

Testimony of Dr. Armand Balboni
December 8, 2020

Thank you, Chairman Johnson, Ranking Member Peters, and the entire Committee for your leadership and the opportunity to speak today about the need for the early treatment of COVID-19.

I've worked on the infectious disease front lines in many roles: with USAAMRIID, as a military fellow at the FDA during the Ebola crisis, as CEO of a biotech, as Citizen Soldier recently off active duty, medical scientist, and husband/father living in Northern VA.

I remain deeply concerned with our long-term viability to combat the COVID-19 pandemic. While the last 11 months have redefined what's possible for vaccine development, we are not done yet. With many ready to say, "we did it with vaccines and some effective treatments," we are failing to adequately build a full continuum of solutions for COVID-19, and the inevitable future pandemics.

We need options to combat the virus now: at every stage and in scalable and readily implementable ways as the crisis worsens daily. But we can't yet treat patients adequately in the outpatient setting. We can't send newly infected patients' home with an IV infusion, which is presently are the only treatment options for them.

So we ask the vast majority of Americans who test positive to self-quarantine and employ watchful waiting, with orders to go to the hospital if their symptoms worsen. That protocol confirms the gap in our treatment landscape – we need an oral, SarsCov2-specific treatment right at that moment of exposure or confirmed infection, and one that is practical, scalable and can "plug and play" into our healthcare system.

As you addressed in your recent hearing, our efforts against COVID-19 must include vaccines and best medical practices. Oral antivirals targeting the SarsCov2 virus offer a strong solution in this spirit, particularly one that we know is safe, and can be easily manufactured and distributed globally, such as favipiravir. They have the potential to play an important role in the hands of physicians treating their COVID patients outside the hospital.

These drugs are not intended to replace COVID-19 vaccines and other therapeutics for severely ill patients, but to cover aspects of disease management beyond the scope of vaccines and therapeutics for severe cases. This includes reducing the size of the inevitable segment of the population who, after becoming infected, progress to stages requiring hospitalization and intensive care.

In addition, with the recent announcement of more than 200,000 hospitalized patients and projections of 450,000+ deaths across the US by Spring, we must consider novel scientific AND regulatory approaches to develop our therapeutic armamentarium. While each treatment must produce evidence of safety and efficacy, the path to such an approval cannot be "one size fits all." We must adequately measure and address the need within the community, particularly within a pandemic.

Many promising oral antivirals are most effective when used early, yet most will never have access to them as we attempt to wring all risk from each product and wait for large, slow, randomized controlled clinical trials (RCTs) to fully read-out. I do not suggest that we abandon our gold standard RCTs, but a singular reliance on RCTs for regulatory decision-making during a pandemic is labor-intensive, costly, and produces data that can have limited applicability in real-world clinical practice.

It does not have to be this way.

There is an urgent need to develop hybrid trial methodology combining the best parts of traditional RCTs and observational study designs to produce real-world evidence that provides adequate data for regulatory decision-making. Making oral, broad spectrum antivirals available in a controlled fashion to gather real-world data (RWD) and real-world evidence (RWE), together with data from traditional RCTs, is our best chance to save lives now and during future outbreaks.

In closing, the Spanish philosopher George Santayana said, "Those who cannot remember the past are condemned to repeat it." If we fail to change our approach to the development and appropriate, safe early use of oral antiviral therapeutics, and continue to rely solely on RCT data collection, without accelerating through RWE augmentation, I fear we will still be faced with hundreds of thousands of deaths due to COVID-19 that might have been preventable. If we don't adapt now, this scenario will play out again in the future. We cannot continue to send 162,000 COVID-19 positive patients home and hope that the vaccine and a mask are going to be enough. We need your assistance and continued leadership to build the toolbox. Thank you for your time.