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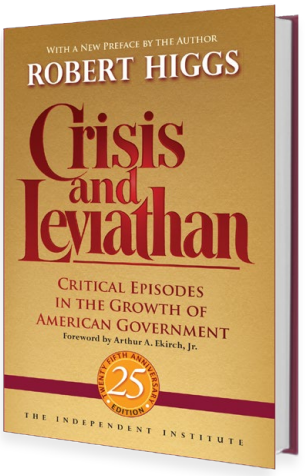

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Flatten the Bureaucracy
Deregulation and COVID-19 Testing

RAYMOND J. MARCH

On January 19, 2020, an urgent-care clinic in Washington State reported the first confirmed case of coronavirus disease 2019 (COVID-19) in the United States (Holshue et al. 2020). COVID-19 infections from travel and community spread quickly spread throughout the country (World Health Organization 2020). By early May, Johns Hopkins University and the Medicine Coronavirus Resource Center (2020) estimated that more than 1,735,000 U.S. citizens had contracted COVID-19, resulting in approximately 103,000 fatalities. Both figures constituted the most cases and fatalities of any nation affected by the virus (Gupta et al. 2020).

To slow the spread of infection and prevent the U.S. health-care sector from becoming overwhelmed with new COVID-19 cases, governments at all levels implemented numerous restrictive measures on personal conduct and economic activity (Gupta et al. 2020; Hale et al. 2020). Among the most restrictive measures were mandated stay-at-home orders. At their peak, stay-at-home rules prohibited approximately 94 percent of the U.S. population from leaving their homes except to obtain necessities or to work for an essential business (Secon 2020).

Much of the COVID-19 literature attempts to estimate the pandemic's longevity and corresponding fatality rate (Campos-Mercade et al. 2020; Fang, Nie, and Penny 2020).

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However, many of these models rest on oversimplified behavioral and policy-related assumptions (Avery et al. 2020). Other COVID-19-related research estimates the effectiveness of various mandated and voluntary efforts to prevent the spread of infection (Castex, Dechter, and Lorca 2020; Chudik, Pesaran, and Rebucci 2020). Another strand of literature examines the economic impact of prolonged lockdown periods and social isolation (Koren and Peto 2020; Mongey, Pilossoph, and Weinberg 2020). These findings have earned the attention of many politicians and policy makers, while many states hesitated to reopen their economies, gradually opened them in phases, or reinstituted lockdown measures.

A noteworthy gap in the COVID-19 literature is that little research examines the effects of deregulation to address pandemic conditions. Although comparatively less examined than policies enacted to curb or slow the spread of COVID-19, deregulation has been pervasive across numerous industries in the United States during the pandemic. Isabelle Morales (2020) documents more than 840 COVID-19-related deregulations and other legal suspensions enacted at all levels of government. Further, assessing the impact of deregulation allows us to analyze whether decreased regulation within the health-care sector specifically allows producers to expand capacity to meet the demands of patients and health-care providers during the pandemic.

In this article, I examine the effects of deregulation for COVID-19 testing enacted by the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC). Although both agencies initially adopted regulations that restricted laboratories' and test developers' abilities to create and perform COVID-19 testing before the pandemic, deregulatory efforts were passed during the early outbreak periods while the country struggled to provide adequate testing. I specifically focus on deregulations to creating and offering COVID-19 testing because testing is critical to determine the spread and impact of the virus as well as to provide essential information needed to develop effective policy responses (Marcel et al. 2020; Tang et al. 2020; J. Wang, Chun, and Brook 2020). By examining the production and development of COVID-19 tests before and after deregulation, I find COVID-19 testing capacity expanded significantly compared to earlier periods. I also find that the variety and innovativeness for COVID-19 testing increased after both agencies deregulated.

This paper proceeds as follows. The first section reviews the previous literature examining decentralization and deregulation during crises. The second section examines the regulatory framework to develop tests for novel viruses prior to the pandemic. The third section details the FDA and CDC's deregulation to allow for more COVID-19 test development and the corresponding increase in testing availability and diversity. The final section concludes and provides insights for current pandemic-response policy and public-health crisis policy more broadly.

