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Legal Lessons from a Very Fast Problem: COVID-19

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The course of a pandemic is as much a function of social structures as protein structures. Law is among the most important of these social structures, and it is among those most capable of the kind of rapid adaptation that is needed against an exponentially replicating virus. Thus, there is an urgent need to scrutinize the role of the law in impeding or supporting timely and effective measures to combat the great pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) and its associated malady, coronavirus disease 2019, better known as COVID-19.

This Essay offers a look back on the initial phase of the COVID-19 catastrophe—a crisis that, at the time of this writing, is still expanding and deepening. We suggest three lessons: First, the free flow of information saves lives, an observation which sounds in constitutional free-speech rights, copyright law, and patent law. Second, politically accountable decisionmaking in the public health sphere has proven inapt in responding to the pandemic; this observation suggests a more prominent role in public health crises for independent administrative agencies and the judiciary. Third, pre-crisis regulations and rulemaking structures for approvals of medical products, and vaccines in particular, have not proven nimble enough in the face of the pandemic; this suggests an opportunity for congressional action to push agencies to move faster.

After framing the nature of the COVID-19 problem, we discuss each of the three lessons—about information flows, public health authority, and regulatory agility—in turn. Taken together, these lessons suggest a need for a systematic and critical perspective on the law's role in a pandemic—a context that is distinguished by a compressed timeframe and rapidly changing social needs.

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I. The COVID-19 Pandemic as a Very Fast Problem

The current global pandemic of COVID-19 began as a small outbreak in China before spreading worldwide. Evidence points to the first emergence of the SARS-CoV-2 virus in late November or early December 2019.[1] A report from the Chinese Center for Disease Control and Prevention identified December 21, 2019 as the date of the first cluster of patients with atypical pneumonia in Wuhan.[2] Public recognition and announcements were scarce over the next few weeks.[3] The World Health Organization (WHO) issued its first situation report on January 21, 2020, which tallied 282 confirmed cases and six deaths.[4] Three months later, on April 21, 2020, there were 2,397,217 reported cases and 162,956 deaths.[5] At that point, the single-day jump was 83,007 fresh cases and 5,109 new deaths,[6] indicating that the COVID-19 pandemic was spreading rapidly worldwide despite unprecedented efforts at public health control through social distancing. At the time of this writing, the global pandemic continues. Worldwide, there have been tens of millions of infections and over one million deaths.[7]

The problems posed by the COVID-19 pandemic have been compounded by the fact that the SARS-CoV-2 virus is a novel virus. It is a member of the coronavirus family but distinct from all previously known strains of coronavirus. Prior to onset of the pandemic, nothing at all was known of the virus, and there were no established tests, documented epidemiology, vaccines, or anti-viral medications to bring to bear against it.

II. Free, Fast-Moving Information Can Save Lives

Information and communication are the bedrock of timely and effective public and private sector responses to the COVID-19 pandemic. Law can impede *or* support needed information gathering and communications. We

1. Kristian G. Andersen, et al., Correspondence, *The Proximal Origin of SARS-CoV-2*, 26 NAT. MED. 450, 450-51 (2020).
2. Wenjie Tan et al., Notes from the Field, *A Novel Coronavirus Genome Identified in a Cluster of Pneumonia Cases—Wuhan, China 2019-2020*, 2 CHINA CDC WKLY. 61, 61 (2020).
3. *See, e.g.*, *WHO Timeline—COVID-19*, WORLD HEALTH ORG., https://perma.cc/55DD-U8EC (archived Oct. 18, 2020).
4. *Novel Coronavirus (2019-nCoV) Situation Report 1*, WORLD HEALTH ORG. 1-2 (Jan. 21, 2020), https://perma.cc/98YM-ZJXX.
5. *Coronavirus Disease 2019 (COVID-19) Situation Report 92*, WORLD HEALTH ORG. 8 (Apr. 21, 2020), https://perma.cc/RJX7-LXZN.
6. *See id.*
7. *See, e.g.*, Henrik Pettersson, Byron Manley & Sergio Hernandez, *Tracking Coronavirus' Global Spread*, CNNHEALTH (Oct. 18, 2020 6:45 PM ET), https://perma.cc/69E5-36AH.

briefly survey the impact of law on pandemic information flows in three spheres: constitutional free-speech rights, copyright law, and patent law.

