

Pandemic Response: Enable Doctors, Nurses, and Innovators to Save More Lives

The coronavirus pandemic has exposed a tragic reality: misguided public policies have created barriers to the health care people need. Laws and regulations enacted over many decades are restricting the ability of innovators and health experts to slow the spread of this disease or provide life-saving medical treatment—limiting the availability of surgical and N95 masks, preventing qualified doctors and nurses from treating more patients, causing severe shortages of hand sanitizers, and much more.

While policymakers have taken steps toward removing some of the most harmful of these restrictions, there is much more that should be done. Below are immediate actions they can take to ensure people who need ventilators can breathe, people who are ill receive the most advanced treatments, people can be tested, and that our country emerges with a stronger health care system including in non-crisis times.

1. Lock in CMS's reforms related to telehealth, occupational licensing, physician supervision and signoff, and communication of patient information.

- A number of temporary, commonsense waivers of existing rules have enabled more patients to be seen, tested, and treated—more quickly and more safely. These should be made permanent:
 - ❑ Telehealth. Recent emergency waivers now let Medicare patients use telehealth outside of rural areas with a physician shortage and also allow “store-and-forward” telemedicine where health care providers can forward videos and images to other doctors.
 - ❑ Occupational Licensing. Doctors and nurses can help patients despite not being licensed in-state, if they are otherwise properly trained. Automatic

reciprocal licensing would help patients by easing local physician and nurse shortages.

- ❑ Physician Supervision. Eliminating non-essential physician supervision and signoff requirements saves patients' precious time in a critical situation.
- ❑ Patient Privacy. HHS's current policy allows for more platforms to be used in provider-patient communication that would be otherwise prohibited by HIPAA. This is helping more patients get access to effective testing, tracing, and treatment.

2. Lock in FDA's recent moves related to rapid deployment of testing, treatment, and prevention.

- Congress should make permanent FDA's current, temporary relaxation of its Emergency Use Authorization (EUA) rules for infectious disease tests, not only with respect to coronavirus but also infectious diseases generally. Specifically:
 - ❑ Allow decentralized testing as the standard approach.
 - ❑ Allow test analysis by private and state labs without requiring centralized permission.
 - ❑ Allow in-home sample collection using tests that are safe and unlikely to produce excessive numbers of false negatives (for example, samples drawn with a finger-prick).
 - ❑ Allow privately manufactured and non-FDA approved tests.

- Congress should also codify and build on FDA's decision to grant an EUA for chloroquine and hydroxychloroquine, decades-old malaria drugs that according to credible reports hold promise to help fight COVID-19. The EUA enables the drugs to be donated to the Strategic National Stockpile and to be distributed when a clinical trial is not available or feasible.

3. Let patients access promising experimental treatments sooner.

- Patients should be allowed to try new treatments that are proven safe, especially in a public health emergency. Eliminating the requirement that a drug be shown to be effective will cut years off the normal FDA drug approval process, enabling sooner access to potentially life-saving treatments.
- Allow "Free Speech in Medicine" so drug manufacturers can share truthful and non-misleading information about off-label uses of their drugs with physicians. To date, the most promising treatments for COVID-19, like hydroxychloroquine, have all been approved for other applications.

4. Empanel a BRAC-style commission to strengthen America's health care system.

- Immediately upon getting through the current crisis, Congress should create a national commission on liberating our country's health care system from unnecessary restrictions, so America is better prepared to face a future crisis and save lives during more normal times.
 - ❑ The commission would have a narrow charge to identify any laws or regulations that could be eliminated or modified to help drive efficiency, expand access, and reduce costs, and then make detailed recommendations to Congress.
 - ❑ Given the importance of the issue, the recommendations, rather than requiring congressional approval, should be implemented automatically, absent an affirmative congressional vote of disapproval.
 - ❑ Once the recommendations are approved, there must be an enforcement mechanism built in to compel

agency implementation. Across-the-board triggers or budgetary consequences can serve that purpose.

- We ask government employees to start tracking these opportunities for increased efficiency as they continue through the crisis, so that they can submit their own lists to the commission.
- We also recommend opening a public comment period for doctors, nurses, innovators, and other non-government employees to submit proposals that would be considered by the commission.

Additional Recommendations

Below are additional steps policymakers can take that will enable more doctors, nurses, and innovators to save people's lives right now and in the future as well.

Food and Drug Administration & Centers for Disease Control and Prevention

Decentralize laboratory testing of COVID-19 test samples.

- Congress should codify FDA's recent policy guidance allowing safe, high-quality private laboratories to receive and analyze infectious-disease tests.

Pre-commit to buying promising therapies, to encourage their rapid production in bulk.

- Some drug candidates, like chloroquine, are generic (off patent), so drug-makers have less incentive to produce them. Congress should ensure HHS has sufficient legal authority and appropriated funds to purchase any drug that shows promise for treating a major infectious disease, at a price sufficient to promote rapid production.

