned by the agencies. As a result of our review, I am satisfied that our regulations establish adequate guidelines to cover situations under the law and do not require changes at this time.

In undertaking our review, we were mindful that a major purpose of the legislation is to establish a framework for permitting employees or former employees or their partners to participate in efforts to commercialize inventions the employees made while in the service of the United States. This would include the authority for those individuals to negotiate licenses or assignments of title to inventions or to negotiate cooperative research and development agreements with their present or former employing agency. These negotiations may, depending upon the facts of the particular situation, present issues under applicable conflict of interest statutes or standards of conduct regulations. The legislation recognizes this, in noting, in section 11(b)(4), that employees or former employees are permitted to participate in commercialization efforts "to the extent consistent with any applicable agency requirements and standards of conduct." The legislative history confirms this intent. The report of the Senate Committee on Commerce, Science, and Transportation (No. 99-283) notes, at page 10, that the legislation

> make[s] no changes in the conflict of interest laws affecting Federal employees or former Federal employees. The Committee does not

> believe that this section releases former employees from conflict of interest restraints in current law, and does not intend this result. Agencies have the flexibility under this section to establish standards for cooperative research arrangements which prevent former employees from benefitting unjustly from their former employment. Conversely, laboratories may need the assistance of former employees to develop the commercial potential of inventions, and this provision is intended to allow their participation according to agency standards.

We have conducted the required review of our regulations with these principles in mind and, as noted above, we have concluded that the regulations are adequate. We have been faced, from time to time, with inquiries from employees about their ability to commercialize inventions developed by them as part of their official activities. Such matters are decided on a case-by-case basis, in which our overall concern is whether the employee is in a better position, due to his employment, to obtain a license or commercially exploit a device than would be members of the general public. In a major study of this issue last year, my office identified four factors to consider in deciding such questions: (1) whether the license applicant/Government employee had any role in development of the device in question, (2) whether he has a role, as a Government employee, in any decision on whether to continue or discontinue Government development, (3) whether he had any role, as a Government employee, in the decision to seek a Government patent or issue a license or to whom to issue the license, and (4) whether he has access to confidential Government information concerning the device. These factors, all derived from existing conflicts-of-interest provisions, allow an employee to obtain a license and exploit an invention while, at the same time, prevent an abuse of the system by prohibiting an employee from using his position or inside information for private gain.

As noted above, these factors will continue to apply. To them, however, we would add a factor that reflects the public policy found in the new legislation. Specifically, we would now take into consideration the expressed Government policy in favor of licensing inventions to Federal employees. I am satisfied this can be done within the framework of our existing regulations, so long as care is taken to ensure that employees receive no unfair advantage due to undisclosed information.

Finally, I note that the full range of Federal conflict-of-interest statutes in title 18 of the U.S. Code would continue to apply. These will, for example, preclude an employee from acting in an official capacity on a matter that will affect his financial interests in a license (18 U.S.C. § 208) and may serve to limit his ability to represent the interests of an outside corporation

regarding its license in the invention before the Government (18 U.S.C. §§ 203 and 205). These restrictions are consistent with the legislation and, in any event, are not addressed by the requirement to review the Department's standards of conduct.

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