A. Free Speech Protections

The world first learned of the new coronavirus in spite of China's authoritarian limits on free speech and because of a Western media that thrives thanks to constitutionally guaranteed free-expression rights. One of the first to raise the alarm was Dr. Li Wenliang of Wuhan Central Hospital.[8] Because of his efforts in December 2019 to alert his colleagues to what looked like a new SARS outbreak, Dr. Li was compelled to sign a self-criticism letter by the Public Security Bureau.[9] In addition, his hospital barred staff from speaking publicly about the virus.[10] By January 2, 2020, the Wuhan Institute of Virology had identified the novel coronavirus and mapped its genome.[11] But a speech-fearing state kept the information secret. It was only after the outbreak was reported by the *Wall Street Journal* that Chinese authorities confirmed the outbreak publicly on January 9 and followed up by sharing the virus's genomic sequence on January 12.[12]

In the end, China did not succeed in keeping information about the novel coronavirus out of the press. And the actions against Dr. Li backfired, causing him to be revered as a hero and martyr when he died of COVID-19 in February. But China's clampdown on speech did have an effect by denying itself and the world a more timely response. The lost opportunity in this regard appears tragic. One computer modeling study published in *Nature* found that if China's public health measures, such as quarantines, travel restrictions, and workplace closures, had been implemented one, two, or three weeks earlier, there would have been, respectively, a 66%, 86%, or 95% decrease in cases.[13] This suggests that free-expression rights may be among the most potent mechanisms humanity has for combating a pandemic, and it powerfully makes the point that the coronavirus pandemic is not just medical or biological but is also *legal* in nature.

The early days of the pandemic showed that the urge to blame or otherwise undermine the press is strong even in a democratic society. President Donald

8. *See* Jeremy Page, Wenxin Fan & Natasha Khan, *How It All Started: China's Early Coronavirus Missteps*, WALL ST. J. (Mar. 6, 2020 9:36 AM ET), https://perma.cc/2KAK-ATJN.

9. *See id.*; *Li Wenliang: Coronavirus Kills Chinese Whistleblower Doctor*, BBC NEWS (Feb. 7, 2020), https://perma.cc/FG8A-WXDW5.

10. *See* Page et al., *supra* note 8.

11. *See id.*

12. *See id.*

13. Shengjie Lai, Nick W. Ruktanonchai, Liangcai Zhou, Olivia Prosper, Wei Luo, Jessica R. Floyd, Amy Wesolowski, Mauricio Santillana, Chi Zhang, Xiangjun Du, Hongjie Yu & Andrew J. Tatem, *Effect of Non-pharmaceutical Interventions to Contain COVID-19 in China*, 585 NATURE 410, 411 (2020).

Trump assailed the news media for unoptimistic coverage of the virus.[14] So too did British medical journal the *Lancet*, which wrote in a January 24, 2020 editorial, "News media that worsen fears by reporting a 'killer virus' only harm efforts to implement a succesful [sic] and safe infection control strategy."[15] Notably, the *Lancet* itself ended up adopting the language it chastised others for using. In a March 7, 2020 editorial, the *Lancet* wrote, "This coronavirus is not benign. It kills."[16]

The takeaway should be that the pandemic context is no exception to the rule that the cure for bad information is more information. In the context of infectious disease control, unfettered information offers its greatest potential impact at the earliest stages of an outbreak when cases remain few and relatively localized—a condition in which there is still a realistic possibility of averting a worldwide pandemic.

We can now observe that there was a tragic mismatch between early opportunities for control of COVID-19 as a localized epidemic in Wuhan and relevant information possessed at that time by the WHO and the public health authorities of other nations. Earlier, better information could have provided more opportunity and impetus for quick, decisive, and internationally coordinated actions such as travel restrictions, quarantines, and contact tracing—before worldwide spread began.

