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ROADMAP TO RESPONSIBLY REOPEN AMERICA

Executive Summary

America is confronting two crises: an economic crisis laying waste to our livelihoods and a health crisis threatening our lives. The twin crises are deeply intertwined: our economy cannot be reopened without credibly addressing fears of infection and resurgence. The immediate reaction, a national lockdown, was successful in slowing the virus. We must now shift to a plan that balances the need to protect our health and reopen our economy by locking down only those who are infectious. This paper presents a simple, scalable, and credible solution: introduce a comprehensive "test and isolate" policy, making it safe for Americans to return to work and keeping the infection rate below 5% of the population.

Until a vaccine is developed and deployed, the simplest and safest path to this outcome is a national testing strategy that marshals our existing resources to test everyone in the U.S. once every two weeks and isolates all those who test positive. It does not rely on any new technologies, is far less disruptive and costly than our current policy, and will work even in a worst-case scenario. Below is a roadmap to a future in which the American people are confident that their health and our economy's future are protected against this virus.

The roadmap is comprised of the following steps:

- 1) Expand the pool of testing capacity by working with federal and state governments to:
 - i) Remove regulatory barriers; and,
 - ii) Establish a testing network of national and university laboratories.
- 2) Identify a revenue stream that the public sector can use to pay for the tests we must give people to find those who are spreading the disease, especially those who show no symptoms. Because this revenue must pay for tests of people who seem healthy, we need to provide a financial incentive to laboratories to do this work.
- **3)** Start testing the essential workers who are already on the job:
 - i) Begin with healthcare and other frontline workers who are most likely to be infected, so we keep one infected worker from spreading the virus to colleagues.
 - **ii)** As our capacity for running tests expands, start testing other essential workers such as grocery clerks.
 - **iii)** Isolate anyone who tests positive; test their family members and close col leagues.
- **4)** Extend the tests to those who we want to urgently return to work, teachers for example.
- **5)** Offer tests to everyone—students in the classroom or customers in the grocery store—and give them permission not to wear a mask in public if they have a recent, negative test for the virus.

"Test and isolate" is the response that we can commit to now, with full confidence that it will protect us from this virus and from the next. It is the fastest path to a revived economy because it is the simplest and safest path. A strong commitment from Congress to provide states with the resources they need to ramp up a comprehensive testing plan will set us on the path to defeating the virus and responsibly reopening the economy.

Introduction

The citizens of the United States face a health crisis caused by an aggressive and dangerous viral pathogen. The health crisis caused an economic crisis because people do not consume, work, or invest when they are afraid.

In response to the mounting health crisis, U.S. policymakers made the right decision. They stopped the spread of the virus by locking down all nonessential workers. The priority now is to switch to an equally effective and far less disruptive strategy: lock down only those who are infectious.

Because we had no way to tell who was infectious, we had to start by locking down everyone who was not an essential worker. We must now make preparations to shift to "test and isolate," a targeted version of lockdown aimed at limiting the spread of the virus to no more than 5% of the population, saving hundreds of thousands of lives. The simplest way to find and isolate is to test everyone regularly and to isolate the small fraction of the population who test positive.

To restore the confidence required to revive the economy, we need a credible plan for keeping the total number infected below 5%. Lifting the lockdown without a plan, surrendering to the virus, and letting it return to its path of exponential growth would be devastating in both economic and human costs. It won't matter if everyone is free to do anything they want. Fear and uncertainty spawned by surrender will paralyze us all.

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The simplest way to find those who are infectious is to test everyone regularly. We should make it our highest priority to massively expand the number of tests we can administer each day and to give those tests to people who do not show any signs of being sick. The simplicity and transparency of this policy is what makes it credible. It won't be easy, but we have the tools and we know they work; there is no question whether we can do each of the steps in this roadmap. The only question is whether Congress will commit to rebuilding confidence in the health of our people and economy so we can get started on the path towards recovery.

To be sure, we can augment tests with supporting measures and explore other ways to prioritize who gets tested next, but it would be a catastrophic mistake to delay the switch to "test and isolate" until we resolve all disagreements about how to implement supplementary measures such as contact tracing, including serious concerns about requiring everyone to carry a smartphone with a tracking app.

