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CRISIS PRACTICE

Coronavirus

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Congressional Oversight of COVID-19 Serological Testing

Trump Administration and Testing Companies Receiving Scrutiny

Throughout the COVID-19 pandemic, both viral and antibody testing have raised significant challenges for the government and private sector. As both federal and state officials wrestle with decisions to begin reopening the country, the Subcommittee on Economic and Consumer Policy of the House Committee on Oversight and Reform has been investigating serological antibody testing. The Subcommittee's inquiry into antibody testing is a leading example of the scrutiny Congress will place on both administrative agencies and private sector entities. Congressional oversight will continue, and expand, to include other U.S. healthcare and life sciences firms associated with COVID-19-related response activities.

On April 29, 2020, Subcommittee Chairman, **Rep. Raja Krishnamoorthi (D-IL), sent a letter to the FDA urging the Agency to increase oversight and enforcement**: "With many plans to reopen the economy requiring the availability of consistently reliable serological testing, we need your answers now, while there is still time to fix shortfalls in FDA policy . . . It is FDA's job to protect the public health. Abdicating that responsibility and trusting privacy industry to regulate itself is unacceptable."

Chairman Krishnamoorthi has also sent letters to four companies, expressing concerns about the recent scientific conclusions that tests on the market by these manufacturers did not meet performance standards claimed in packaging. The four manufacturer letters also demand production of related communications with FDA, relevant validation data, and a list of all test kit recipients, including quantities of delivered test kits. These letters follow **Committee letters sent to three companies on April 22nd**.

In March, FDA issued a policy to allow developers of certain serological tests to market or use their tests, allowing tests to be offered based on

manufacturer-reported data without formal FDA clearance. That led to dozens of tests entering the market based on self-validation by manufacturers, and widespread challenges of their reliability. Among others, former FDA Commissioner Scott Gottlieb has publicly advised the public not to rely on results from these tests due to high false positive results.

Responding to this state of affairs, on April 24, 2020, Chairman Krishnamoorthi's Subcommittee released a memorandum titled "Preliminary Findings of the Subcommittee's Coronavirus Antibody Testing Investigation." The investigation's focus on Coronavirus antibody tests specifically addressed relevant FDA oversight, industry claims, and the White House's dependence on the availability of the tests in announcing plans to reopen the economy. In sum, the Subcommittee criticizes the White House's dependence on the tests, criticizes FDA for a lack of enforcement and lack of standards and guidelines, and alleges that some companies are taking advantage of the Coronavirus crisis by refusing to voluntarily submit tests for validation and are marketing fraudulent tests.

The Subcommittee's preliminary findings are:

- **White House plans to reopen economy are flawed** by their dependence on coronavirus antibody tests, which face unanswered scientific questions of utility and accuracy.
- The Food and Drug Administration (FDA) did not review any coronavirus "rapid" antibody test kits before they went on the market, and a lack of enforcement by **FDA has allowed manufacturers to make fraudulent claims about their efficacy**.
- **FDA is unable to validate the accuracy of the antibody tests that are already on the market**, and companies are ignoring requests from the Department of Health and Human Services (HHS) to voluntarily submit their tests for validation.
- **FDA and the Centers for Disease Control and Prevention (CDC) have not put forth standards and guidelines for serological antibody tests**, departing from practices governing molecular tests.
- **FDA has failed to police the coronavirus serological antibody test market**, has taken no public enforcement action against any company, and has not conveyed any clear policy on serological tests, but rather has issued a series of unclear "clarifications."
- **Numerous companies appear to be marketing fraudulent tests**.

The letters to FDA and the manufacturers described above grew out of the Subcommittee's investigation, which, given recent developments, is likely to continue and expand, along with other Congressional oversight related to the COVID-19 crisis.

In response to concerns about the serology tests surfaced by the Subcommittee and by the media, FDA has strengthened its standards. On April 28, 2020, FDA issued an umbrella Emergency Use Authorization, which provides a new pathway for serology tests to obtain EUAs that includes review by the National Cancer Institute ("NCI") in the National Institutes of Health. In addition, on May 5, 2020, FDA revised and reissued the March guidance, to change its policy regarding serology tests. Under the May version of the guidance, manufacturers of all serology tests now must submit a request for Emergency Use Authorization 10 business days from the date of publication of the revised guidance, or 10 days from the date the manufacturer notifies FDA of its intent to market a serology test, whichever is later.

Regardless, Rep. Raja Krishnamoorthi's May 4, 2020 press release indicates his interest has not subsided: "Now, FDA must expeditiously conduct its review and clear the market of tests that don't work or aren't submitted for review, so that consumers can take confidence that testing services they receive are reliable and trustworthy."

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As the country emerges from the COVID-19 crisis, companies should recognize that congressional investigations will significantly affect and likely propel parallel government investigations by federal and state enforcement agencies. Perennially recognized by Chambers USA, King & Spalding's Congressional Investigations practice is uniquely positioned to help clients understand and mitigate significant investigative, public relations, and political risks relating to COVID-19.

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