Pandemics, Health Care, and Deregulation

Economic insight helps illustrate why preventing infectious-disease spread is often difficult (Malani and Laxminarayan 2011). Many actions that individuals can take to

prevent the spread of disease, including wearing a face mask, limiting travel outside the home, and maintaining physical distance from others, are personally costly, and a portion of their benefits extend to third parties. As a consequence, preventing infectious-disease spread frequently constitutes a collective-action problem and provides a positive externality (Malani and Laxminarayan 2011; Chen and Toxvaerd 2014). Weaker institutions as well as differing assessments of the risk for becoming infected can also reduce the willingness of individuals to engage in actions to prevent disease spread (Bhattacharyya 2009; Campos-Mercade et al. 2020).

Challenges to attaining enough social cooperation to prevent or slow the spread of disease motivate many to hold that government-imposed restrictions are necessary during public-health crises (T. Johnson et al. 2020). Susan Erickson maintains that pandemics in particular demonstrate "what governments are good for" because they can provide more effective governance than private efforts can (2020, 441). These concerns have motivated much of the restrictive measures enacted by the federal and state governments during the current pandemic to enforce compliance with public-health guidelines (Greenstone and Nigam 2020).[1]

However, some literature examining governmental responses to crises finds that such overarching approaches can fail to achieve their desired outcome and in some cases even delay recovery periods (Boettke et al. 2007; Sobel and Leeson 2008). Expansion of governmental oversight during a crisis can also increase the scope and authority of state agencies, which frequently lack the incentives and knowledge to resolve crises (Sobel and Leeson 2007; Coyne 2013). During the ongoing pandemic, state enforcement of public-health guidelines has demonstrated mixed results (Castex, Dechter, and Lorca 2020; Chudik, Pesaran, and Rebucci 2020).

Although less examined than financial crises and natural disasters, public-health crises also expand the scope of government into public health (Rothstein 2002). Robert Higgs (1995) finds that the FDA's scope of regulatory authority expanded during the 1990s following a perceived crisis of unsafe drugs on the market caused by a lack of federal oversight, and previous literature finds that the FDA provides overly stringent regulation when approving medicine and medical devices (Ward 1992; Miller 1998; Evans and Watson 2015).

Alternatively, less regulatory oversight from a centralized authority can allow for firms, groups, and individuals to better adapt to and recover from crises (Storr and Haeffele-Balch 2012). Christian Bjørnskov (2016) finds that countries that were comparatively more open to entrepreneurial activity from 1993 to 2010 experienced comparatively shorter recessions and quicker recovery times from economic crises. Similarly, Jamie Bolonga Pavlik and Vincent Geloso (forthcoming) find that states with comparatively higher amounts of economic freedom recovered more quickly financially than less-free states during the Spanish flu pandemic.

1. These and other similar efforts are sometimes referred to as "flattening the curve."

A critical component of the benefits of less regulation during health crises is that private actors can discover how to avoid the spread of disease and how to manage outbreaks effectively when they occur. Byron Carson (2016) finds that public-health guidelines provided by firms and other private actors successfully prevented the spread of malaria during the early 1900s. Private efforts to prevent disease spread are also an important component of the ongoing COVID-19 pandemic. Sumedha Gupta and her colleagues find that "a substantial portion of the response to the epidemic was not induced by specific government policies" and that "the policy response mainly operates through a voluntary channel" (2020, 2, 1).

Recent examples of deregulation undertaken to address public-health crises have been successful. In 2005, South Korea experienced an outbreak of the Middle East respiratory system (MERS) virus, which resulted in the death of thirty-eight people (World Health Organization n.d.). Frustrated with a lack of available MERS testing during the outbreak, the South Korean government implemented emergency approval measures to quickly approve testing kits for emerging infectious diseases (X. Wang et al. 2020). These measures allowed South Korean biotechnology companies to have their COVID-19 testing kits approved by the Korean Centers for Disease Control and Prevention within two weeks of South Korea's first confirmed COVID-19 infection (Kim and Denyer 2020). South Korea's ability to develop and administer testing quickly during the country's initial outbreaks allowed the transition from its being one of the nations most affected by COVID-19 to its being one of the first to experience more patient recoveries than new cases (Marcel et al. 2020).