There is a simple roadmap for shifting from locking down all nonessential workers to locking down the very few who are infectious:

- 1) Expand the pool of testing capacity by working with federal and state governments to:
 - i) Remove regulatory barriers; and,
 - ii) Establish a testing network of national and university laboratories.
- **2)** Identify a revenue stream that the public sector can use to pay for the tests we must give people to find those who are spreading the disease, especially those who show no symptoms. Because this revenue must pay for tests of people who seem healthy, we need to provide a financial incentive to laboratories to do this work.

- **3)** Start testing the essential workers who are already on the job:
 - i) Begin with healthcare and other frontline workers who are most likely to be infected, so we keep one infected worker from spreading the virus to colleagues.
 - **ii)** As our capacity for running tests expands, start testing other essential workers such as grocery clerks.
 - iii) Isolate anyone who tests positive; test their family members and close colleagues.
- 4) Extend the tests to those who we want to urgently return to work, teachers for example.
- **5)** Offer tests to everyone—students in the classroom or customers in the grocery store—and give them permission not to wear a mask in public if they have a recent, negative test for the virus.

There is no question whether we can do each of these steps. The only question is whether we will; and if we will, when we start.

Criteria For A Viable Containment Strategy

The virus can only do one of two things: exponentially grow, or exponentially decline. Even if the number of infections drops very low (or hits zero), easing containment policies without a viable alternative like "test and isolate" in place would resume exponential growth of the virus, likely bringing us back to our current situation. Our strategy, once implemented, must not only be able to continue for the next 12-18 months (or more) until a vaccine is widely available, but it also must be able to adapt to the unforeseeable challenges that will arise between now and then.

To stop the spread of Covid-19 and protect our nation from future resurgence, our containment strategy must:

- Instill confidence in the American people: Fear is driving part of the current economic downturn—fear for our own health and fear of additional lockdowns. Our policy must be simple and feasible enough to instill confidence in the American people that the health crisis is being effectively managed; that federal, state and local governments, along with the business and health communities, are working closely together on this policy; and that its implementation will prevent additional economic losses.
- Use resources that are available now: A national policy that calms fears and moves quickly, two essential features of success against the virus, cannot require yet-undiscovered breakthroughs and additional uncertainty. We do not have time to wait for new developments, nor do we need to. This plan does not require new scientific breakthroughs—we must use what we have now with intention and purpose.
- Have the resources to continue for an extended period of time: Our policy needs to be sustainable so that it can provide continuous support until we have a vaccine. This requires that the policy's benefits always outweigh its economic and health costs, and that the resources needed to execute the policy have the full backing of the federal government.
- Offer a comprehensive solution across different scenarios: The policy must eventually be available to all Americans across the country. A partial solution that is only available in a handful of states or for a short period of time is destined to fail over the long-term, as our nation will only be as resilient as the state with the most infections. Even if our best guesses about the future turn out to be wrong, we must be able to deploy a strategy that adequately meets the most severe scenarios of the virus' spread.

Widespread testing is the most viable option that's optimal for both the economy and our public health.

"Test and Isolate": The Most Viable Option

A return to normalcy isn't possible without a vaccine. But we can get close with a national "test and isolate" strategy. The fundamental approach is simple:

- 1) Test everyone to find out who is infectious.
- 2) Isolate them.
- **3)** Continue testing, and continue isolating.

"Test and isolate" builds on the same logic that goes into the lockdown approach: mass lockdown works because it isolates people who are infected. But instead of isolating everyone, we must transition to an "identify and isolate" strategy, finding those who are infected, including asymptomatic carriers, and selectively isolating them.

We have the testing technology, and we know it works. We simply need to scale up our capacity. The simplicity and certainty that testing conveys, no matter the scale of the pandemic, instills confidence in the policy.

The Case For Testing Everyone

To control this pandemic, and any future pandemic, the U.S. should make the investment necessary to test people every two weeks, which would mean 25 million tests per day on an ongoing basis. It should also have a surge capacity of twice this amount, which would allow us to test every American every week if needed. At the moment, the U.S. is testing around 150,000 people daily, and to make matters worse, we are testing the wrong people. Instead of testing those with symptoms, our urgent priority should be to test people who might be asymptomatic spreaders of the virus.

