



February 23, 2018

Maria C. Freire, Ph.D.  
President and Executive Director  
Foundation for the National Institutes of Health  
11400 Rockville Pike, Suite 600  
North Bethesda, Maryland 20852

Dear Dr. Freire:

Thank you for the strong support of the Foundation for the National Institutes of Health (FNIH) in partnering with NIH to rapidly advance our efforts to address the opioids epidemic, a public health crisis which is devastating our nation. One critical part of NIH's response to this crisis is a research partnership with private sector companies to both address the immediate needs of solving the opioids addiction and overdose problem, as well as a longer-term focus on developing non-addictive, effective pain medications. FNIH has been a crucial partner in helping NIH work with industry to develop a compelling scientific blueprint for that partnership.

As the work over the past year has progressed, the public dialogue around this crisis has evolved. In particular, serious questions have been raised about the role played by companies that produce, market, or distribute opioid medications. Legal actions are being taken by several states and communities, arguing that some companies contributed to the current epidemic with marketing strategies that served to increase their profits. While some of these companies have expressed a strong interest in contributing to a research partnership with NIH, the ethics of their participation in the partnership has been called into question.

NIH believes that it could be appropriate for these companies to play a role in funding this research partnership, provided that governance of the partnership includes an unambiguous firewall that excludes companies with equities in opioids manufacturing or distribution from any decision making related to the research direction, conduct and oversight of the research, or reporting of the research results. To ensure that NIH is considering all ethical issues, potential conflicts, and appropriate governance mechanisms, Dr. Collins has asked a working group of his national Advisory Committee (the Advisory Committee to the NIH Director [ACD]) to examine this complex problem and make recommendations to the ACD in late March or early April. The final recommendations by the ACD on the subject will inform NIH's final decision about moving the partnership forward.

In parallel, I write to ask you to consider discussing this partnership with your Board. I recognize this is a deviation from the normal process of submitting a Request for Collaboration (RFC) that has been approved by the NIH-FNIH Steering Committee. Nonetheless, I believe it would be helpful to begin this discussion early, so we can have some indication of the boundaries surrounding the role of FNIH in this potential partnership. Once we have guidance from our ACD, and upon further discussion with you, we will, of course, put together an RFC for implementation through the normal Steering Committee process.

FNIH has been, and continues to be, an essential partner for NIH in supporting the science that improves human health. Given the urgency of the current health crisis, I hope we can forge a successful pathway forward in the next phase of the public-private partnership on opioids.

Sincerely,



Lawrence A. Tabak, D.D.S., Ph.D.  
Principal Deputy Director

cc: Francis Collins, M.D., Ph.D.  
Carrie Wolinetz, Ph.D.