While an independent media with free speech protections is a key mechanism to promulgate facts and mitigate misinformation, the sensitive nature of medical information complicates the media's role in dispersing knowledge. Patient privacy regulation and professional medical norms mean that the media cannot access all the relevant medical data needed to construct a comprehensive picture of an infectious disease outbreak. It is therefore desirable that a free press be buttressed by politically insulated national public health agencies—with mandates to acquire and synthesize medical data about infectious disease outbreaks and to issue reports for the media and direct public consumption. That may be a special challenge in the global pandemic context. At the international level, the public health role of collating and distributing outbreak information belongs to the WHO, which has been criticized for being politically influenced.[17] And the WHO's information is only as good as what it

14. *See, e.g.*, Aaron Blake, *'Something That We Have Tremendous Control Over': A Timeline of Trump Playing Down the Coronavirus Threat*, WASH. POST (Mar. 16, 2020 at 8:42 AM CDT) (quoting a tweet from President Donald Trump from March 9, 2020: "The Fake News Media and their partner, the Democrat Party, is doing everything within its semi-considerable power (it used to be greater!) to inflame the CoronaVirus situation, far beyond what the facts would warrant. Surgeon General, 'The risk is low to the average American.'").

15. Editorial, *Emerging Understandings of 2019-nCoV*, 395 LANCET 311, 311 (2020).

16. Editorial, *COVID-19: Too Little, Too Late?*, 395 LANCET 755, 755 (2020).

17. *See, e.g*, Kathy Gilsinan, *How China Deceived the WHO*, ATLANTIC (Apr. 12, 2020), https://perma.cc/82ZG-P9N2 (arguing that "inherent structural problems at the

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receives from national-level agencies, which themselves may be hampered by a lack of political independence.[18] COVID-19 offers a sobering lesson that politically motivated barriers to public health data acquisition, sharing, and reporting may be a profoundly self-defeating strategy.

At the end of the day, lives will be saved by law protecting free speech and by law fortifying the independent informational role of public health agencies. Had such legal protections been stronger and reached further around the globe, many more lives would have been saved.

B. Copyright Law

Copyright law is another legal lever affecting the transmission of knowledge. By providing a legal means to exclude content from persons who have not paid for it, copyright can ensure a revenue stream that pays for quality investigations, editing, and wide dissemination of scientific papers and other reporting. The downside is that the resulting paywalls impede information flow. Worse, paywalls can keep research from people who have the means to use it but not the means to pay for it.[19]

The access problem is multiplied many times over when the relevant information is scattered piecemeal across a very large number of outlets—as it has been in this globally dispersed pandemic—with relevant clinical and public health experiences and data arising simultaneously from countless medical facilities and municipalities as each have begun to deal with the realities of COVID-19. Search costs in such circumstances are exceptionally high. Without the barriers imposed by copyright law and existing paywall structures, we can speculate that entrepreneurial ventures might have succeeded in lowering search costs with better aggregated and systematized medical and scientific information.

Understanding the potency of fast-moving information in a fast-moving public health emergency, elite traditional medical publishing outlets made new

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WHO . . . make the organization vulnerable to misinformation and political influence" and noting that the WHO's reluctance to upset member countries applies not just to economic powerhouses but even to small developing countries).

18. We discuss political insulation and independence for public health agencies in more depth below. *See infra* Part III.

19. *See* Jorge L. Contreras, *Confronting the Crisis in Scientific Publishing: Latency, Licensing, and Access*, 53 SANTA CLARA L. REV. 491, 574-75 (2013) ("Over-protection of scientific literature has enabled commercial publishers to increase subscription rates to a point at which access to scientific information has been curtailed with negative social welfare consequences."); Jamie O'Keeffe, John Willinsky & Lauren Maggio, *Public Access and Use of Health Research: An Exploratory Study of the National Institutes of Health (NIH) Public Access Policy Using Interviews and Surveys of Health Personnel*, 13 J. MED. INTERNET RSCH., Oct.-Dec. 2011, at 74-75, 78 (concluding that increased open access to medical literature will have positive impacts on evidence-based patient care, and reporting interview findings that the dominant non-point-of-care resources consulted by health personnel were Google and Wikipedia).

COVID-19 content open to all, including the *Journal of the American Medical Association*, the *New England Journal of Medicine*, the *Lancet*, and *Cell*. But negative effects remain. New research must leverage old research, and a vast reserve of pre-pandemic scientific information relevant to fighting COVID-19 remains paywalled. Moreover, physicians around the world do not merely need coronavirus-specific information to help patients; they need more generally applicable information about supportive pulmonary care, hospital best practices, and so on. Much of the best research in these areas remains paywalled as well. The ideal of open-source, online, living documentation about COVID-19—which synthesizes new data and provides guidance with multi-institutional and multi-national inputs—remains elusive.