Achieving this level of testing is difficult, but entirely feasible. The sooner we focus our efforts towards the necessary steps to making testing ubiquitous, the sooner we can reopen the economy and restore people's confidence in the future. It is the only path to certainty that makes it safe to return to work, safe to visit your grandparents, safe to put your child back in school, and a myriad other things that have become dilemmas during the pandemic.

By shifting the focus toward testing the people most likely to spread Covid-19, we are significantly refining our isolation policy and creating the necessary confidence for all others to begin safely returning to work. All who test positive must isolate themselves. While voluntary contact tracing is not the solution on its own, it can be implemented in situations like these to amplify the reach of every individual test result, pinpointing those who are likely spreaders and isolating them from the rest of the workforce. Screening and targeted isolation will need to continue until we have a vaccine.

For this plan to work, we must:

- 1) Expand the pool of testing capacity by working with federal and state governments to:
 - i) Remove regulatory barriers; and,
 - ii) Establish a testing network of national and university laboratories.
- 2) Identify a revenue stream that the public sector can use to pay for the tests we must give

people to find those who are spreading the disease, especially those who show no symptoms. Because this revenue must pay for tests of people who seem healthy, we need to provide a financial incentive to laboratories to do this work.

- **3)** Start testing the essential workers who are already on the job:
 - i) Begin with healthcare and other frontline workers who are most likely to be infected, so we keep one infected worker from spreading the virus to colleagues.
 - **ii)** As our capacity for running tests expands, start testing other essential workers such as grocery clerks.
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- **4)** Extend the tests to those who we want to urgently return to work, teachers for example.
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We will almost surely discover additional policies that improve and refine our testing strategy as it is put into action. At this moment, we need to move quickly and decisively towards national testing, and be open to adopting any refinements if they turn out to be as effective as advocates promise. Reaching consensus on the need to test everyone is the first step, and we are well on our way to agreement here. Now, we must start taking action to reopen America responsibly.

The Roadmap To Testing Everyone

1) Expand the pool of testing capacity.

First, we need to widen the pool of talent for running tests and remove the regulatory hurdles. Many of the current shortages can be attributed to artificial bottlenecks created by regulatory requirements. Researchers in university labs have already solved all of the constraints that have been holding back labs operating under the restrictive regulation of clinical diagnostic tests managed by the FDA.

We should not only allow these workarounds to alleviate supply chain pressure, we should also fast-track trusted university labs and marshal national laboratories to increase processing capacity. This would introduce competition to the testing market, lowering the price of tests without jeopardizing trust in the testing process. There are 20 laboratories in the U.S. that offer Pacific Biosciences next-generation sequencing equipment and 16 laboratories with comparable equipment made by ThermoFisher (see Appendices A & B). Recent research papers suggest that any one of these has the potential to scale up to millions of tests per day.

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The bottom line is resources, not scientific breakthroughs, are needed to expand our capacity for testing. If we commit to this type of expansion, technological innovations will lower the cost and increase the speed of the existing tests. We are already seeing promising results from different ways of testing that conserve supplies, including genetic lab-developed methods that rely on automation and allow the pooling of tests to run multiple at once. Once regulatory permissions are cleared and capacity is scaled up to the necessary level, new technologies can be implemented as they are proven ready to refine and streamline the testing process.

2) Identify a revenue stream.

Clearing the roadblocks is a first step, but the market will not solve the issue alone as testing evolves into a public good. Building this capacity will take an investment from the federal government to ensure labs can count on a funding stream.

At scale, a reasonable estimate would be a \$10 cost per test for labs. 20 million tests per day translates into about \$73 billion per year. Along with other costs for infrastructure, training, and production of supplies, I estimate the government will need to allocate \$100 billion to the development of a testing strategy. I urge Congress to include the \$100 billion in the Phase 4 coronavirus stimulus bill to generate a revenue stream for labs as soon as possible. The market cannot independently solve this problem. The need for a new revenue stream that creates necessary incentives for labs to innovate at the scale possible is inescapable.

