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ONE HUNDRED SIXTEENTH CONGRESS

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Congress of the United States
House of Representatives
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October 2, 2020

The Honorable Admiral Brett P. Giroir, M.D.
Assistant Secretary for Health
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Assistant Secretary Giroir:

The Subcommittee on Economic and Consumer Policy requests documents and information about the procurement of SARS-CoV-2 antigen tests by the Department of Health and Human Services (HHS) and their deployment in nursing homes, schools, and other high-risk areas for "screening" of asymptomatic individuals. Because antigen diagnostic tests can be faster, more convenient, and less expensive than molecular diagnostic tests, they could play an important role in our testing program—if they are used effectively. HHS must issue clear guidance on the best ways to use the antigen tests it distributes, or it risks squandering a valuable new tool in the fight against coronavirus.

On July 14, 2020, HHS announced a large-scale procurement of antigen-testing systems, which it would distribute to nursing homes in regions suffering outbreaks of COVID-19. In announcing the program, HHS stated:

> Nursing homes must have the capability to screen and test residents, and test staff on a weekly basis or according to specific guidance by the state and local health departments. This procurement will also enable testing of visitors if appropriate for that facility.[1]

On August 20, HHS announced that it "leveraged the Defense Production Act (DPA) to apply priority rated orders" for procurement of large volumes of antigen testing equipment and tests. HHS promised to "expedite shipments of these systems and assays to every nursing home" certified to operate such tests—about 14,000 nursing homes.[2]

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[1] Department of Health and Human Services, *Trump Administration Announces Initiative for More and Faster COVID-19 Testing in Nursing Homes* (July 14, 2020) (online at www.hhs.gov/about/news/2020/07/14/trump-administration-announces-initiative-more-faster-covid-19-testing-nursing-homes.html).

[2] Department of Health and Human Services, *Trump Administration Uses Defense Production Act to Aid Our Most Vulnerable* (Aug. 20, 2020) (online at www.hhs.gov/about/news/2020/08/20/trump-administration-uses-defense-production-act-to-aid-our-most-vulnerable.html).

On August 27, it was reported that the Administration was entering into a $750 million deal to acquire 150 million units of a just-authorized 15-minute, point-of-care antigen test to deploy in nursing homes, schools, and other high-risk areas.[3]

The Subcommittee is concerned that HHS is not providing clear guidance on how to use these antigen tests, resulting in widespread confusion. When used improperly, tests can create dangerous situations. Epidemiologists have shared a concern with me that if tests with insufficient sensitivity are used to "screen" visitors to nursing homes, false negatives risk allowing entry to contagious persons who could seed a deadly outbreak.

Nursing homes reported that HHS provided antigen tests without any protocol or instruction. Rather than show leadership in remedying this obvious deficiency, HHS said that manufacturers would provide instructions and videos to train staff on the devices.[4]

However, the manufacturers' instructions do not offer guidance on a protocol to "screen" patients in the way HHS apparently meant the tests to be used. To the contrary, the manufacturers' instructions suggest the tests should not be used for screening of asymptomatic individuals. For all of the antigen tests currently authorized for use, fact sheets approved by FDA say in boldface type that the "test is to be performed only" for "individuals who are suspected of COVID-19 by their healthcare provider" after "the onset of symptoms."[5]

Adding to the confusion, the federal government's health authorities have sent mixed messages about whether rapid antigen tests can be used for screening of asymptomatic individuals. The Centers for Disease Control and Prevention raises doubts about this use, stating, "There are limited data to guide the use of rapid antigen tests as screening tests on asymptomatic persons to detect or exclude COVID-19, or to determine whether a previously confirmed case is still infectious."[6] In addition, while FDA has only authorized antigen tests for diagnosis of suspected symptomatic cases, FDA's website appears to condone "off-label" usage outside of the scope of FDA's own authorization.[7]

HHS's antigen-test program has also run into conflict with professional guidance and state regulations. After HHS overstated the specificity of antigen tests and nursing

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[3] *Trump Set to Announce Purchase of 150M Rapid Coronavirus Tests*, Politico (Aug. 27, 2020) (online at www.politico.com/news/2020/08/27/trump-rapid-coronavirus-tests-403602).

[4] *HHS Sent Rapid Testing Machines to Nursing Homes Without Direction, Resulting in Mass Confusion*, Talking Points Memo (Aug. 19, 2020) (online at https://talkingpointsmemo.com/muckraker/hhs-sent-rapid-testing-machines-to-nursing-homes-without-direction-resulting-in-mass-confusion).

[5] Food and Drug Administration, *Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2* (online at www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas#individual-antigen) (accessed Sept. 11, 2020).

