# FasterCures, A Center of the Milken Institute
# COVID-19 Action Recommendations

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The Milken Institute is a nonprofit, nonpartisan think tank determined to increase global prosperity by advancing collaborative solutions that widen access to capital, create jobs, and improve health. With an independent voice, FasterCures is working to build a system that is effective, efficient, and driven by a clear vision: patient needs above all else. We believe that transformative and life-saving science should be fully realized and deliver better treatments to the people who need them.

The COVID-19 pandemic is putting severe stress on health systems and economies around the globe. As public health and health-care workers battle the spread of the virus and scramble to save lives, scientists and companies are jumping into the fray to rapidly develop diagnostics, treatments, and vaccines. In the process, we are seeing many fault lines exposed that FasterCures has identified as slowing progress in biomedical R&D even in the best of times. While there are myriad pressure points in the ecosystem that must be addressed to accelerate progress now and in the future, we focus our recommendations for action here on a few specific agencies and sectors: **the Food and Drug Administration (FDA), the Centers for Medicare & Medicaid Services (CMS), the Biomedical Advanced Research and Development Authority (BARDA), and the nonprofit sector**. We also call on the **National Institutes of Health (NIH)** to play an increased role in providing leadership and access to infrastructure and resources to the research community.

In addition to these recommendations, we are currently developing an approach to global surveillance and will be updating these recommendations with specific guidance on using data and technology to create an "early warning system" to identify and contain future outbreaks. We are working with leaders in the sector to form a point of view on what is needed and the potential policy implications of a system such as this.

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**COVID-19 Action Recommendations**

**Food and Drug Administration**

1. Establish an FDA Veterans Corps to provide surge capacity.
2. Coordinate system-wide to speed point-of-care diagnostics and therapeutic/prophylactic treatments by creating a diagnostics task force and a therapeutics task force.
3. Collaborate with CMS to facilitate clarity around access to new COVID-19 therapies.
4. Utilize real-world evidence from established data sets for product evaluation.
5. Implement a new or improved mechanism for providing access to investigational products or those approved for another indication while moving them toward clinical testing to understand their efficacy in COVID-19.
6. Facilitate transition to advanced manufacturing technologies for drugs and vaccines.
7. Create a budget adequate for the responsibilities assigned to the FDA.
8. Provide resources and authorities to hire, train, and retain the staff they need.
9. Develop appropriate mechanisms to evaluate and approve diagnostics and therapeutics in an emergent situation (which may offer lessons and opportunities for processes in non-emergent situations).
10. Implement a more workable structure for coordination between FDA and CMS.
11. Provide expertise to stay abreast of and drive developments in applications of new data types, sources, and technologies to product evaluations and approvals.

**Centers for Medicare & Medicaid Services**

12. Establish clear and expansive coverage policies to support the reopening of the US.
13. Develop billing codes and novel payment methods that accommodate COVID-19 treatments and vaccines.
14. Collaborate with the FDA to ensure new treatments and vaccines meet evidentiary standards for approval and reimbursement that are in alignment and that coding and coverage policies are in place immediately.
15. Quickly review which of its emergency policies should be kept in place after the public health emergency has abated.

**Biomedical Advanced Research and Development Authority**

16. Ensure predictable and consistent support into the future, particularly to fund platform technologies and manufacturing infrastructure that can be quickly deployed in response to an emerging infectious disease.

**National Institutes of Health**

17. Create a hub for access to resources across NIH with relevance for COVID-19 R&D.
18. Provide focus and leadership to the scientific response.
19. Facilitate continuity of existing research.

**The Nonprofit Community**

20. Treat nonprofit organizations with parity as employers.
21. Temporarily increase the tax benefit for charitable contributions.
22. Support nonprofits in their role as service providers.
23. Facilitate the rapid restart of vital work supported by medical research nonprofits.

## Food and Drug Administration

After the Centers for Disease Control and Prevention, the Food and Drug Administration is possibly the federal health agency most in the thick of the current COVID-19 outbreak. Its employees are on the front lines of approving absolutely critical new diagnostics and ensuring they are accurate so that we can get a better handle on the scope and scale of the problem we are facing as well as the most effective solutions. They are responsible for speeding existing and new potential therapies and vaccines for COVID-19 through the process of determining whether they are safe and if they actually work. They oversee the safety and scaling up of manufacturing capacity for the drugs and medical devices now urgently needed by millions. And, as is true of every other health institution right now, they are doing all this in addition to their "day jobs" of assuring the safety of the food supply, reviewing and approving new treatments for cancer and every other dread disease, and grappling with the application of new technologies and an explosion of data to their work. In short, FDA needs help, and it needs it fast.