Bureaucracy and COVID-19 Testing before Deregulation

Regulatory Barriers to Developing COVID-19 Tests

Although the FDA's typical regulatory scope includes pharmaceuticals and medical devices, its "evolving regulatory powers" have granted it oversight over a variety of diagnostic technologies and medical tests as well (U.S. FDA 2018a, 1). In 1976, Congress expanded the FDA's authority to include laboratory-developed tests (LDTs). As defined by the FDA, an LDT includes any diagnostic test "designed, manufactured, and used within a single laboratory" (U.S. FDA 2018b, 1).

As laboratories began to develop their own tests for a variety of ailments and conditions from the 1980s into the 2000s, the FDA began to increase its scrutiny over LDT development (U.S. FDA 2018b). In 2014, the FDA drafted guidance for a rigorous regulatory review process for LDTs, which included notifying the FDA when any new LDTs were developed, reporting adverse events, going through a premarket review process, submitting clinical literature that supports the validity of the proposed LDT, and using a risk-based phase-in approach to implementing premarket reviews

(U.S. FDA 2014, 15).[2] Despite never formally adopting these guidelines, the FDA began enforcing this regulatory review process in 2017 (Shapiro 2019).

The FDA's unorthodox adoption of this regulatory review process left labs that were developing LDTs unsure of how to complete the process (Genzen 2019). Many labs also lacked the financial resources to meet the FDA's requirements (Genzen 2019). Dr. Duane Newton, director of clinical microbiology at the University of Michigan, holds that the FDA's LDT regulations "hamper the willingness and ability of manufacturers and laboratories to invest resources into developing and implementing new tests" (quoted in Patel 2020b, 8). According to the FDA, because COVID-19 tests require testing for a novel virus, any laboratory-developed test kit is classified as an LDT.

When disease threatens the state of domestic public health, the CDC utilizes biosafety laboratories to develop testing kits. The COVID-19 pandemic prompted the CDC to develop its own testing kit named the CDC 2019-Novel Coronavirus Real-Time Reverse Transcriptase-PCR diagnostic panel (U.S. Department of Health and Human Services, Office of the Inspector General 2020). This test was submitted to the FDA for approval, where it received an Emergency Use Authorization (EUA) on February 3, 2020 (U.S. CDC 2020). The FDA's emergency-use application process allows for drugs, medical devices, and diagnostic equipment to be administered without undergoing the agency's formal approval process.

Because the FDA's restrictions on developing LDTs included COVID-19 test kits, the CDC's COVID-19 test was the only test available during the early U.S. COVID-19 outbreaks (Patel 2020b). Unfortunately, a combination of pressures to have test kits distributed quickly and test contaminations stemming from manufacturing issues resulted in numerous faulty CDC testing kits (Patel 2020b). As a consequence, many tests reported false negatives, leading to false information regarding the spread of the virus and the state of the pandemic (West, Montori, and Sampathkumar 2020). The CDC also failed to produce enough kits to meet the demands of patients and healthcare providers (Loftus and Abbot 2020). Approximately two months after the first confirmed case of COVID-19, the United States had tested only approximately 1,235 patients for COVID-19 (Patel 2020b). In contrast, other countries were able to administer millions of tests over a similar period (Patel 2020b).

Regulatory Barriers Preventing Laboratories from Processing COVID-19 Tests

Both agencies also prohibited most laboratories from performing the CDC's COVID-19 test. After the CDC develops a test and receives the FDA's approval, the agency distributes the test to state public-health laboratories. State public-health laboratories

2. The guideline requirements varied based on whether the FDA considered the tests to be low, moderate, or high risk. The agency distinguishes the level of risk based on a wide variety of factors (U.S. FDA 2014, 12).

then distribute these tests at their discretion (U.S. Department of Health and Human Services 2020b).

