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Opening Statement Chairman Raja Krishnamoorthi Subcommittee on Economic and Consumer Policy Briefing on “COVID-19 Antibody Testing: Uses, Abuses, Limitations, and the Federal Response” June 9, 2020

This Subcommittee is doing everything we can to protect the public health in these trying times. When we see problems, we step up to address them. That’s what happened with antibody tests, the tests that detect if an individual has previously been exposed to COVID-19. *When used properly*, accurate, reliable tests hold great promise.

But in March, FDA set a policy that would allow any company to sell any antibody test if they told the FDA that they had self-validated the tests. Nothing more—FDA took the companies at their word. When I ask my kids to clean their room, I can tell you, I don’t rely on a self-validation.

In essence, FDA declared that it wouldn’t regulate antibody tests. The Administration attracted a lot of negative attention for its slow rollout of diagnostic testing, so here they swung completely in the opposite direction by allowing any test, regardless of accuracy or reliability, to go to market.

This drew in scam-artists and shysters with no experience in serological testing, who quickly flooded the market with hundreds of faulty tests. They have been peddling hope to a public hungry for answers and an easy route back to normal activities.

It opened the door for companies like VitaStik, maker of vaping devices, and Jiangsu Eubo Biotechnology whose other offerings are male enhancement powders, cures for baldness, and steroids. It also attracted companies like Vivera, whose owner was previously sued by FDA for illegally selling untested dietary supplements. You can still buy the Vivera test, by the way, and FDA has yet to vet it.

One company claimed a positive result meant people could quote “discontinue social distancing.” The Subcommittee worked with that company and convinced it to mail correction letters to tens of thousands of misinformed customers.

This Subcommittee recognized the problem early on. We wrote to the FDA Commissioner multiple times, we had a briefing with FDA and CDC, and we ultimately issued a Staff Report detailing the problems with the policy.

The result?...FDA listened! Within days, it changed its policy. It set standards. It required manufacturers to submit to FDA review and provide details on how well their tests perform. It's an example of the good that can come from Congressional oversight and a responsive public health agency. The improved policy will literally save lives.

As heartening as it was to see FDA improve its policy, our work is not done. Right after the policy change, 34 tests were pulled from market, 23 of them were junk tests from China. But there are still 192 tests on the market that FDA has not reviewed. FDA must quickly complete its review, recall junk tests, and ensure that people only use quality tests for the right purposes.

The truth is, many people mistakenly view antibodies as a "get-out-of-jail-free card" to return to normal life, a dangerous misconception used as a selling point by bad actors.

Antibody tests are *not* a ticket to normalcy. A lot of the tests simply don't work that well. Even tests meeting FDA's standards can be false more than half of the time, especially if the prevalence of COVID-19 in the surrounding population is low. And even with a true positive, scientists aren't sure what that means. While a prior infection likely confers *some level* of immunity, we don't know how much, and we don't know how long it will last.

People who mistakenly think they are immune will stop taking precautions, risk infection, and risk spreading the disease to others.

Because of those question marks, the CDC says we can't yet use these tests for guiding individual life decisions. But, bafflingly, it's still easy for someone to go and get an antibody test, and that test is likely to be a junk test.

Today, I look forward to hearing from some of our country's most renowned experts on this subject, and I hope we learn more about the current status of the FDA's antibody policy and what we must do to further protect American public health and safety.

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