Lowell 4/13

The major difference I see is that the delegations stop at the PHS Agency head level unless redelegated — There is no incentive to redelegate.

Further they fuzz over a lot of specifics that were clear in our delegation.

I think they set the stage for interminable argument for anyone who wishes to create a problem.

Norm

4/12 Norm - compare to our Delegation Draft.

Public Health Service

PHS Agency Heads, Federal Technology Transfer Act; Delegation of Authority

Notice is hereby given that in furtherance of the delegation of June 23, 1987, by the Secretary of Health and Human Services to the Assistant Secretary for Health, the Assistant Secretary for Health has delegated to the PHS Agency Heads, in their dual capacity as heads of Federal agencies and heads of Federal laboratories, with authority to redelegate, all of the authorities under the Stevenson-Wydler Technology Innovation Act of 1980 (15 U.S.C. 3701 *et seq.*), as amended by the Federal Technology Transfer Act of 1986, Pub. L. 99-502, and under Executive Order No. 12591 of April 10, 1987, as amended hereafter, as they pertain to the functions of their respective agencies. This delegation excludes the authorities listed below under Restrictions.

Case by case

Restrictions

1. The Secretary has retained the authority to promulgate regulations and submit reports to the Congress.

2. This delegation does not include the authority to:

- Approve agreements and contracts with invention management organizations, such as the National Technical Information Service, under Section 11(a)(2); and
- Propose necessary statutory changes regarding conflict of interest to be forwarded to its authorizing committee in Congress under Section 11(c)(3)(B).

3. The following authorities may be redelegated only to a senior official in the immediate office of the Agency Head:

Section 11—Cooperative Research and Development Agreements:

(c)(5)(A)—The authority to disapprove or require the modification of cooperative research and development agreements and licensing agreements within a 60-day period, beginning on the date the agreement is presented to the head of the PHS agency by the head of the laboratory concerned;

(c)(5)(B)—The authority to transmit a written explanation of such disapproval or modification to the head of the laboratory concerned, in any case in which the head of the PHS agency disapproves or requires the modification of an agreement presented under this section.

4. The following authorities may not be redelegated:

Section 11—Cooperative Research and Development Agreements:

(b)(3)—The authority to waive, subject to reservation by the Government of a nonexclusive, irrevocable, paid-up license to practice the invention or have the invention practiced throughout the world by or on behalf of the Government, in advance, in whole or in part, any right of ownership which the Federal Government may have to any subject invention made under the agreement by a collaborating party or employee of a collaborating party;

(b)(4)—The authority, to the extent consistent with any applicable agency requirements and standards of conduct, to permit employees or former employees of the laboratory to participate in efforts to commercialize inventions they made while in the service of the United States.

(c)(3)(A)—The authority to review employee standards of conduct for resolving potential conflicts of interest to make sure they adequately establish guidelines for situations likely to arise through the use of this authority including but not limited to cases where present or former employees or their partners negotiate licenses or assignments of titles to inventions or negotiate cooperative research and development agreements with Federal agencies (including the agency with which the employee involved is or was formerly employed).

Section 13—Distribution of Royalties Received by Federal Agencies:

(a)(1)—The authority to retain any royalties or other income, except as provided in paragraph (a)(2) of this section, from the licensing or assignment of inventions under agreements entered into under section 11, and inventions of Government-operated Federal laboratories licensed under section 207 of Title 35, United States Code, or under any other provision of law.

(a)(1)(A)(i)—The authority to pay at least 15 percent of the royalties or other income the agency receives on account of any invention to the inventor (or co-inventors) if the inventor (or each such co-inventor) was an employee of the agency at the time the invention was made.

5. Any authorities delegated by the PHS Agency Heads may not be further redelegated.

6. After providing prior notice, the Assistant Secretary for Health may elect to exercise any authority included in this delegation.

Prior Delegations and Supersessions

The delegations of authority dated October 14, 1987, under the Federal Technology Transfer Act, and November 24, 1987, under 37 CFR Part 401 are hereby rescinded. Furthermore, the Federal Register notice of August 22, 1986 (51 FR 30130), "AIDS Vaccine Development: Private Sector/Government Collaborative Efforts," which establishes a framework for collaborative efforts between the Public Health Service (PHS) and the private sector for the development, testing, production and distribution of a vaccine for the prevention of Acquired Immune Deficiency Syndrome (AIDS), is hereby superseded.

Information and Guidance

5 U.S.C. 3701 *et seq.*, and memorandum of February 4, 1988 which transmits this delegation of authority.

Effective Date: Effective February 4, 1988.

Robert E. Windom,

Assistant Secretary for Health.

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Surgeon General; Delegation of Authority

A. Notice is hereby given that pursuant to the delegation of authority of January 20, 1988, from the Secretary of Health and Human Services to the Assistant Secretary for Health, I have delegated to the Surgeon General the authority to:

1. Appoint individuals in the Reserve Corps of the PHS Commissioned Corps pursuant to 42 U.S.C. 204;

2. Terminate commissions of Reserve Corps officers without the consent of the officers concerned pursuant to 42 U.S.C. 209(a)(2);

3. Make or terminate temporary promotions of regular and Reserve Corps officers pursuant to 42 U.S.C. 211(a), (k), and (l); and

4. Prescribe titles, appropriate to the several grades, for PHS commissioned officers, other than medical officers, pursuant to 42 U.S.C. 207(b).

These authorities may be exercised by and redelegated to only those officials of the Public Health Service who are required to be appointed by the President, by and with the advice and consent of the Senate.

B. I have also delegated to the Surgeon General, with authority to redelegate except as noted below, those authorities delegated to the Assistant Secretary for Health which are necessary to administer the PHS