To provide the CDC's COVID-19 test, a laboratory was required to be a certified clinical laboratory, which required approval from both the FDA and the CDC. Under the normal state of affairs, to receive the FDA's approval, the laboratory must first receive approval from the Centers for Medicare and Medicaid Services (CMS). The CMS provides its approval based on the requirements established by state and regional agencies. The CDC has its own requirements and will not issue its clinical laboratory certification unless the laboratory receives the FDA's approval first. The approval process often takes months to complete (Fink and Baker 2020). As a consequence of this complicated approval process, only forty public-health laboratories and a small group of commercial laboratories in the United States had access to COVID-19 test kits two months after the first confirmed case emerged (Soucheray 2020).

Hospitals without an approved laboratory were required to send their patients' COVID-19 tests to a certified laboratory, which later informed the hospital of the test result. Lag times between administering a test and receiving a diagnosis could be considerable depending on the distance between hospitals and processing laboratory. These delays hindered the ability of hospitals to quickly diagnose those most harmed by the COVID-19 virus. As Robert Gerrett, CEO of Meridian Health, expressed, "If you have a [testing] process where everything needs to be distributed through a central group you can't possibly keep up with the number of infections" (qtd. in S. Johnson 2020, 4).

The FDA and CDC maintained strict enforcement of their certification requirements even while the threat of a COVID-19 outbreak emerged. Less than a month after the first confirmed case, infectious-disease specialist Dr. Helen Chu began collecting nasal swabs from patients in Washington State while conducting influenza research. Several of Dr. Chu's patients reported experiencing symptoms associated with COVID-19 (Fink and Baker 2020). After administering a COVID-19 test that her research laboratory developed, Dr. Chu found evidence of communal spread. She reported her findings to the CDC and the FDA. However, in response the FDA ordered Dr. Chu to cease testing because her laboratory was not certified (Fink and Baker 2020). Shortly after that, the Seattle–Tacoma area witnessed the first outbreak of COVID-19 in the United States (U.S. CDC 2020). By late February, state public-health laboratories in Washington State and much of the Pacific Northwest were still largely unable to provide adequate COVID-19 testing due to contamination issues with the CDC's tests, as noted earlier (Branswell 2020).

Deregulation of COVID-19 Testing

On February 29, 2020, the FDA took decisive action to "achieve more rapid testing capacity" by issuing a policy "enabling laboratories to immediately use tests they

developed and validated" (U.S. FDA 2020j, 1, 6). This policy also applied to commercial manufacturers looking to develop and distribute their own COVID-19 test-kits (U.S. FDA 2020j). Newly developed COVID-19 tests still require the submission of an EUA to the FDA. However, laboratories and test developers can provide evidence of their test's effectiveness after submitting their application.

Allowing laboratories and commercial manufacturers to develop and provide COVID-19 tests prior to receiving the FDA's approval ensured that "certain laboratories who develop [self-]validated tests for coronavirus would begin using them right away prior to FDA review" (U.S. FDA 2020e, 11). Enacting this deregulatory policy removed previous regulatory requirements for laboratories developing LDTs to undertake the premarket review process as well as to submit clinical literature and take the risk-based phase-in approach noted earlier.

Laboratories hoping to process COVID-19 tests were still required to meet the standards determined by the CMS under the Clinical Laboratory Improvements Amendments (CLIA) (U.S. FDA 2020e). However, the FDA allowed laboratories to receive CLIA certification quickly by allowing states to determine which laboratories could test for COVID-19 and by providing an "umbrella EUA approach" to allow many commercial serology tests to reach patients and health-care providers (U.S. FDA 2020i, 7). Any FDA-issued EUA for COVID-19 testing also removed the CDC's regulatory authority to restrict laboratories from processing tests (U.S. FDA 2020e).

COVID-19 Testing Availability after Deregulation

After the FDA allowed laboratories and other developers to create and offer COVID-19 tests, the number of COVID-19 tests expanded significantly. According to a statement prepared eighteen days after the revised policy was issued, FDA commissioner Stephen Hahn noted the agency was then working with more than one hundred test developers working toward emergency approval of eighty different COVID-19 tests (U.S. FDA 2020e, 7). In the same statement, Hahn noted, "We know that people want to know the current numbers of tests in the field and how many patients are being tested. This number fluctuates daily as more and more test developers get their tests in the field and start testing patients" (10).

