Date: March 20, 2023

To: Rose M. Freel, Ph.D. Senior Licensing and Patenting Manager Via: rose.freel@nih.gov

From: James Love, KEI

RE: Prospective Grant of an Exclusive Patent License: The Development of a CD276 Antibody-Drug Conjugate (ADC) for the Treatment of Solid Tumors" (<u>88 FR 13450</u>) for BrickBio") located in Woburn, Massachusetts.

KEI offers the following comments on the Prospective Grant of an Exclusive Patent License: The Development of a CD276 Antibody-Drug Conjugate (ADC) for the Treatment of Solid Tumors" (88 FR 13450) to BrickBio, Inc. located in Woburn, Massachusetts. It's not obvious how much capacity the company has to work the license. It seems as if 8 persons are listed in Linkedin as having current employment at BrickBio, some on a part time basis.

The company appears to be part of Tiger Gene Ventures, which was founded by Tiger Management L.L.C. hedge fund and John Boyce (https://www.tigergeneventures.com/). Given that the company's goal is to make as much money as it can, KEI is concerned about the pricing of treatments that may result from this license.

Earlier we asked, "How will the NIH ensure that US patients are not charged more for any resultant treatment than patients in other high income countries?" On March 10, 2023, you replied "I believe you have asked a similar question on previous licenses advertised by NIH and our response and treatment of this license will be the same."

KEI would appreciate an answer to the question, particularly in light of the highly publicized speeches by President Biden on his desire to protect US residents from high drug prices. If the answer is that the NIH will place no restrictions on the pricing of products relative to other high income countries, state that, so the tax paying public can evaluate the credibility of the Administration's public concerns on drug pricing.

International referencing pricing cap

In any event, KEI again asks that the NIH require in the license that prices for products using the license not exceed the median prices charged in the seven countries with the largest GDP and at least 50 percent of US per capita income. In this regard, we note that the U.S. government negotiated international reference pricing agreements with both Merck and Pfizer for COVID-19 therapeutics.

KEI also asks the NIH to limit the geographic scope of the exclusive nature of the license to countries with at least 30 percent of US per capita income.

Finally, KEI asks the NIH to abide by the transparency norms in resolution WHA72.8, which were supported by the US government, including by requiring in the license every transparency element referred to in the resolution.