**PROPOSED CHANGES TO FEDERAL TECHNOLOGY TRANSFER LAWS**

SUBJECT: RFI Response: Federal Technology Transfer Authorities and Processes

1. Add a new 15 USC 3710a(3) that reads: “(3) that authority may be further delegated.”

Rationale: Efficiency and Effectiveness. The reality at federal laboratories is that the director is often away on business, and his/her Chiefs of Research, and/or Department or Division heads are in a better position to determine the appropriateness of any particular CRADA proposal. The Department of Defense T2 Directive and some other agencies already allow for this delegation of authority.

1. Modify the second sentence of 15 USC 3710a(b)(1) to read:

“The laboratory shall ensure, through such agreement, that the collaborating party has the option to choose, at a minimum, an exclusive license for a pre-negotiated field of use for any such invention under the agreement or, if there is more than one collaborating party, that the collaborating parties are offered the option to hold licensing rights that collectively encompass the rights that would be held under such an exclusive license by one party.”

Rationale: The modification clears up what was congressional intent in establishing the required option for CRADA collaborators. See attached, “Collaborator License Options to Laboratory Inventions Made under CRADAs,” by Guy M. Miller, Patent Attorney, AMC Legal Center, U.S. Army Research Laboratory, Office of the Chief Counsel – Intellectual Property Law Branch. (Used with permission of author).

3. Modif**y** the first sentence of 15 USC 3710a(b)(1)(A) so that it reads:

“The collaborating party agrees to execute or to have executed and promptly deliver to the laboratory a nonexclusive, nontransferable, irrevocable, paid-up license to practice the subject invention by or on behalf of the Government wherever rights in the invention have been established or confirmed throughout the world.”

Rationale: The current language is poorly drafted and confusing. Read literally, it requires the collaborating party to provide the laboratory a nonexclusive, nontransferable, irrevocable, paid-up license to practice the invention throughout the world. However, rarely, if ever, does the collaborating party have the right to grant such world-wide rights, because its patent coverage does not cover every country. Therefore, the current language would require that the collaborating party to obtain patent protection in every country in the world in order to give the Government the right to practice the invention throughout the world. The proposed modification reflects the reality of what is sought.

4. Delete 15 USC 3710a(b)(3)(D). This subparagraph allows the federal lab to waive, in whole or in part, any right of ownership the lab may have in any subject invention made by a collaborating party or employee of a collaborating party, subject to the reservation of a Government use license.

Rationale: This subparagraph is inconsistent with language in subsection 3710a(b)(2), which allows the collaborating party to retain title to any invention made solely by its employee in exchange for “normally” granting the Government a Government use license. The better practice is to allow the laboratory the flexibility to determine, in light of the whole proposal, whether requiring a Government use license for any collaborator-only invention has any substantive value for the Government. If, prior to the collaboration, the collaborator has already invested significantly in the technology in question (e.g., through its own R&D funds and patenting), and the government lab’s T2 goal is, in that instance, solely to accelerate the development of private sector technologies so that they will be available sooner for commercial purchase, then requiring that the Government to maintain a Government Use license only discourages the collaborator from working with the laboratory. This frequently happens in the medical R&D realm, where the collaboration is a clinical trial at a government hospital of the private sector collaborator’s experimental (i.e., not yet approved by FDA) technology (e.g., drug, device, or vaccine). The overarching aim in these collaborations is to help the collaborator obtain sufficient evidence for the effectiveness of their technology for regulatory approval; it is not to obtain IP rights for the federal laboratory to experiment with.

5. Delete15 USC 3710a(c)(5)(A) and (B).

Rationale: After over 32 years of CRADA practice by the agencies, there is no evidence that permitting the agency heads or their designees 30 days in which to disapprove or require modifications to a proposed CRADA provides value to the Government, and only adds an element of risk and uncertainty for non-federal parties when considering a collaboration with the laboratories.

6. Inserta new 15 USC 3710a(c)(3) that reads:

“(3) In accordance with agency conflict of interest rules and export control laws and regulations, Federal laboratories may enter into cooperative research and development agreements with federal contractors, grantees, and other federal award recipients or subrecipients, and may accept, retain, and use funds and other resources from such parties where the director of the Federal laboratory determines that the technical subject matter of the funding is sufficiently distinct from that of the cooperative research and development agreement.” (Renumber the subparagraphs that follow.)

Rationale: To clarify congressional intent, as set forth in the FTTA Congressional record and in the CRADA statute, that, in passing the FTTA, Congress intended to allow Federal laboratories to collaborate under CRADAs with federal award recipients and subrecipients, to include allowing federal award funds to pass from those recipients/subrecipients to the laboratories. Many, if not most, agencies do not understand this and consider such activities to be somehow improper or illegal under fiscal laws. I know this misunderstanding exists from having discussed the issue dozens of times with T2 and federal contracting colleagues from throughout the federal sector, and it causes significant impediments to Federal laboratories participation in CRADAs where there is no internal funding to support the laboratories efforts.

Reference, Senate Report NO. 99-283, April 21, 1986, (which was part of the joint conference committee report on the FTTA, along with House Report 3773) in explaining the definition of a CRADA (codified at 15 USC 3710a(d)(1)), states: “Section 5 defines cooperative agreements (i.e., CRADAs) as those in which the Federal government provides resources, but not funds, along with a collaborating party, toward the conduct of specific research or development which is consistent with the missions of the agency. *Nevertheless, this section is not intended to prohibit Federal financial contributions as might be authorized and appropriated by other acts of Congress.* *To effectuate cooperative research agreements, the section gives Federal laboratories the authority to accept funds,* services, and property from the collaborating parties; . . .” (Emphasis added.)

The congressional intent to allow for “Federal financial contributions as might be authorized and appropriated by other acts of Congress” was put into the statute at what is now 15 USC 3710a(f), which states: “(f) Relationship to other laws – Nothing in this section is intended to limit or diminish existing authorities of any agency.”

Recent Commerce Department regulations also explicitly recognize the legality of federal contractors providing funding to a laboratory under a CRADA. In 15 CFR Part 17, at section 17.3, it reads: “The existence of a funding agreement between a Federal laboratory and a contractor shall not preclude the Federal laboratory from using its authority under 15 U.S.C. 3710a to enter into a CRDA with a contract as a collaborating party for the conduct of specified research or development efforts, where the director of the Federal laboratory determines that the technical subject matter of the funding is sufficiently distinct from that of the CRADA.”

Some Federal agencies recognize congressional intent and explicitly allow for funds from an agency award recipient to pass to be provided to a Federal laboratory under a CRADA. For example, the SBA allows this; see FR/Vol. 70, No. 241, Friday, Dec. 16, 2005/Notices, page 74937, paragraph 9(c)(2)(i)-(iii). See also, the DHHS Grants Policy.

7. Modify15 USC 3710c(a)(3) to allow payments to inventors increase to $350,000 per year to any one person from the current $150,000.

Rationale: The proposed change will keep this statutory incentive program up with inflation.