Because of the need to quickly work to fill in the void of knowledge about the novel COVID-19 virus and its pathology, the pandemic became a showcase for the potency of non-traditional publishing on preprint servers such as bioRxiv, medRxiv, arXiv, and SSRN, all of which are open-access.[20] Research suggests that because of the rapidity with which preprints can be released, research communicated in preprints likely influenced policymaking discussions and may have driven discourse around COVID-19 even more than peer-reviewed research.[21]

C. Patent Law

A third barrier to free, fast-moving innovation is patent law, which gives a term of exclusive rights to inventions that represent new, nonobvious advances over existing technologies. Patent law disincentivizes the disclosure of useful research results in two ways. First, patent law can discourage the sharing of unpatentable insights that might point the way toward a patentable innovation. This follows from patenting being a winner-take-all system. Even if many research teams are closing in on a patentable discovery, the first team to the patent office gets all the rights. This deters researchers from sharing unpatentable insights that could, with further work, lead to patentable treatments.

Outside of the pandemic context, it is at least plausible to argue that patent law's winner-take-all system makes sense. With so many health-care challenges to go around, siloed research might focus efforts in a productive way. The pandemic context, however, calls for something different—something more like a community barn raising, where everyone works together to accomplish a massive task in a short timeframe.

Given the winner-take-all structure of patent law, it is heartening that great numbers of researchers quickly shared promising insights about SARS-

20. *See* Maimuna S. Majumder & Kenneth D. Mandl, Comment, *Early in the Epidemic: Impact of Preprints on Global Discourse About COVID-19 Transmissibility*, 8 LANCET GLOB. HEALTH e627, e627-e628 (2020).

21. *Id.* at e628.

CoV-2 and COVID-19 notwithstanding the fact that doing so may have been detrimental to their ability to claim intellectual property rights in the future.[22] But patent law's powerful incentives are undoubtedly keeping still other useful insights under wraps. Although this may serve to achieve a faster *relative* speed of research output by one group of investigators compared to others—by slowing others through withheld data—it may impede and slow the *absolute* speed of developing and rolling out key breakthroughs in COVID-19 testing, vaccination, and treatment. To put it in game theory terms, mutual defection by adversarial researchers from cooperative sharing of data may lead to suboptimal rates of effective breakthroughs for fighting the COVID-19 pandemic.[23]

The second way in which patent law discourages information sharing comes from the fact that laws in many countries bar researchers from a patent if they fully disclose a patentable innovation before first filing a patent application.[24] Because valuable inventions will be patented in multiple jurisdictions around the world, universities—for whom knowledge sharing is a core value—may undertake considerable efforts to stop their scientists from sharing patentable advances until after the necessary legal work is done.[25] Universities pursue these policies notwithstanding mission statements built around a commitment to spreading knowledge. As a general matter, universities may argue that it is inconsequential to delay the sharing of research results while technology transfer offices do their work.[26] But in the pandemic context, that argument falls flat. Even short delays in the dissemination of useful research may translate to many lives lost.

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22. Myriad examples can be found by searching pre-prints on *bioRxiv*, COLD HARBOR SPRING LAB'Y, https://perma.cc/MTW4-M8J4 (last visited Oct. 18, 2020) and *medRxiv*, COLD HARBOR SPRING LAB'Y, https://perma.cc/T4G4-XVPK (last visited Oct. 18, 2020).

23. We can think of this as the "pandemic dilemma," drawing an analogy to game theory's "prisoner's dilemma." For a description of the prisoner's dilemma, see Maya Steinitz & Paul Gowder, *Transnational Litigation as a Prisoner's Dilemma*, 94 N.C.L. REV. 751, 767 (2016).

24. *See generally* Karen E. Sandrik, *A Uniform Grace Period: Promoting International Research and Development Collaboration*, 91 TUL. L. REV. 99, 114-15 (2016) (describing the novelty requirements and the grace periods, or lack thereof, in several major patent jurisdictions and noting that many have "what might fairly be termed a 'near absolute' novelty requirement").

25. *See, e.g.*, Michael S. Mireles, Jr., *States as Innovation System Laboratories: California, Patents, and Stem Cell Technology*, 28 CARDOZO L. REV. 1133, 1171 (2006) ("The impetus to keep information secret and delay publication may come from with [sic] the university itself to protect its ability to patent government-funded inventions and thus its ability to profit from those inventions or from industry collaborators that do not want to give up an advantage to a competing firm.").

