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Medicine — Pharmaceutical Company Pushes New, Unproven COVID Treatment Drug

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The patient arrives in the emergency department breathing three to four times faster than normal — a physiologic response to the lungs' inability to transmit sufficient oxygen to the body. It creates a sensation one might feel if they were drowning. She looks scared. Desperate. I introduce myself as an emergency medicine physician and try to reassure her that she'll feel more comfortable with the supplemental oxygen the nurse is busily setting up.

The patient has already been diagnosed with COVID-19 and had been attempting to recover at home before her symptoms worsened, prompting her to return to the hospital. She manages a question through her gasps for air: "Is there a medicine for this yet?"

Like most of my colleagues, I've spent countless hours following the COVID-19 medical literature in anticipation of a treatment for patients like the one I described. Unfortunately, the reality is that there are no proven therapies, and despite considerable excitement and fanfare, much of the research thus far has been lackluster and <u>driven by pharmaceutical companies</u> motivated by financial interests.

Many of the interventions proposed thus far involve adapting existing medicines like the malarial drug chloroquine or the antifungal ivermectin, in hopes that the drugs might be useful treating the novel coronavirus. Unfortunately, the results have been disappointing. The biological implausibility of using medications that were developed to treat nonviral illnesses has led many clinicians and scientists to view these interventions skeptically. However, it has not stopped officials pushing them as treatment options.

Remdesivir, an antiviral originally developed to treat hemorrhagic fever caused by Ebola and Marburg viruses, is the latest potential treatment to drum up considerable excitement.

The initial study used as justification for its use consisted of a small collection of COVID-19 patients. While a large proportion of the patients taking the drug improved, there was no control group for comparison, making it impossible to credit remdesivir for their improvement. This is a far cry from the accepted standard for testing a new therapy — a randomized control trial, where a treatment group receives the new drug and their clinical outcome is compared to a control group that received standard measures or a placebo. That didn't stop Gilead, the pharmaceutical company that owns remdesivir, from boasting success, raising hope — and their own stock prices.

The decision to conduct a methodologically dubious study such as the one described — and its subsequent publication in one of the world's top medical journals — at best reflects the medical field's desperation during a crisis, in which there is a willingness to sacrifice quality data for speedy results. A less generous view would see this as a cynical ploy to stir up excitement for a drug without the risk of a negative trial — where the treatment group shows no significant improvement compared to a control group.

The story of a novel treatment which showed promise in early studies, only to prove disappointing in later, more rigorous ones is worth keeping in mind as the science unfolds for remdesivir's use in COVID-19.

One might point out the difficulty in running a well-designed clinical trial, with both treatment and control groups, under the burden of a global pandemic — where much of our overtaxed health care resources are focused on the delivery of care, making large multi-institutional clinical trials a distant second priority. In that respect, remdesivir's use in other settings provides an instructive lesson.

Last December, a team of researchers <u>published</u> the results of a randomized controlled trial (where participants are randomly assigned to either experimental treatment or standard care) comparing remdesivir to other treatments for Ebola virus disease. What's remarkable about the study is not that the researchers were able to employ such rigorous research methodology, it's that they did it in the war-torn Congo ... during an Ebola virus outbreak.

For their part, Gilead has initiated multiple clinical trials to further evaluate the remdesivir's effectiveness in treating COVID-19. Last month, preliminary data was released from a National Institute of Allergy and Infectious Diseases study showing modest benefit to infected patients receiving the drug in terms of length of hospital stay, though it failed to show a decrease in mortality. The medical journal *The Lancet*, perhaps in an effort to tamp overzealous excitement, released data from a yet-to-be published randomized controlled trial that refutes this modest benefit and suggests remdesivir may not be useful in COVID-19 patients. Despite limitations of preliminary data, the U.S. Food and Drug Administration announced that it would authorize the regular use of the drug in hospitalized patients, stoking the frenzied buzz that a treatment might be within reach.

Incidentally, the recent trial of remdesivir for Ebola in the Congo refuted earlier, methodologically inferior studies, and suggested that other treatments were in fact superior to remdesivir for use in Ebola virus disease. This is not to say that the drug's effectiveness, or lack thereof, in treating Ebola can be used as evidence for how it may fare with regards to COVID-19 — a completely different disease process. However, the story of a novel treatment which showed promise in early studies, only to prove disappointing in later, more rigorous ones is worth keeping in mind as the science unfolds for remdesivir's use in COVID-19.

Like all physicians, I yearn to tell patients like the one I described that, indeed I do have a medicine to give you. But I want to know that its indication is based on medical science and not <u>corporate</u> greed or panicked imprudence. The researchers studying Ebola in the Congo prove that a calamity is no excuse for sloppy science. In fact, in times of crisis such as these, society relies on medical science to be a bulwark of rationality.

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P.S.

- Truthout. May 12, 2020: https://truthout.org/articles/pharmaceutical-company-pushes-new-unproven-covid-treatment-drug/
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• William Bruno, M.D., is an emergency medicine resident physician at the LAC+USC Medical Center in Los Angeles, California. In addition to working clinically in the emergency department, William has research interests in humanitarian response and the ethics of conducting research in disaster settings. Follow William on Twitter and Instagram.

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