

June 15, 2020



Vivera Pharmaceuticals Statement on Recent Article

In March of this year, right as the COVID-19 pandemic hit the United States full force, Vivera was ready to take action. Our track record speaks for itself. With pending clinical trials, and multiple medical device and pharmaceuticals products under development, Vivera's team was hard at work on addressing the opioid crisis. Even before COVID-19, Vivera was in the middle of planning our advanced diagnostics division launch in Q3 of this year. Vivera was able to quickly pivot and bring on board early, validated, COVID-19 testing, a true glimpse as to the dynamic ability of our team.

It is disheartening to read an article that disingenuously lumps Vivera with other potential bad actors in the space. We do not know the other companies addressed in the recent USA Today article. What we do know is that David Heath's personal attack on Vivera's CEO, Paul Edalat, had nothing to do with the quality of Vivera's tests or even Vivera itself. The quality of Mr. Heath's journalism is a testament to the click-bait culture required to keep up in today's mass media market. Where Mr. Heath could have focused on the over 30 serology antibody tests banned from distribution by the FDA, he instead chose to dig up years old litigation that has absolutely no bearing on Vivera or its current operations.

Vivera must make clear, that in addition to the attacks on our CEO and Chief Medical Officer, Mr. Heath's blatant disregard of Vivera's scientific team is an insult to the integrity and expertise of our Chief Scientific Officer and Chief Scientific Advisor. Mr. Heath quite correctly points out that Vivera proudly has former athletes on its advisory board. Had he inquired he would have clearly found out that they are integral parts to Vivera's outreach to the community. Instead, Mr. Heath uses this as a misguided accusation. On the very same page Mr. Heath would find the names of numerous other individuals who provide the wealth of their extensive knowledge to Vivera. We are honored to have the advisory board we currently have. Each member of our team is as key to our success as the next.

In times of crisis it is important that crucial news relating to COVID-19 is factually accurate. Adding to the confusion serves no purpose other than to spur fear. While Vivera believes whole-heartedly in the need for in-depth coverage of this pandemic, we also believe in the need to point out inaccuracies in reporting. While Mr. Heath's true motive will never be known, the resulting article had no connection with Mr. Heath's initial contact with Vivera. Both Mr. Edalat and Dr. McColgan were happy to speak to Mr. Heath on a Saturday for nearly half an hour. It is illogical to believe that any company or its executives who were attempting to hide something would willingly speak to a reporter. Mr. Heath's article paints the exact opposite picture.

Vivera has submitted for Emergency Use Authorization of its COVID-19 Rapid Test and COVx-RT SARS-CoV-2 rapid test products. FDA requires validation testing to be performed

and fully disclosed in pursuit of an Emergency Use Authorization. Both products have been voluntarily submitted to the FDA's validation pathway program with the National Cancer Institute. In fact, Vivera's COVID-19 Rapid Test was submitted far in advance of this article's publication. Results from this FDA/NCI partnership are publicly posted as they are made available in a completely open and transparent process. For his own purposes, Mr. Heath neglected to mention this.

Mr. Heath further stated that Vivera had not posted test specification data on its website, which is simply untrue. Had Mr. Heath bothered to confirm, he would have been directed to the correct website where the COVID-19 Rapid Test has its specificity, sensitivity, and IgG/IgM specific data posted.

Validation data information is readily available to any who requests it – which Mr. Heath did not do. Instead, Mr. Heath chose to twist the words of Vivera's Chief Medical Officer Dr. Stephen McColgan into a parody of the conversation that took place. While it is true that the communications between applicants and the FDA are confidential, it is not true that Dr. McColgan refused to disclose the clinical performance of the Vivera tests.

The numerous fallacious statements made by Mr. Heath speak to an unknown motive. Had Mr. Heath truly sought to investigate bad actors in the space, his article would have focused on those tests that have not followed FDA's clear guidance. Tests that have marketed themselves as safe for at home use, for point-of-care use, or have misleadingly stated approval by the FDA where none existed. Mr. Heath could have easily discussed the flood of imported Chinese tests on the market - with no validation - that took advantage of the FDA's Emergency Use process.

Vivera has reached out to USA Today in an attempt to resolve what was initially seen as a misunderstanding on the part of Mr. Heath. It is now clear that the publication, its editorial board, and its authors' have a political vendetta. It is clear that USA Today as an institution is vehemently against the current administration in Washington. While Vivera takes no political stance, Dr. McColgan's recent appearance on FOX News did not go unnoticed. It is a shame that partisan politics have convoluted reality.

We will as a team move forward and continue to offer products of the highest integrity and quality. We will continue to expand our footprint, moving forward in the development of potentially life-saving therapies, and working towards our ultimate goal of putting patient's first.