

STATEMENT OF JESSE L. GOODMAN, MD, MPH 6-9-2020

Good morning Chairman Krishnamoorthi and other committee members. I am Dr. Jesse Goodman. I am a practicing infectious diseases physician and currently Professor of Medicine and Infectious Diseases at Georgetown. I was formerly Chief Scientist of the FDA and in that capacity helped lead many US and global public health responses, including serving in our government's leadership for the 2009 H1N1 pandemic. As such, I have broad experience with development, regulation and public health and clinical use of diagnostics for infectious diseases. I appreciate the opportunity to be here today to discuss testing for COVID-19, a very important area where a number of challenges have occurred.

As an introduction, it may be helpful to review the two major types of diagnostics for infectious diseases. The first type detects the presence of virus in samples, for example a patient's respiratory secretions. For COVID-19, we usually detect the virus' genes. This diagnoses the presence of infection, and these tests are positive in around 80% of patients when they present with symptoms. The second type of test does not detect the virus but instead detects the body's response to infection. Typically, this is done with a serology test that detects antibodies, proteins in the patient's blood made in response to infection. Serologic tests do not usually turn positive until at least several days after infection and may remain positive long after the infection is over. Thus, serologic tests are generally not sensitive for making a diagnosis when the patient first presents. While they may help in some diagnostic dilemmas, the main use for COVID-19 serology is to tell whether a person has previously been infected, which may be useful in understanding where and how much the virus has spread in the community. In addition, if having antibodies is shown to be protective against infection, which is not yet proven, it could help predict a person's future risk from exposure.

With that background, I'd like to emphasize 2 points. First, while people tend to focus on vaccines and treatments, diagnostics are critically important from day 1 of an outbreak. we can see what happened when efforts to develop tests for COVID-19 stumbled. In essence, both

public health and medicine were flying blind in a storm with no radar. We could not test enough people to tell where the infection was and control it, and could not quickly diagnose patients. This had a real impact on the pandemic's spread and people's lives and illustrates the importance of diagnostic tests, and the need to never count on just one test or developer in an emergency.

More robust efforts must be made in future emergencies to facilitate development of multiple tests very early, even as the disease emerges. The government can play a major role by engaging and working with industry and academic partners, including obtaining and sharing needed samples and making clear the desired test performance and regulatory expectations, including, where appropriate, accelerating test availability using FDA's Emergency Use Authorization (EUA) provisions. This happened effectively during the H1N1 pandemic and, before that, the West Nile outbreak, so we know it can be done. More investment before outbreaks to prepare the testing infrastructure, including engaging commercial test developers who have widespread instruments in place, could make this a more foolproof, rapid process.

Second, in addition to facilitating test development, recent events illustrate the need for FDA to be fully engaged as an independent assessor of diagnostic tests. Unfortunately, in March, FDA, in an unprecedented action, opened the door for widespread marketing of COVID-19 serologic tests by commercial manufacturers without any review, regulatory framework or controls. The chaos that not surprisingly ensued demonstrates why we have an FDA to ensure our medicines and diagnostics are safe. Both qualified and unqualified entities flooded the market with tests. Many are now being withdrawn due to poor sensitivity (e.g. failures in detection of prior infection), poor specificity (e.g. positive test results even in people who were never infected) or both. False negative tests may convince a patient or doctor that a person does not have coronavirus (even though they do) and false positives might lead someone to believe they are protected from future exposure, which we just do not know yet. This simply should not have happened. While FDA was rightfully trying to accelerate test access, there should have been needed oversight and quality control requirements, such as through the EUA mechanism.

FDA is thankfully now acting to correct the situation and is requiring EUA submissions, including validation data, for commercial serology tests. They must move quickly to assess the nearly 200 tests already out there and remove any that are not reliable. It is also a positive development that FDA and NCI are working together to facilitate objective evaluation of the performance of serologic tests using well characterized specimens. However, test users must remain aware that in many cases test evaluations are still based on fairly small numbers of samples, making it hard to fully understand or compare the accuracy of different tests. Thus, FDA and its partners ideally would expand testing panel sample numbers as feasible to more comprehensively evaluate tests in common use and manufacturers expected to continue to submit data on test performance even after EUAs are approved.

In closing, proactive FDA engagement and review are essential not just to facilitate test development and access but also to protect the public from tests that don't work. It is essential that when a test is marketed users can be confident it meets standards, even when these must be flexible, preliminary standards tailored to an emergency.

Thank you very much.