For each month of lockdown, the U.S. economy suffers a loss of \$500 billion from lost output that month and lost capacity to produce in the future. Lifting the lockdown without a clear containment strategy will have relatively little financial impact due to continued fear and uncertainty (we may cut the loss to \$400 billion a month) and will undoubtedly carry extraordinary human cost. A temporary relaxation of lockdown will offer little economic benefit because it won't give consumers or firms the necessary confidence to plan and invest.

The economic argument for investing in an approach we know will provide certainty and safety is undeniable. A \$100 billion annual investment in testing until all Americans have been vaccinated would pay for itself many times over, and it would provide the necessary revenue stream for labs to rapidly expand testing capacity.

Allocation of the \$100 billion via block grants to the states is the fastest and most precise path to ubiquitous testing, though any program will require extensive federal guidance and regulatory agency participation.

It is critical that this revenue stream is separate from the public and private systems that pay for people's healthcare. These tests will need to become more of a public good than a medical procedure, and we will need to test everyone regardless of symptoms. Knowing the status of everyone—even asymptomatic spreaders—is crucial to making people feel safe and confident to return to work.

There is broad consensus that testing is the only way to reopen America safely, and I have demonstrated why mass testing is the most viable option to address the economic and health crises we are currently facing. Speed of response is now a critical factor. Allocation of the \$100 billion via block grants to the states is the fastest and most precise path to ubiquitous testing, though any program will require extensive federal guidance and regulatory agency participation. Programs such as the Emergency Network for Covid-19 Testing proposed by the Rockefeller Foundation, which uses federal and state agencies to negotiate with testing facilities, may be the fastest route to creating sustainable, universal testing operations across the country. Regardless, the need for bold, decisive investment at the national level, to signal the adoption and pursuit of a containment strategy based on testing, is vital.

3) Start testing the essential workers who are already on the job.

Right now, we are focused on testing the wrong people. Those who are already symptomatic should self-isolate, and doctors should proceed with treating severe, hospitalized cases as presumed positives. Until we have a vaccine or therapy to treat Covid-19, testing already ill people is not a practical use of testing resources, nor does it harm those patients to move the target of testing elsewhere.

Instead, we need to focus on healthcare workers and other first responders such as police officers and emergency technicians. These frontline workers are most likely to be infected, so we must keep these infected workers from spreading the virus to their essential colleagues and the general population with whom they interact daily. As our capacity for running tests expands, we can start testing other essential workers such as grocery clerks, sanitation workers, and transportation personnel.

Throughout this process, we must isolate anyone who tests positive and move to immediately test their family members and close colleagues.

4) Extend the tests to those who we want to urgently return to work.

Moving down a hierarchy of essential workers, we can begin to safely reactivate parts of our economy such as schools, restaurants, retail businesses, manufacturers, and other urgently needed services that may not be considered "essential" during lockdown. As testing capacity increases and processes are refined, these categories can expand, following the same protocol as healthcare and frontline workers. We can potentially start moving the contacts of anyone who tests positive to the front of the line for testing, while continuing to test the family members and close colleagues of anyone who tests positive.

5) Offer tests to everyone.

Lastly, the rest of the workforce can safely resume activity knowing that those who are infected, even though they may not show symptoms, are isolating at home. Those who test positive and isolate themselves may need financial support, which will cost significantly less than financially supporting the entire population in a mass lockdown scenario like the one we are in now.

With a national commitment to widespread testing and necessary funding in place, states can focus on implementation and enforcement on a broader scale. Armed with the data to precisely target containment efforts, we can move priorities from a rapid scale-up of testing to focusing on areas that are most in-need and refining testing technologies. A central data-sharing platform will likely be necessary to facilitate resource allocation and identify supply needs. Complementary strategies, including contact tracing and antibody testing, can help maximize efficient use of testing resources if their benefits come to fruition, but they cannot serve as the sole solution now.

Other Containment Policy Options

Experts from across industries have put forth other strategies to contain the virus, all in pursuit of the universal goal of restarting the economy while curbing Covid-19. While these other policies can certainly help contribute to recovery, none constitute a successful containment strategy alone.

Lockdown: The most immediate option is a continued lockdown. This is not a viable option. It does not inspire confidence in the American people (it looks more like surrendering to the virus than defeating it), it is not sustainable, it is not comprehensive, and it does not limit economic damage. Economically, it is too costly to pursue for even the next month, much less the next 12–18 months before a vaccine (if not longer). And with businesses and government eager to reopen states and the national economy, if our collective will to protect the public good and sustain lockdowns flounders without a viable alternative in place, we face a vicious cycle involving periodic returns to lockdown, arresting both our lives and economic productivity.