FDA is chronically underfunded; it regulates 20 cents of every dollar spent by US consumers annually, but its total FY19 budget of $5.7 billion was roughly the same as that year's operating budget for Montgomery County, Maryland, where FDA is headquartered. It is continually being asked to do more with less. The agency's appropriated budget has seen only single-digit increases each year from FY2010 through FY2019. By FY19, industry-provided user fees had increased to 45 percent of the agency's total budget. Combined, these trends have resulted in an agency that has less and less flexibility to allocate its limited resources in the ways necessary to accomplish its vital mission—much less deal with a crisis of this speed and severity. At the same time, the agency struggles to build, train, and maintain its workforce given the complex federal hiring process and fierce competition from industry for highly trained medical product reviewers, leaving it regularly with hundreds of unfilled positions.

The CARES Act stimulus bill in response to the coronavirus provided $80 million for the FDA to support salaries and expenses focused on COVID 19 response domestically and internationally. In addition, to accommodate FDA's immediate needs, we recommend to:

1. **Establish an FDA Veterans Corps to provide surge capacity.** The stimulus bill funding must be allocated quickly and effectively, especially given FDA's chronic difficulties finding and training qualified staff. Some will be spent on consultants, undoubtedly. But some have suggested recruiting former and retired FDA staff, similar to how retired doctors and nurses are being asked to return to service. Now is the time to establish an **FDA Veterans Corps** to contribute their time and expertise to this crisis but also to all the ongoing work at the agency so other innovation is not slowed or abandoned.

2. **Coordinate system-wide to speed point-of-care diagnostics and therapeutic/prophylactic treatments by creating a diagnostics task force and a**

**therapeutics task force.** In a working paper released on March 19, former FDA Commissioners (and FasterCures Advisory Board members) Mark McClellan and Scott Gottlieb propose in detail the creation of two FDA-led task forces, including manufacturers and other federal agencies, to provide leadership on these critical needs.

- The **diagnostics task force** would: "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 Emergency Use Authorization (EUA) authority for these tests; and clarify positions on Clinical Laboratory Improvement Amendment (CLIA) waiver rules for these tests."

- The **therapeutics task force** would "identify the best candidates for therapeutics and prophylaxis, enabling nationwide access to multiple classes of promising experimental drugs; develop an efficient clinical trial framework tailored to this outbreak, using novel approaches for data collection; leverage master protocols that incorporate data from 'real-world' digital sources; use expanded access-like enrollment and monitoring; and set up a nationwide clinical trial network to evaluate multiple prophylactic treatments simultaneously." In addition, the FDA should be reviewing clinical trial data as they come in "real-time" from ongoing studies rather than waiting until completion of new drug application (NDA) paperwork.

The Department of Justice and the Federal Trade Commission have issued guidance to alleviate concerns about **antitrust enforcement** with regards to collaborations to address COVID-19. Still, companies need assurance that task forces such as these comply. And to the greatest extent possible, there also needs to be **coordination with international regulatory bodies** on these issues.

3. **Collaborate with the Centers for Medicare & Medicaid Services (CMS) to facilitate clarity around access to new COVID-19 therapies** including potential solutions to facilitate advance purchase commitments for new treatments as they become available, coding (to facilitate continued research in addition to care and reimbursement), and coverage for diagnostics and therapeutics. A more efficient and streamlined path is needed, especially for Emergency Use Authorization products, in which CMS reviews data along with FDA and provides for coding and reimbursement at the time of authorization. Coordination between the two agencies has been challenging for many years—a joint FDA-CMS "parallel review" program has completed only two pilots in eight years—but it is a must-have now, not a nice-to-have.

4. **Utilize real-world evidence from established data sets for product evaluation**. In recent years, FDA has put increased focus on the use of real-world data and evidence in its decision-making, issuing guidance on their use by drug and device makers in regulatory submissions. But we are living in a real-life, high-speed use case, in which front-line providers are experimenting with a number of treatments and combinations. We need to be learning as much as we can from the outcomes of as many of those patients as possible. Despite the shortcomings of our electronic health record systems, we have data sets and networks like Medicare, Sentinel, PCORnet, the National Cancer Institute-Designated Cancer Centers, and others that can give us rapid insight leading to guidance while more rigorous clinical trials are unfolding. FDA is central to coordinating and overseeing this activity, perhaps even prescribing a set of code data elements related to COVID-19 that should be collected across care settings to facilitate analysis.