[6] Centers for Disease Control and Prevention, *Using Antigen Tests* (online at www.cdc.gov/coronavirus/2019-ncov/lab/resources/antigen-tests-guidelines.html) (accessed Sept. 11, 2020).

[7] Food and Drug Administration, *FAQs on Testing for SARS-CoV-2* (online at www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2#general) (accessed Sept. 11, 2020).

homes identified false positives, a professional organization released recommendations that positive antigen test results should be confirmed with more-specific PCR tests.[8] Some state public health agencies restrict the use of rapid antigen tests, and nursing homes have been urged to consult with state health agencies for guidance on appropriate use.[9]

HHS has recently taken some actions to offer guidance and clear up the confusion. On August 25, the Centers for Medicare and Medicaid Services released guidance requiring frequent "screening" testing of nursing home staff, including recommendations on rapid antigen tests.[10] And on August 31, you invoked the Public Readiness and Emergency Preparedness Act to expand the use of rapid point-of-care antigen tests by expressly authorizing their use and preempting state and local restrictions.[11]

Despite these measures, there are still reports that nursing homes are wary of using antigen tests in ways that conflict with state requirements and many such tests are sitting idle. Nursing homes are also concerned that they will not be able to rely on the antigen tests for long-term screening regimens due to difficulties in reordering more supplies.[12]

Thus, a lack of guidance from HHS has exacerbated the difficulties for nursing homes and schools in designing testing protocols that use available technology to effectively control the spread of coronavirus. The Subcommittee seeks your commitment that, as HHS ramps up its antigen test deployment to a massive scale with the procurement of 150 million more antigen tests, it will provide clear and effective guidance to nursing homes, schools, states, and communities on how to use them appropriately.

To assist the Subcommittee in its review of the U.S. government's procurement and deployment of antigen tests, provide the following documents and information by October 16, 2020:

1. Copies of all contracts for procurement of antigen tests;

2. All policies and procedures for distributing antigen tests, and how recipients are prioritized;

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[8] *HHS to Provide 400 Tests as Part of Initial Nursing Home Round, with $25/Test Cost Afterwards*, Skilled Nursing News (July 15, 2020) (online at https://skillednursingnews.com/2020/07/hhs-to-provide-400-tests-as-part-of-initial-nursing-home-round-with-25-test-cost-afterwards/).

[9] *As Federal Government Rolls Out Point-of-Care Units, Not All States Allow Nursing Homes to Use Them*, Skilled Nursing News (July 31, 2020) (online at https://skillednursingnews.com/2020/07/as-federal-government-rolls-out-point-of-care-units-not-all-states-allow-nursing-homes-to-use-them/).

[10] Centers for Medicare and Medicaid Services, *CMS Posts Guidance for Implementing New Testing Requirements in Nursing Homes and Labs* (Aug. 26, 2020) (online at www.cms.gov/newsroom/press-releases/cms-posts-guidance-implementing-new-testing-requirements-nursing-homes-and-labs).

[11] *HHS Expands Coverage of Point-of-Care Tests for Nursing Home COVID-19 Screening, Superseding State Bans*, Skilled Nursing News (Aug. 31, 2020) (online at https://skillednursingnews.com/2020/08/hhs-expands-coverage-of-point-of-care-tests-for-nursing-home-covid-19-screening-superseding-state-bans/).

[12] *Nursing Homes Fret Over Trump's Testing Mandate*, Politico (Sept. 8, 2020) (online at www.politico.com/news/2020/09/08/nursing-homes-coronavirus-testing-mandate-410229).

3. All protocols, instructions, and guidance that HHS has provided to recipients of antigen tests and state and local public health officials, and all drafts thereof, on appropriate uses of the tests, including how to interpret results, "off-label" uses, confirmatory PCR testing, reporting to state and federal public health authorities, and ordering additional supplies;

4. A list of all nursing homes, schools, and other locations in the distribution program, and, for each, the number of tests allocated, delivered, and administered;

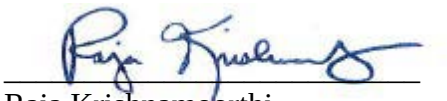
5. All communications and documents regarding use of antigen tests by nursing homes, schools, and other locations in the distribution program, including reports of inaccurate test results;

6. A description of interagency coordination on antigen test deployment, including a list of FDA and CDC officials who reviewed any protocols, instructions, or guidance provided to recipients of antigen tests; and

7. A written explanation of how specifically the Defense Production Act was "leveraged" in antigen test procurement.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. An attachment to this letter provides additional instructions for responding to the Committee's request. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



Raja Krishnamoorthi
Chairman
Subcommittee on Economic and Consumer Policy

Enclosure

cc: The Honorable Michael Cloud, Ranking Member