Corporate laboratories greatly contributed to the proliferation of available COVID-19 tests. In a statement released by the American Clinical Laboratory Association (2020), clinical laboratories provided approximately 280,000 tests per week by April 1. LabCorp, a private U.S.-based laboratory, was performing 10,000 COVID-19 tests a day by late March and 20,000 a day by April 1 (LabCorp 2020). Quest Diagnostics (2020) introduced its own COVID-19 test ten days after the FDA announced its revised policy and performed approximately 4.65 million tests between the test's development and June 1.

Hospitals and academic medical establishments also developed COVID-19 tests. Zachary Brennan (2020) finds that a dozen hospitals and medical schools developed and self-validated their COVID-19 tests and began testing patients by March 15. Diagnostic-testing manufacturers also flourished under the FDA's deregulation. By March 16, laboratory equipment provider ThermoFisher Scientific (2020) developed a COVID-19 test kit, received the FDA's emergency-use approval, and produced 1.5 million tests for distribution to two hundred laboratories.

The COVID-19 Action Tracker maintained by the American Enterprise Institute (2020) estimates that the total testing capacity of the United States expanded from 7,840 patients per day on March 2 to 36,810 patients per day by March 16. Much of this capacity expansion stems from private development and offering of COVID-19 testing. Laura Strickler and Adiel Kaplan note, "In the month since they began testing, private labs have conducted nearly 1.5 million tests—more than 85 percent of all US tests" (2020). In comparison, public-health laboratories before the FDA's new policy processed approximately a mere 18,644 tests between January 18 and March 12 (Scott 2020, 8).[3] By April 21, the FDA had approved fifty separate COVID-19 test kits and engaged with more than 350 test developers (U.S. FDA 2020e). Neel Patel notes that as of late June many laboratories in the United States were capable of running thousands of tests per day and that the country "now has more COVID-19 tests than it knows what to do with" (2020a, 1).[4]

Innovation in COVID-19 Testing after Deregulation

The FDA's deregulation also provided private test developers with the ability to diversify the features and benefits of COVID-19 testing. On April 21, the FDA issued an EUA for LabCorps' Pixel test kit. Pixel was the first at-home COVID-19 test, requiring the patient to mail in a self-administered nasal swab to a LabCorp laboratory (U.S. FDA 2020c). As FDA commissioner Stephen Hahn expressed, "There is now a convenient and reliable option for patient sample collection from the comfort and safety of their home" (U.S. FDA 2020c, 2).

Competing testing developers soon offered alternative ways to test for COVID-19. On May 8, the FDA granted an EUA to the Rutgers Clinical Genomics Laboratory for the first saliva-based at-home COVID-19 test (U.S. FDA 2020a). Using a saliva sample to test for COVID-19 provided an equally effective and less-painful method than a nasal swab (Azzi et al. 2020; Schuba 2020). Although at-home tests provided

3. Kimberly Scott also notes, "The number of patients tested was likely lower than that since labs initially were testing two specimens per patient" (2020, 8).

4. Federal and state legislative acts requiring health insurance providers to cover COVID-19 testing and subsidies provided for health-care providers to offer testing also improved testing availability (Alder and Young 2020; U.S. Department of Health and Human Services 2020b). However, developing and producing COVID-19 testing options precede efforts to make them available.

benefits for patients, the FDA's EUA specifically notes these tests would be available only with a prescription and could be processed only at their developers' laboratories (U.S. FDA 2020a, 2020c).

Less than a month after at-home COVID-19 tests became available, test developer Everlywell Inc. received an EUA for an at-home COVID-19 test, which required only that patients complete an online questionnaire (U.S. FDA 2020b). Online questionnaires were submitted to Everlywell Inc.'s online physician network, which dispensed COVID-19 tests that could be processed at multiple laboratories. The process allowed results to reach patients quickly and with less risk of exposing others to the virus (U.S. FDA 2020b). The ability to deliver tests to patients' homes also reduces burdens on health-care facilities servicing rural areas, which commonly suffer from a shortage of tests and comparatively fewer testing facilities and personnel (Emanuel et al. 2020).

