Date: 17 August 2020
To: THOMAS A. CLARE, P.C.
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Cc: Daniel P. Watkins, Kathryn Ardizzone
From: James Love
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Dear Thomas A. Clare,

Your colleague, Daniel P. Watkins, forwarded me a PDF of a letter dated July 14, 2020, signed by you, regarding "Recent Comments in The Washington Post Regarding Potential COVID-19 Antiviral."

Before commenting on the letter, allow me to convey my sympathies to the entire Holman family for the tragedy of having a ten-year-old daughter who has cancer. My wife is a stage 4 cancer patent, and I can't imagine how difficult it is for everyone when a young child faces this disease.

I also appreciated this statement in your letter:

> "We understand that news articles do not always accurately capture quotes or statements. And we are hopeful that you provided more background information to contextualize your damaging statements, and that this broader intended meaning was lost during the editing process— especially given your decades-long track record of promoting access to pharmaceutical drugs throughout the African continent."

In this case I believe the *Washington Post* did quote me accurately, and I will comment on the context you appear to be concerned about below.

I have asked Mr. Watkins for a copy of the original article, since the link he sent me was only for the revised version. However, I will address the two points you have raised.

A. Molecule-flipping

Your letter says:

> "Describing Ridgeback's efforts to develop EIDD-2801 as somehow akin to speculative "flipping" of real estate is demonstrably false. Ridgeback has not "flipped" anything and the company continues to invest significant funds, time, and sweat equity to develop a potential cure for the novel coronavirus. On behalf of my client, I demand that you set the record straight by immediately retracting your defamatory remarks."

Before I can evaluate if I have anything to retract, it will be helpful to have some clarification of some facts.

1. **The Drug Innovation Ventures at Emory (DRIVE) LLC agreement.**

The *Post* article states that Ridgeback signed an agreement with Drug Innovation Ventures at Emory (DRIVE) LLC on March 19, 2020, linking to this press release from Emory: https://news.emory.edu/stories/2020/03/coronavirus_drive_ridgeback/index.html

Is this in fact when Ridgeback acquired rights in EIDD-2801?

Further, since you make a number of claims regarding Ridgeback's role in this development effort, will you share a copy of the agreement between DRIVE and Ridgeback?

2. **The Date of the Merck agreement.**

The *Washington Post* indicates that in late May, Ridgeback transferred rights to Merck. This is in the "corrected" version of the *Post* story, after the company agreed to talk to the *Post*, so I assume it is correct, but can you confirm the date?

3. **The Nature of Ridgeback's role in the continuing development of EIDD-2801.**

Your letter of July 14, 2020 makes a number of claims about Ridgeback continuing a role as partner in the development of EIDD-2801. The June 25 (the revised) version of the *Post* story reports, "Ridgeback said it will remain involved in developing the drug." This statement is referenced in the editor's note on the clarifications of the June 11 version of the *Post* story, which says:

> "The company, which declined to answer questions during the reporting of the story, said after publication that it will continue to be closely involved in the development of the coronavirus therapy, as the story now indicates."

Since the nature of Ridgeback's role in the future of EIDD-2801 is relevant to the characterisation of "flipping" the asset, will Ridgeback share a copy of the agreement with Merck, outlining the relative roles of Merck and Ridgeback in the development of EIDD-2801?

B. Backwater

I'll admit, I was surprised to read so much about the use of the term "backwater" as it relates to private investments in drugs and vaccines for viral outbreaks, or however you have chosen to describe my comments in your letter. This is my quote and the context of the quote in the *Post* story:

> The flood of government money is spurring attention to diseases that have been neglected by large drug companies. Vaccines and therapies for viruses do not hold the promise of large, lucrative drug sales because they are not taken as regular treatments for chronic conditions. Many virus outbreaks disappear on their own, making it risky for companies to spend on research. To plug the gap, U.S. government agencies support academic research, or invent and develop drugs directly in government labs.
>
> "When it was limited to things like Ebola and SARS, you didn't see as much as engagement by the private sectors. These were normally backwater areas in neglected disease," said Love. "People now are rushing in and scaling up."

As is clear from the *Post* story the issue is the historical relative neglect of R&D in certain diseases, by private sector investors. This is an issue that I did not and do not think was controversial. As someone who has spent considerable time, since 1999, to promote global agreements to enhance funding for tropical diseases and new antibiotic drugs, as well as in other areas lacking sufficient R&D investments, I doubt there is much need to provide you with a massive list of references on this issue (there is a reason many, including the United Nations and the US FDA use terms like "neglected diseases"). Moreover, obviously the discussion in the *Post*, including my quote, is not specific to any one company, but rather, "the private sectors," of which Ridgeback, as admirable as the company may be, is hardly the leading light or representative, having, for example, no approved products and lacking a well known brand.

