

U.S. Public Health Service Bethesda, Maryland 20892

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April 6, 2020

James Packard Love Director Knowledge Ecology International james.love@keionline.org

Dear Mr. Love,

Thank you for your letter of March 13 to Alex Azar, Secretary, Department of Health and Human Services (HHS) concerning Section 202 of the Bayh-Dole Act and recommendations for exercising these authorities during the novel coronavirus pandemic. I was asked to respond on his behalf. You discuss entering into international agreements to utilize authorities under 35 U.S.C. §202(c)(4), licensing of non-federally funded-owned patents under 35 U.S.C. §202(f), and the use of "exceptional circumstances" to obtain greater rights in contractors' subject inventions under 35 U.S.C. §202(a). These are among the range of authorities available to NIH to accomplish its mission at this critical time for public health.

NIH is working actively with its grantees and contractors as well as with industry collaborators to identify treatments for COVID-19 and vaccines to prevent infection. For example, the National Institute of Allergy and Infectious Diseases (NIAID), which has the primary mission in this effort, supports basic research on coronaviruses to understand how such viruses cause illness in animals and in humans. NIAID also supports applied research to develop diagnostics, vaccines, and therapeutics against these viruses. In response to the COVID-19 outbreak, NIAID is accelerating ongoing coronavirus research efforts and partnering with other U.S. agencies, foreign governments, and private companies throughout the world to speed the development of medical countermeasures that could help control the current pandemic and future outbreaks. At this time, NIAID is actively working across government agencies and with experts in the scientific community to establish in vitro reagents and assays and to develop appropriate animal models for testing therapeutic candidates against this new virus. The NIH will consider the use of all its authorities, including the ones you identified, to hasten the goal of identifying safe and effective technologies to treat and prevent COVID-19 infections.

Sincerely,

/s/ Mark L. Rohrbaugh, Ph.D., J.D. Special Advisor for Technology Transfer