5. **Implement a new or improved mechanism for providing access to investigational products or those approved for another indication while moving them toward clinical testing to understand their efficacy in COVID-19.** This crisis has highlighted shortcomings with the compassionate use and expanded access programs in these kinds of emergent circumstances. Patients and doctors understandably want to try anything that might help them, especially in life-threatening situations. Companies and the FDA understandably want to ensure patients aren't harmed, to learn as much as they can from the use of these products in the real world in real time, and to protect the supply of unapproved medicines that aren't meant to be widely available yet. There could be a need for a new process to better accommodate clinical testing in an urgent public health crisis such as this. Particularly for a drug already approved for and with an acceptable benefit-risk profile in at least one indication, limited testing in a very small number of patients at a few sites could provide rapid proof-of-concept enabling a go/no-go decision about establishing a randomized controlled trial and an expanded access program.

6. **Facilitate transition to advanced manufacturing technologies for drugs and vaccines.** Most drugs and vaccines today are manufactured using traditional batch processing, which involves a multi-step assembly of various components of a drug or vaccine. After each step in the process, production is stopped so that samples can be tested for quality. These materials may then be stored and transported to different factories to continue the production process. Advanced manufacturing technologies, such as continuous manufacturing and 3D printing, seek to compress this process by eliminating the down time between steps. Advanced manufacturing technologies enable more rapid scale-up of drug or vaccine production during public health emergencies, reduce the potential for contamination and human error, and lower overall manufacturing costs, which would enhance US companies' competitiveness in drug manufacturing.

- **Create incentives to encourage the adoption of advanced manufacturing technologies.** Transitioning to advanced manufacturing technologies is costly, as it requires investments in new equipment and facilities.

- **Clarify the regulatory approval process for advanced manufacturing.** FDA issued guidance on continuous manufacturing in 2019. Still, questions remain about the details and, in particular, how it will relate to the guidelines on continuous manufacturing that are being developed by the International Council for Harmonization.

- **Create a dedicated Advanced Manufacturing unit within FDA's Emerging Technology Program.** The Emerging Technology Program enables drug companies to meet with FDA representatives to identify and resolve potential technical and regulatory issues regarding the development and implementation of novel manufacturing processes prior to filing a regulatory submission. The program should be expanded to include a unit dedicated to advanced manufacturing technologies, which would expedite the evaluation and approval of advanced technologies that can support public health emergency and pandemic preparedness and response.

As in all other realms related to the current crisis, we hope and assume a comprehensive "after-action review" will identify the ongoing needs at the agency that the response made clear—and result in a commitment to address those needs going forward, which include to:

7. **Create a budget adequate for the responsibilities assigned to the FDA**.

8. **Provide resources and authorities to hire, train, and retain the staff they need.**

9. **Develop appropriate mechanisms to evaluate and approve diagnostics and therapeutics in an emergent situation (which may offer lessons and opportunities for processes in non-emergent situations).**

10. **Implement a more workable structure for coordination between FDA and CMS.**

11. **Provide expertise to stay abreast of and drive developments in applications of new data types, sources, and technologies to product evaluations and approvals.**

## The Centers for Medicare & Medicaid Services

The Centers for Medicare & Medicaid Services is not the only payer for health-care services in the US, with its heterogeneous, fragmented health insurance landscape. But as the single largest payer, it plays an outsized role, and its policies set the tone for other insurers.

CMS has taken dozens of actions that aim to provide flexibility and clarity across an incredible range of issues in this public health emergency, from the provision of telehealth services to conditions in nursing homes to policies in Medicaid and Medicare Advantage plans. But more is needed where coverage for new diagnostics, treatments, and ultimately vaccines (as well as existing products with potential application to COVID-19) necessary to quell the outbreak are concerned. We recommend that CMS should:

12. **Establish clear and expansive coverage policies to support the reopening of the US.** There must be no disincentives for individuals to seek testing or treatment or to providers to deliver it. In a second white paper by McClellan and Gottlieb and others laying out a roadmap for a national surveillance system that will allow the US to reopen, "payment and coverage policies are critical for effective surveillance … CMS should collaborate with private payers and state Medicaid programs to encourage aligned policies across all payers, to support the capabilities and timely data sharing needed for effective surveillance." In this instance, good health policy is a necessary precondition for vital economic policy.