Automatically approve drugs and vaccines that have been approved in the EU and Japan.

- If a drug is approved in the European Union or Japan, it should be approved here as well. Right now, that is not the case. Congress can change this by requiring FDA to automatically approve new drugs and devices that have been approved by nations whose drug-approval processes we trust. This commonsense reform is contained in the RESULTS Act (S.2161) proposed by Senators Cruz and Lee.

Extend orphan drug status to promising drug candidates.

- FDA has granted Gilead Sciences' Remdesiver orphan drug status, even though that drug is still in clinical trials and not approved for treating any disease, let alone a disease for a small population (the purpose of the orphan-drug pathway). In doing this, FDA has helpfully given the manufacturer a financial incentive to expedite production and distribution of the promising drug.
- Congress should build on this by creating a new orphan drug-like pathway for drugs that show promise for addressing infectious-disease.

Expand the federal list of reliable low-risk tests that pharmacies may routinely perform in-store.

- This would enable patients to use pharmacies for tests, rather than being limited to other kinds of medical facilities. Pharmacies are already allowed by FDA to administer certain kinds of low-risk, high-accuracy tests. The list of such tests should be expanded.

Overhaul outdated barriers to health care.

- To prevent a repeat of FDA and CDC's testing-related failures of early 2020, Congress should review all four of the following regulatory structures (see Appendix for more information):
 - FDA's EUA emergency-use guidelines,
 - CDC's CLIA testing-safety rules,
 - CMS's HIPAA privacy rules, and
 - HHS's Common Rule (relating to the protection of human research subjects).

Multi-agency

Overhaul outdated government restrictions to allow the use of drone technology to protect public health.

- Drone technology offers a promising tool to help protect public health and reduce the spread of infectious disease, not only during an emergency but generally. Federal hurdles should be removed to permit drone use for delivering necessary medicine, medical supplies, and other items. They include:
 - Outdated FAA policies that do not envision drones leaving an operator's line of site, being flown at night, or flying over buildings and vehicles.
 - FCC communications guidance about how remote operators can ensure uninterrupted monitoring and control of remotely operated drones.
 - A lack of new standards from DOD and DHS to protect lawfully deployed drones from attacks by hostile parties.

Appendix

Bureaucratic Errors: Test Kits

Between early February and mid-March 2020, the U.S. lost six crucial weeks because federal health agencies stuck to rigid rules and restrictions instead of adapting as new information came in. While the existing rules might have made sense in normal times, they proved disastrous in a pandemic.

Ideally, at the first sign of a pandemic, the U.S. would have followed South Korea's successful strategy of “track, test, and trace” that enabled it to avoid heavy-handed use of social isolation and quarantines, thanks to its robust capacity to test people in large numbers. Korea had a large supply of test kits ready quickly, because it did not try to centralize the process. Germany has had similarly successful results from a decentralized approach. Italy, on the other hand, had no strategy and relied completely on its National Health Service to innovate and execute treatment plans for its entire population. Their nationalized health system's slow response and inadequate capacity is in part to blame for the sudden and tragic mortality seen in Italy.

Unfortunately, the U.S. had an insufficient supply of tests and overly narrow federal restrictions on who qualified for testing and which laboratories could receive and analyze tests. FDA initially declined to certify COVID-19 diagnostic tests produced by private companies that were better suited for rapid mass testing.

It also barred CDC from using a diagnostic test already approved by the World Health Organization. CDC officials then botched an initial test kit developed in its own labs and had to retract many tests. CDC and FDA also resisted calls from state officials and medical providers to broaden the list of who can be tested, and to relax requirements that samples be shipped to Atlanta for analysis.

Under current rules, when HHS declares a public health emergency, the bureaucratic impediments to deploying drugs and vaccines go down somewhat, but the impediments to marketing test kits go up. Unlike in normal conditions, under a declared emergency manufacturers who wish to market test kits must first obtain an Emergency Use Authorization (EUA) from FDA. In the present crisis, because of the aforementioned errors, that additional requirement slowed down the private sector's ability to meet demand.

Eventually, the White House ordered that all Americans should have access to a test, and FDA was forced to issue a general EUA waiver allowing private companies to market tests directly to the public without having to obtain a specific EUA. And similarly, FDA allowed such tests to be received and analyzed by laboratories that meet CLIA quality-control standards without additional FDA signoff. These changes were good and should have happened sooner. FDA continues, however, to effectively ban in-home sample collection.

There have been four major regulatory barriers so far to scaling up testing by public labs and private companies:

1. FDA's requirement to obtain an Emergency Use Authorization (EUA) to market products,
2. CDC's requirements related to being certified to perform high-complexity testing consistent with requirements under Clinical Laboratory Improvement Amendments (CLIA),
3. CMS's requirements related to complying with the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, and
4. HHS's requirements related to complying with the federal Common Rule for the protection of human research subjects.