Advancing Treatments to Save Lives and Reduce the Risk of COVID-19

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Many potentially beneficial treatments for COVID-19 are in various stages of development. Patients facing the risk of serious complications from the virus and no therapeutic alternatives will understandably want access to them. We need to determine which treatments work best to advance safe and effective products to market efficiently, while providing the best possible care for patients with COVID-19 and enabling access to promising treatments for patients who might benefit from them now.

To accomplish these goals, we can support large scale access to different drugs that have shown they may be effective against the coronavirus in a framework that enables us to collect good information to determine which medicines are working best for patients, and ultimately merit full FDA approval. At the same time, we can advance treatments that can help protect people from becoming infected with coronavirus in the first place. We also need more tools for early detection of the virus so we can prevent future outbreaks.

Building on approaches taken in prior public health emergencies and on improved capabilities for data collection and analysis, all these things are possible to address the COVID-19 pandemic.

We need these drugs and testing tools to help patients now. We also need them for the long term. With the isolation and other steps we are taking now, it's possible that the epidemic spread of coronavirus will wane in the coming weeks and months. But it's also possible that there will be additional waves of viral spread with the risk of another epidemic in the future.

At the same time that we focus on developing a drug that can directly target the virus for those who've become infected and ill, we must also position ourselves to rapidly identify and contain small outbreaks and protect those most at risk with prophylactic therapies like antibody drugs.

All these steps are needed ahead of the availability of COVID-19 vaccines. Indeed, these networks and collaborations to advance treatments now can also support the development, evaluation, and deployment of vaccines.

We can advance right away the technology and tools to achieve these goals.

The most efficient pathway to launching medical products to combat the current and future outbreaks of COVID-19 would be to support FDA in working directly with manufacturers that have high potential to develop and deliver point-of-care (POC) diagnostics, therapeutics, and prophylactics. **FDA should establish two task forces, chaired by the medical product Center Directors on special assignment. In addition, the White House should also accelerate steps on a nationwide COVID-19 surveillance partnership to support these efforts and help target further interventions.**

Each task force should have, at their discretion, broad authority to:

- Convene outside experts for advice
- Interact directly with regulated industry
- Propose legislative changes if new authorities are required
- Call in the support of other HHS Operating Divisions and Staff Divisions as needed
- Be exempt from regulatory requirements that are overly burdensome in the context of a public health emergency. These could include the Paperwork Reduction Act, Federal Advisory Committee Act, Good Guidance Practices, among others. The task forces should also have direct rapid hiring authority for needed personnel.

Similar authorities have been employed to support responses to prior public health emergencies, such as the FDA-led team created after 9-11 for the development of the "Animal Rule" and Project BioShield. The approach would be fashioned as a modern "Manhattan Project" consisting of the best private company scientists sharing data and conducting joint studies of promising agents.

Point of Care Diagnostics:

One FDA-led task force should have the goal of rapid development of point of care (POC) diagnostics. The FDA's Center for Devices and Radiological Health (CDRH), with input from experts as needed, should identify manufacturers for participation in a working group, based on their existing platforms and relevant expertise in developing point of care (POC) diagnostics and the collective capacity for national implementation.

CDRH should work directly with manufacturers to:

- develop common protocols
- agree on validation steps and timelines
- determine which testing sites could be used
- identify and address long term supply chain needs
- clarify position applicability of EUA authority for these tests
- clarify position on CLIA waiver rules for these tests

Other Federal partners needed to participate in the task force include:

NIAID - data collection and research support per request of working group

BARDA - funding for rapid diagnostic validation testing (some of this is happening already) and pre-commitment for purchase of effective POC diagnostics in partnership with private health insurers

ASPR - supplies needed to research and develop POC testing, and maintain testing supplies for a set period of time

CMS and health plans - coverage for rapid diagnostic testing and interpretation, promote private payer coverage, with data collection to help assess the results and impact of the POC tests

CDC - clarify how POC testing would integrate into any federal and state reporting expectations to identify early outbreaks

Therapeutics and Prophylaxis:

To reduce the risk of severe disease and death and mitigate the virus' impact, therapeutics are urgently needed to treat severely ill patients, as is prophylaxis that can be used to reduce the risk of infection for front line healthcare workers and those at significant risk of poor outcomes (e.g., the elderly, those with impaired heart and lung function, those who are immunocompromised) . Potentially effective therapeutic strategies could include antibodies, immune globulins, anti-inflammatory drugs that mitigate severe disease, and direct acting antiviral drugs.