13. **Develop billing codes and novel payment methods that accommodate COVID-19 treatments and vaccines**. When treatments and vaccines become available, this will ensure that there are no delays in their use or confusion among providers about billing and payment. For existing treatments that have an application for COVID-19, CMS should have a process for quickly moving forward with new payment approaches, such as indication-specific pricing. For new treatments, CMS should collaborate with other departments like the Department of Veterans Affairs and Department of Defense to negotiate advance purchase commitments with product developers. Finally, CMS should work with the FDA to ensure there is a coordinated effort on data collection once a treatment reaches the market.

14. **Collaborate with the FDA to ensure new treatments and vaccines meet evidentiary standards for approval and reimbursement that are in alignment and that coding and coverage policies are in place immediately.** As noted above, CMS and FDA must work hand-in-glove as new diagnostics, treatments, and vaccines are moving toward approval to ensure that evidentiary standards for approval and reimbursement are in alignment and that coding and coverage policies are in place immediately.

15. **Quickly review which of its emergency policies should be kept in place after the public health emergency has abated.** Its support for telehealth services, for example, has been widely praised, and there is short-term evidence that these services have

been effective and cost-effective; innovations such as this born out of exigency should remain in place.

### The Biomedical Advanced Research and Development Authority

The Biomedical Advanced Research and Development Authority is part of the Department of Health and Human Services' (HHS) Office of the Assistant Secretary for Preparedness and Response, established in 2006 "to aid in securing our nation from chemical, biological, radiological, and nuclear (CBRN) threats, as well as from pandemic influenza (PI) and emerging infectious diseases (EID). BARDA supports the transition of medical countermeasures such as vaccines, drugs, and diagnostics from research through advanced development towards consideration for approval by the FDA and inclusion into the Strategic National Stockpile."

In the midst of the COVID-19 crisis, BARDA has received significant appropriations and has already proven itself to be a rapid and effective partner to industry for funding and expertise in developing new diagnostics and therapeutics to combat the virus. The most recent relief package, **the CARES Act, includes $3.5 billion** for BARDA to support research, development, and procurement of vaccines, therapeutics, and diagnostics to prevent or treat the effects of coronavirus.

BARDA has not always been so fortunate in its funding, despite its nimble responsiveness and effectiveness over more than a decade. Its FY20 budget was $562 million, and the president's request for FY21 (submitted before the outbreak) was the same (no increase). It frequently has its resources redirected from existing priorities to combating the latest outbreak. Its role will be increasingly necessary and challenging as the world comes to grips with not only the possibility of more pandemics like this one but also ongoing threats such as antimicrobial resistance.

16. Going forward, policymakers must **ensure more predictable and consistent support for BARDA**, particularly to fund platform technologies and manufacturing infrastructure that can be quickly deployed in response to an emerging infectious disease.

### National Institutes of Health

The National Institutes of Health is the **largest single funder of biomedical research** in the world. The National Institute for Allergy and Infectious Diseases (NIAID) at the NIH is at the center of government-funded R&D related to the novel coronavirus, and its director, Anthony Fauci, has become the public face of the scientific response to the crisis.

NIAID received **more than $1.5 billion in additional research funding** in the federal relief packages (which requires that vaccines, therapeutics, and diagnostics developed using taxpayer

funds must be available for purchase by the federal government at a fair and reasonable price, and "allows" the secretary of HHS to ensure that they are also affordable in the commercial market). And it is a partner in the most notable **clinical trials** underway thus far, including of the antiviral treatment remdesivir (a platform trial that can accommodate additional drug candidates in the future) and of an mRNA vaccine candidate. NIH has also just launched an important natural history study of the disease to determine the scope of infection and immune status of the population.

In addition to funding R&D at or in collaboration with academic institutions and companies, NIH plays other roles and provides other resources critical to coordinating and accelerating research. It **sets policies** for its awardees around issues such as sharing of results and data, public access, and rigor and reproducibility. It provides **access to core infrastructure and resources**, including clinical research networks, compound libraries, and data assets. NIH can continue to play a significant leadership role in the following areas:

17. **Create a hub for access to resources across NIH with relevance for COVID-19 R&D.** It is currently challenging if not impossible to find all the resources across the institutes that could contribute to solutions to this crisis. In addition to the large COVID-specific grant programs, there are valuable assets all across NIH, some of which are being activated for COVID-19 research, such as NIH's 3D Print Exchange, which has partnered with other agencies and a nonprofit of "makers" to produce personal protective equipment, or CURE ID, an app created by the National Center for Advancing Translational Sciences and FDA to give providers an easy way to share real-world experience and data when putting existing drugs to novel use in treating infectious disease patients, which has not surprisingly seen an uptick in use recently. The Biotechnology Innovation Organization has set up a Coronavirus Hub to facilitate connections among member companies with capacity and resources and those who need them. An NIH platform of this kind would be extremely valuable.