Contact Tracing: As calls for contact tracing increase, we must remember that while it may be a suitable complement to proven containment policies like "test and isolate," it is not yet viable enough to be counted on independently. It is unreliable (it requires inherently unreliable data, whether collected manually or digitally), it does not inspire confidence (it is not definitive on who

is infected), it is not comprehensive (it does not address asymptomatic spreaders of the virus), it is not robust (the technological capabilities and human capital needed to rapidly scale when an infection spikes are immense), and it is not feasible (it is not available today and it is unlikely to secure buy-in from key decision-makers due to civil liberties concerns). As such, contact tracing cannot be considered a viable option for widespread containment response, but it remains a helpful tool for epidemiological disease surveillance.

Antibody Testing: Antibody testing seems like a promising solution at face value, and it certainly should not be ignored while assessing the immunity of an individual or of larger communities. Yet it is not robust enough on its own to generate any substantial benefits, and the medical community has not reached a consensus around whether or not contracting the virus guarantees immunity. Antibody testing might develop to the point where it plays an important role in keeping infections to less than 5% of our total population, but as of now it is best deployed for disease surveillance, not for ensuring the safe return of Americans to the workplace.

Other policies may prove complementary to a broader strategy, but none of these strategies are sufficient on their own to address the twin health and economic crises.

Conclusion

For my whole career I've been focused on a single idea: just because something is unfamiliar doesn't mean it's impossible. We are at a point now where we must choose between fighting this virus with all of America's resources, intellect, and will, or surrendering because an answer we can have confidence in feels too hard to execute. Yes, the numbers are large, but the case for mass testing is strong from economic, ethical, and public health standpoints. It is without a doubt the best option right now with the resources we have and the challenges we are facing. By expanding the pool of testing capacity, providing government funding to states to execute, implementing a wide-scale testing program starting with healthcare workers, and supporting those in isolation as the rest of the workforce resumes activity, we can truly and finally start to recover from this pandemic.

Of course, we need more than private- and public-sector discussions on a plan to address the health and economic crises from which we suffer. We need courage, creativity, and bold leadership from our elected leaders and we need it now. Congress must provide states the resources they need to set up a comprehensive national testing plan so we can reopen our economy confidently and responsibly.

With hope and confidence,

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Appendix A: Labs In The United States That Offer Pacific Biosciences Next Generation Sequencing Equipment

- Brigham Young University, DNA Sequencing Center, Department of Biology
- City of Hope Integrated Genomics Core
- Cold Spring Harbor Laboratory Next Generation Genomics Core
- Corteva Agriscience
- GENEWIZ
- Histogenetics
- HudsonAlpha Genome Sequencing Center
- Icahn Institute for Genomics and Multiscale Biology at Mount Sinai
- Maryland Genomics Institute of Genome Sciences
- McDonnell Genome Institute at Washington University School of Medicine
- McGill University and Génome Québec Innovation Centre
- MOgene LC
- RTLGenomics
- Rutgers University, Waksman Genomics Facility
- University of Delaware—DNA Sequencing & Genotyping Center Delaware Biotechnology Institute
- University of Georgia Athens (UGA)—Georgia Genomics and Bioinformatics Core (GGBC)
- University of Minnesota Genomics Center
- University of Washington, DNA Sequencing Center
- University of Wisconsin Biotechnology Center
- Washington State University, Molecular Biology and Genomics Core

Appendix B: Labs In The United States That Offer ThermoFisher Next Generation Sequencing Equipment

- Boston University
- Cedars Sinai
- Children's Hospital Los Angeles
- Claritas Genomics
- The Hospital for Sick Kids
- Kashi Laboratories
- Memorial Sloan-Kettering Cancer Center
- The Molecular Resource Center
- Ohio State University
- PrimBio Research Institute
- Roswell Park Cancer Institute
- RUCDR Infinite Biologics
- University of Arizona
- University of British Columbia
- · University of New Mexico
- WuXi AppTec