To more rapidly advance these opportunities, a second task force led by FDA should be established with the goal of rapid development of effective therapeutics and prophylaxis. It would consist of a central team to oversee therapeutic development in a specialized, high priority project to be led by the Director of the Center for Drug Evaluation and Research (CDER).

The task force, with input from FDA data and trial experts, task force participants, and outside experts as needed, should identify the best candidates for therapeutics and prophylaxis, enabling nationwide access to multiple classes of promising experimental drugs for COVID-19.

The task force should work directly with manufacturers to:

- develop an efficient clinical trial framework tailored to this outbreak, using novel approaches for data collection that are suited to the challenge of evaluating products in the setting of a public health emergency (where typical site based evaluation may not be feasible because of isolation protocols and stress on the healthcare system). The effort should consider unapproved drugs and unapproved uses of approved drugs, including:
    - antivirals,
    - anti-inflammatory drugs
    - antibody-based treatments,
    - immune globulins,
    - other therapeutic options that show potential patient benefit
- leverage master protocols that incorporate data from "real-world" digital sources to simultaneously evaluate more than one investigational drug within the same overall trial structure
- use expanded access-like enrollment to make it easy for COVID-19 patients to receive a treatment, with simple templates for enrollment and monitoring, delivered in the course of clinical care for these patients
- identify sites that are best suited to participation, including sites in affected regions outside of the United States

At the same time, leveraging the same tools and strategies such as a master protocol, the task force and manufacturers should set up a nationwide clinical trial network to evaluate multiple prophylactic treatments simultaneously.

Other Federal partners needed to participate in the task force include:

NIAID - data collection and research support per request of working group, and clinical trial management as needed

BARDA - funding for research and some development, and advance purchase commitments health plans

CMS and Health plans – advance purchase commitments from Medicare and private health plans for products that meet minimum standards of effectiveness, to create a guaranteed market to accelerate investment

Surveillance:

Without more comprehensive national surveillance for both new cases and exposures, further steps to prevent the current and possible future waves of COVID-19 infections will not be as effective and efficient as possible. The influenza like illness (ILI) surveillance network was designed, in part, to detect the risk of emerging strains of influenza. This surveillance system needs to be adapted and dramatically expanded to provide sentinel surveillance for COVID-19 at nationwide scale. Such a network would provide the tools to identify risks and early warning signs so that medical and nonmedical countermeasures can be deployed effectively.

This effort will represent a significant expansion of surveillance testing that would leverage private commercial labs and academic labs, in addition to public health labs. We can leverage the testing capacity that has been created to respond to the current epidemic, and that can be repurposed to the task of surveillance once the current crisis has subsided.

This approach needs to incorporate an efficient reporting system that doesn't put more burdens on the already overwhelmed state public health agencies.

Hot spots can emerge anywhere. Sentinel surveillance should be widely distributed across the country and not confined to just a subset of large cities.

A public-private partnership led by the White House, with participation across government, should be established to:

- identify specific data needed from commercial laboratories, academic medical centers, and large hospital networks to achieve optimal surveillance
- coordinate data collection and dissemination
- employ our best technology for efficient submission, and use machine learning and artificial intelligence to analyze data and enable predictions to improve coronavirus response efforts

- gather and disseminate to the public health community additional data about exposure to the virus, severity of clinical presentations, identifying high risk populations, detecting underlying conditions that are associated with severe illness, and other critical clinical information to better inform treatment and management of COVID-19