But since you have raised the issue, and ask for some new statement from me, based upon your own company's investments in treatments for Ebola or other viral diseases, I would need some additional information, not only to evaluate if such clarification was warranted, but to know what Ridgeback's record is, particularly if Ridgeback has an outstanding record in this area.

Specifically, your letter of July 14, 2020 says:

> "In fact, Ridgeback has invested countless hours and tens of millions of dollars to bring its Ebola therapeutic, mAb114, to licensure. And although Ridgeback has received $25 million in assistance from BARDA to defray some amount of development costs, this is only a small fraction of the total investment that Ridgeback has assumed to take mAb114 from a preclinical project to a lifesaving therapy which awaits FDA approval."

EIDD-2018, rather than mAb114, was the subject of the *Post* story, but that said, could you tell me how much of the money spent on the development of mAB114 so far has come from the U.S. government and how much from Ridgeback? Also, in the funding agreement between Ridgeback and BARDA, did it include language similar to that from the Stevens Amendment to various HHS appropriations bills? This amendment states, in its most recent version:

> **Further Consolidated Appropriations Act, 2020, Public Law No. 116-94**

> Sec. 505. When issuing statements, press releases, requests for proposals, bid solicitations and other documents describing projects or programs funded in whole or in part with Federal money, all grantees receiving Federal funds included in this Act, including but not limited to State and local governments and recipients of Federal research grants, shall clearly state--
> (1) the percentage of the total costs of the program or project which will be financed with Federal money;
> (2) the dollar amount of Federal funds for the project or program; and
> (3) percentage and dollar amount of the total costs of the project or program that will be financed by non-governmental sources.

As to how the term “backwater is to be defined, there are dozens of definitions available, and of course, the context is everything. I believe I have used the term once before, in a paper I published in 2006. The quote and context for that use is as follows:

> https://www.keionline.org/sites/default/files/Love_Hubbard_Big_Idea.pdf
>
> III. PRIZE SYSTEMS TO SIMULATE INVESTMENTS IN MEDICAL INNOVATION
>
> Economists have long seen prizes as a possible alternative to systems of exclusive marketing rights. In recent years, work on prizes was an academic backwater, seen more as a novelty than an important policy option. It was more than a decade after Brian Wright’s widely read 1983 paper in the American Economic Review that academic economists begin to display much interest in prizes. But by the late 1990s, as the impact of the Internet and other new business models began to shake the technology sector, interest in new business models for knowledge goods began to grow.

My 2006 paper included discussions of the “Allocation of Set-Asides for Priority or Neglected Areas,” referring to a preferred allocation of innovation inducement prize fund money for global infection diseases and other global health priorities.

Your July 14, 2020 letter notes that Ebola is a devastating disease, and I don’t know anyone who thinks otherwise. A problem that many have identified in the innovation sector is that the current incentives for investing in R&D are not necessarily correlated with the public health importance, particularly if the lives of low income and/or underinsured persons are considered. This is also an issue in other situations, such as when interventions can prevent diseases, the use of new antibiotic drugs is limited to cases where resistance exists to older drugs, as well as in treatments for potential infectious disease outbreaks or bioterrorism, treatments for childhood cancers, and funding basic research, to mention a few area where private sectors investments are considered small relative to the public health need. I’m not in a position to suggest otherwise, regarding the industry-wide problem, under the current set of investment incentives.

That said, if Ridgeback wants some type of compliment for its efforts in this space, regarding its risking its own money, I am happy to look at this, but of course, would need facts and more than just a letter from a boutique law firm that specializes in defamation litigation.

In the past, KEI and myself have frequently been a critic of abusive prices or practices as regards drugs and other medical technologies, but we have also defended companies when appropriate, for example, by endorsing Gilead Sciences for the Patents for Humanity award from the USPTO, for its work with the Medicines Patent Pool.

If your client wants to engage in a discussion of these issues, you might want to put me in touch with the Holmans directly, to find out their concerns, and to see if I am in position to provide additional commentary on their business practices that they would welcome.

Sincerely,

P.S. I do not consider your July 14, 2020 letter to me or this letter to you in response privileged in any way.