26. *See, e.g.*, Rebecca S. Eisenberg, *Academic Freedom and Academic Values in Sponsored Research*, 66 TEX. L. REV. 1363, 1378-79 (1988) (discussing a subcommittee of the American Association of University Professors writing dismissively of short delays in publication for the purposes of applying for patents).

There is no questioning the significance the patent system has had to date in helping to build the medical profession's current armamentarium to fight disease. Yet the COVID-19 pandemic suggests a need for re-evaluation. Where there is a premium on moving fast to counter a health threat that grows exponentially, the patent system might not be the optimal incentive system, at least not on its own. The coronavirus crisis provides fresh reason to consider alternative or adjunctive incentive schemes, such as the announcement of monetary prizes that will be awarded on an ex post basis to those who made substantial contributions toward effective means of preventing and treating disease.[27] As long as the pandemic rages, legislatures around the world should consider setting aside money for such awards. Such legislation should direct that awards be given not just to those who produced finished therapies or prophylaxis, but also those who quickly shared promising research others could build upon.[28]

III. Political Insulation May Be More Important Than Political Accountability in Public Health Decisionmaking

Laws affecting information flows are not the only valves in the legal system that affect the volume of infections and deaths in a pandemic. The laws that control the design and leadership of bureaucratic agencies play a crucial role as well.

Looking back at the first few months of the pandemic, it is clear that the response in the United States was consistently driven by what was politically feasible rather than by what would have been technically effective. That does not mean we should forego democratic governance in a pandemic, but it does mean we need a larger role for expertise-driven decisionmaking that is sheltered from the full force of political winds.

Over the initial arc of the pandemic, many observers suggested that the leveling off of the effective reproduction number (R) of SARS-CoV-2 in China

27. *See, e.g.*, Steven Shavell & Tanguy van Ypersele, *Rewards Versus Intellectual Property Rights*, 44 J.L. & ECON. 525, 530-31 (2001) (discussing how ex post rewards can encourage innovation).

28. Laws aimed at stimulating technology transfer, such as the Bayh-Dole Act in the United States, may also be of use in this regard. *See* Bayh-Dole University and Small Business Patent Procedures Act of 1980, Pub. L. No. 96-517, ch. 30, 94 Stat. 3015 (codified as amended at 35 U.S.C. §§ 200-212). Universities receiving patents under Bayh-Dole could build timely and affordable product access conditions into their technology transfer agreements, perhaps keyed to pandemic-specific circumstances. But note that the Bayh-Dole Act has been heavily criticized as failing to promote the dissemination of scientific advances. *See., e.g.*, Lorelei Ritchie de Larena, *The Price of Progress: Are Universities Adding to the Cost?*, 43 HOUS. L. REV. 1373, 1376 (2007) (stating that Bayh-Dole has led to "irresponsible" over-patenting by universities, which "may deter important follow-on research by even noncommercial researchers"); Clifton Leaf, *The Law of Unintended Consequences*, FORTUNE, Sept. 19, 2005 (arguing that Bayh-Dole has kept discoveries from being disclosed to the scientific community and has diverted scientists' efforts from scientific work).

was thanks to China's draconian public health measures, made possible by that nation's authoritarian form of government. Western democracies were seen as ineffective in comparison. The pandemic has indeed pointed to efficacy gaps in how different nations responded, but the binary choice of effectiveness or authoritarianism is a false one.

The nations we call "free democracies" are, of course, much more complex than that label suggests. Such nations are a mosaic of three sorts of decisionmaking models. The first is elected, politically accountable power, such as a president, parliament, and whatever agencies those political actors control. The second is politically insulated judicial power charged with upholding the rule of law, even when doing so may be against political will. The third is politically insulated independent regulatory agencies charged with making decisions on the basis of sound expertise, also in circumstances where doing so means acting contrary to political will. The question is how to strike the right balance among them.

In the United States, public health agencies are generally subject to political control. At the federal level, the U.S. Public Health Service (USPHS), of which the Centers for Disease Control and Prevention (CDC) is a part, is an executive branch agency accountable to the president. This is in contradistinction to independent agencies, such as the Federal Reserve Board, whose leaders, once appointed, have been understood not to be removable at the president's will.