18. **Provide focus and leadership to the scientific response.** This crisis has created an incredible response in the biomedical research community, with new collaborations, formal and informal, coming together daily across the globe, with data and knowledge being shared and analyzed in real time using online tools and platforms. Some speculate it could have a lasting impact on the way research is conducted going forward. It would not be possible or even desirable for there to be one central controlling authority over all this innovation. But we do feel that NIH has the opportunity to play a leadership role to bring some level of coordination and focus to these highly distributed efforts—to lead a new Manhattan Project or Human Genome Project, accelerated for the digital era. A more recent example is the HEAL Initiative, which provides focus and coordination to scientific efforts to address the opioid crisis.

19. **Facilitate continuity of existing research.** NIH has already taken a proactive role in providing the clarity and flexibility current recipients of funding need to continue their work as best they can under current circumstances. This is an important role for them to continue to play, to ensure that other science that holds promise for patients is not severely delayed or even abandoned.

### The Nonprofit Community

FasterCures has longstanding close relationships in the community of nonprofit foundations that fund biomedical research and serve the needs of patients, as evidenced currently by our Changemakers advisory group of nonprofit CEOs, The Research Acceleration and Innovation Network organizational capacity building program, and our new LeadersLink leadership development program for emerging nonprofit leaders. In the current COVID-19 outbreak, they are challenged in many ways, as all of us and our organizations are. "Conversations about sustainability have turned into conversations about survivability," according to the National Council of Nonprofits. While they have not been forgotten in the federal economic relief actions that have been taken to date, we draw attention to the following ongoing needs.

20. **Continue to treat nonprofit organizations with parity as employers.** We tend to forget the role that nonprofit organizations across all focus areas (health, education, arts and entertainment, etc.) play as employers. According to the National Council of Nonprofits, they provide jobs for more than 12 million people, the third highest of any sector, and they spend more than $2 trillion every year, of which $826 million is salaries, benefits, and payroll taxes. Previous disaster relief packages have often excluded them from benefits provided by other employers. So far the COVID-19 relief packages, in particular the CARES Act, seem to make the same benefits available to them and their employees, whether economic injury loans, incentives to retain employees (tailored to reflect the fact that nonprofits do not pay income taxes but do pay other taxes such as payroll taxes), or paid sick and family leave. Future relief actions must continue to provide them the same, if not greater, levels of benefits.

21. **Temporarily increase the tax benefit for charitable contributions.** Nonprofits are suffering the same consequences as everyone else from the precipitous declines in financial markets, whether as drops in their endowments or declines in annual giving as donors scale back and fundraisers are canceled or move online. The CARES Act includes a new above-the-line deduction but limits it to contributions up to $300. It also lifts the cap for itemizers from 60 percent of AGI to 100 percent (from 10 percent to 25 percent for corporate donors). This year, every incentive is needed for individuals and companies to be as generous as they can be; consideration should be given to raising some of these limits.

22. **Continue to support nonprofits in their role as service providers.** Provisions in the CARES Act support greater access to telehealth and home health services, greater flexibility around provision of prescription drugs, enhanced support for mental health services, and other provisions that could aid nonprofits in performing this role. Future relief packages should include additional flexibility that supports nonprofits' ability to look after the health of their patient populations at a time when health-care resources and institutions are stretched thin.

23. **Facilitate the rapid restart of vital work supported by medical research nonprofits.** Desperately needed research is being slowed and, in some cases, could be halted altogether at academic institutions as well as companies. Most major pharmaceutical companies are suspending existing clinical trials in one fashion or another and grappling with how to keep some with life-altering consequences going. When the immediate threat of COVID-19 subsides, we know we cannot return to business as usual and that attention and resources must be devoted to solving the challenges that have been exposed of infectious disease research and product development, as well as pandemic preparedness. But we cannot afford in the medium term to take attention and resources from the fight to cure cancer, Alzheimer's, rare diseases, diabetes, and others at a time when there is so much promising science in the pipeline.