Test developers also created tests that provided diagnoses more quickly. On March 27, the FDA granted an EUA to Abbott Laboratories point-of-care test (U.S. FDA 2020f). The point-of-care test provides a COVID-19 diagnosis in five minutes (Hauck 2020). The point-of-care test kit is the size of a toaster and weighs approximately 6.6 pounds, making it easily transportable (Hauck 2020). As of June 1, Abbott Laboratories had sent approximately 4.5 million point-of-care test kits to all fifty states, with the priority of providing testing within outbreak areas (Abbott Laboratories 2020).

Physicians and medical researchers also began to repurpose previously existing medical technology to test for COVID-19 after deregulation. Researchers at the Columbia University Fertility Center developed a saliva-based COVID-19 test adapted from technology used to test for genetic abnormalities in embryos (Wei et al. 2020). The test provides results within thirty minutes and, like Abbot Laboratories point-of-contact test, does not require expensive instruments or proprietary components (Shen et al. 2020). As noted by Dr. Zev Williams, chief of the division of reproductive endocrinology at Columbia University Irving Medical Center, the test thus could be employed in airports, nursing homes, and schools to "help us safely reopen economies closed by the pandemic and prevent future outbreaks" (Columbia University Irving Medical Center 2020, 4).

Newly developed test kits were also reliable despite being distributed with less regulatory oversight. On May 14, the FDA released a statement noting it had received only fifteen reported cases of false-negative results from Abbott Laboratories' point-of-care contact tests (U.S. FDA 2020d). At the time, Abbott manufactured approximately 50,000 tests a day (Abbott Laboratories 2020). Other COVID-19 tests have demonstrated similar effectiveness. As of August 20, the FDA issued EUAs for 140 COVID-19 diagnostic tests (U.S. FDA 2020h). Only two diagnostic tests had their EUAs withdrawn as of the same date (U.S. FDA 2020g).[5]

5. The price to perform a COVID-19 test remains variable based on a variety of factors. Nisha Kurani and her colleagues (2020) find publicly posted prices to test for COVID-19 ranging from $20 to $850 despite legislation requiring insurance providers to cover testing. However, continued development of COVID-19 testing as well as improving availability and variety have lowered the price to produce and conduct COVID-19 testing (Nemo 2020).

Conclusion

FDA and CDC deregulations to provide more COVID-19 testing allowed laboratories and test developers to swiftly develop large quantities of tests and innovative ways to test for the virus. This entrepreneurial effort quickly expanded COVID-19 testing capacity to tens of thousands of tests per day and developed tests for at-home use by means of either nasal swabs or saliva samples. By following the development of newly developed tests and increases in testing availability before and after the FDA deregulatory actions, my findings strongly suggest that the deregulation was instrumental in providing urgently needed testing during the ongoing pandemic.

These findings provide critical insights for contemporary pandemic policy. Pandemics can last several years, involving periods of peaks and declines in infections and fatalities. COVID-19 may follow a similar pattern, making research examining how to best address pandemic conditions timely for contemporary public-health policy. Deregulation for COVID-19 testing has been a critical part of providing sufficient testing to track the current pandemic. Such findings suggest that the deregulation of other vital medical goods and services, such as ventilators and potential COVID-19 treatments, and the loosening of occupational-licensing requirements for health-care professions could also help expand health-care capacity.

More broadly, this paper's findings provide insight for the regulatory structure of public health within a free society. Where much of the United States and other countries have enacted restrictions on personal and economic freedom to address the COVID-19 pandemic, my findings suggest that deregulation provides an effective means to address pandemics and other health crises, allowing free-market providers to expand health-care capacity to meet the demands a pandemic places on the health-care sector in place of curbing liberties in an effort to prevent the overwhelming of hospitals and other health-care establishments.

Although my findings clearly show that deregulation has increased the availability and diversity of COVID-19 testing, additional analysis of deregulation's impact during a pandemic will also be fruitful. Examining the role of EUAs for pharmaceuticals in helping treat patients who have contracted COVID-19 and of deregulations enacted across various industries at the state level will also provide timely insight. Heterogeneous effects of COVID-19 across the country and the corresponding state-level measures taken to address the pandemic will also enhance our understanding of the determinants of health-care capacity.

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