March 23, 2020

The Honorable Nancy Pelosi
Speaker
House of Representatives
Washington, D.C. 20515

Dear Madam Speaker:

Knowledge Ecology International (KEI) is following technology transfer, intellectual property rights and transparency issues related to the COVID-19 pandemic response. We write to direct your attention to Section 3301 of the current draft of the Senate's version of the coronavirus funding bill (H.R. 748), which proposes to expand the authority of Biomedical Advanced Research and Development Authority (BARDA) to enter into "Other Transactions" for R&D funding agreements, in the case of public health emergencies. We oppose the use and expansion of this authority because it does not protect taxpayers' investment in government-funded research and development.

"Other transactions" are agreements that are not standard government contracts, cooperative agreements, or Cooperative Research and Development Agreements (CRADAs). So far, Congress has extended "Other Transaction Authority" (OTA) to at least 11 federal agencies. The Department of Health and Human Services (HHS)/BARDA was granted OTA through the enactment of the Pandemic and All Hazards Preparedness Act of 2006, Pub. L. No. 101-417 (42 U.S.C. § 247d-7e).

Section 3301 would amend 42 U.S.C. § 247d-7e to eliminate, in cases of public health emergencies, the limitation that HHS may execute other transaction agreements "in excess of $100,000,000 only upon a written determination by the Assistant Secretary for Financial Resources, that the use of such authority is essential to promoting the success of the project."

Under the Bayh-Dole Act, 35 U.S.C. § 200 *et seq*., businesses and nonprofit organizations that receive federal funding to conduct research and development may retain title to an invention that arises out of the funding agreement, subject to certain safeguards that were implemented to protect taxpayers' investment in federally-funded research and to ensure that the invention is available to the public on reasonable terms. As it stands, OTA has been interpreted by federal agencies so as to allow them to operate outside of that framework.

While there may be some legal uncertainty about the applicability of federal laws to "other transactions," federal agencies including HHS have expressed the position that OTA

agreements are not subject to the safeguards of the Bayh-Dole Act,[1] which include march-in rights and the government's royalty-free right to practice the invention on behalf of the United States.

According to the GAO, "[w]hen agencies use other transaction agreements, the standard intellectual property provisions and protections that are included in traditional contracting mechanisms do not have to be included[.]"[2]

KEI opposes the expansion of "Other Transactions Authority" in this instance and the use of OTA for government-funded R&D in general, especially with regard to efforts to address the COVID-19 pandemic, where the demand for useful technologies is high, shortages are likely, and the public is particularly susceptible to price gouging.

We request that Congress protects the public's investment in biomedical R&D by stipulating that any funding agreements related to the coronavirus pandemic, including "other transactions," retain at least the current Bayh-Dole reservations of the royalty-free right to use the inventions under 35 U.S.C. § 202 and the march-in authority under 35 U.S.C. § 203, modified to permit the immediate grant of march-in rights to a licensee without waiting for the exhaustion of appeals under 35 U.S.C. § 203(b).

We also ask the Congress to require HHS and other funding agencies to invoke the "exceptional circumstances" provision under 35 U.S.C. § 202(a), to execute funding agreements that reserve the government's right to retain title to inventions funded by the U.S. government that are related to the COVID-19 pandemic. Finally, we ask Congress to enter into an agreement with the World Health Organization (WHO) that will enable the U.S. government to assign rights in federally-funded inventions to other WHO member states and affiliated health organizations during the COVID-19 pandemic, should that be in the U.S. interest.

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[1] HHS's Model Other Transactions Agreement contains Bayh-Dole Act government rights clauses at Article VII; however, Article VIII of the Model Agreement states: "This article and Article VII are fluid and negotiable. The government will consider present and future government and industry needs in exercising good business judgment in negotiating IP." https://www.phe.gov/about/amcg/otar/Documents/otar-consortium.pdf. Also, in what appears to be a training document prepared by the Department of Health and Human Services, HHS writes that "OTA is not subject to Bayh-Dole Act[.]" https://www.medicalcountermeasures.gov/BARDA/documents/Day2_GlynisFisher_John%20Ablard-OtherTransactionAuthority-508.pdf.

[2] GAO, GAO-16-209, Federal Acquisitions: Use of "Other Transaction" Agreements Limited and Mostly for Research and Development Activities 13 (2016), available at https://www.gao.gov/assets/680/674534.pdf.

We would like to follow up with a call with your staff on these issues.

Sincerely,

James Love

Kathryn Ardizzone

Knowledge Ecology International (KEI)

cc: Wendell Primus

ANNEX

Examples of existing OTA contracts involving HHS:

HHSO100201700018C, an expanded agreement between HHS and Johnson and Johnson related to the development of a coronavirus vaccine.
https://www.jnj.com/johnson-johnson-announces-collaboration-with-u-s-department-of-health-human-services-to-accelerate-development-of-a-potential-novel-coronavirus-vaccine

Expanded agreement between HHS and Regeneron Pharmaceuticals, Inc. “to develop new treatments combating the novel coronavirus, 2019-nCoV[.]”
https://investor.regeneron.com/index.php/news-releases/news-release-details/regeneron-announces-expanded-collaboration-hhs-develop-antibody