While historians will debate the details, it seems very clear at this point that politically accountable leaders of the public health response in the United States did not act as optimal decisionmakers. Even as late as early March, while the tally of cases and deaths mounted overseas, authorities in the United States acted with only a light touch—arguing broad social distancing measures were not necessary, discouraging the wearing of masks, and putting in place only minimal travel restrictions.[29] Only in mid-March, after the virus was widespread in the United States, were full-fledged social-distancing measures implemented.[30] At that point, it was late enough in the crisis that virtually

29. *See, e.g.*, *Hearing Before the S. Health, Educ., Lab. & Pensions Comm.*, 116th Cong. (Mar. 3, 2020) (statement of Dr. Anthony Fauci, Director, National Institute of Allergy and Infectious Diseases) (testifying that Americans should not all be wearing masks "[b]ecause right now there isn't anything going around in the community, certainly not coronavirus, that is calling for the broad use of masks in the community"); Mary Kekatos & Natalie Rahhal, *NY Governor Andrew Cuomo Blasts CDC and 'Bad Government' Over Mixed Messages About Coronavirus Testing After Top NIH Official Dr. Anthony Fauci Says He Cannot Promise to Get at Least One Million Test Kits in Next Two Weeks*, MAILONLINE (Mar. 6, 2020), https://perma.cc/U73J-KFQU (reporting that Dr. Anthony Fauci believed that social distancing was not appropriate nationwide in the United States).

30. By March 16, 2020, COVID-19 cases were confirmed in every state except West Virginia. *See* Andrew Soergel, *Coronavirus Relief Bill Passes House as Apple Shuts Down Stores*, U.S. NEWS & WORLD REP. (Mar. 14, 2020, 9:49 AM), https://perma.cc/9YA4-7KKY. On March 11, some West Coast states banned very large gatherings. Deborah Bloom, *How 3 West Coast States Led the Way in Bending*

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everyone could see the measures were necessary, but it was also late enough that the public health measures had suboptimal epidemiological effect even while inflicting maximal economic damage.

It is not plausible to expect politicians or politically controlled agencies to exercise decisive leadership—before a threat fully materializes—with tough-to-swallow measures such as halting travel, banning public events, and mandating social distancing. Politicians and politically accountable agency heads will, quite rationally, anticipate being called "chicken littles." Consider that in the best-case scenario, where such measures work brilliantly to prevent the spread of the virus, healthy but annoyed citizens will conclude they were inconvenienced needlessly for a crisis that never materialized. The politically astute play is not to anticipate the crisis, but instead to react as it unfolds, shifting blame for lives lost. This is exactly what happened in the United States. And this is exactly what should not happen if the response to a pandemic is to be timely and effective.

We can blame politicians for miscalculating. Yet it seems highly plausible that they indeed made the right *political* calculations. The problem is that they made the wrong *public health* calculations. Thus, we need to scrutinize the governance design of public health authority that makes such decisions political ones in the first place.

The threshold for implementing economically painful social-distancing measures and business closures cannot be the point at which there will be widespread popular agreement that they are necessary. That point is always going to be too late. An independent agency led by a commission of experts—who will spend every working hour pouring over the science—would stand a much better chance of correctly calibrating the ideal timing and severity of closures and distancing orders. We thus need to consider restructuring public health authorities to have political independence. For instance, we could refashion the USPHS on the model of independent agencies such as the Federal Reserve Board. Leaders, once appointed, would not be removable at the president's will. Yet the Federal Reserve Board is an imperfect paradigm. While the Federal Reserve Board exerts enormous power, it does not present the kind of direct capacity for impinging on personal liberties as a public health agency can. Thus, to prevent tyrannical overreach by a politically insulated public health authority during a pandemic, there is a need for judicial review. A law establishing an independent USPHS could require that public health measures be approved in advance by a federal court, which could review petitions on an emergency basis. Indeed, the U.S. Constitution requires that liberty-limiting public health measures satisfy due process strictures by being necessary to

the Coronavirus Curve, VOICE AMERICA NEWS (Apr. 14, 2020), https://perma.cc/YMZ9-S7NP. On March 16, several states ordered bars and restaurants closed and San Francisco issued the first stay-at-home order. *See id.*

protect the public from a significant risk.[31] Creating a new public health agency design along these lines would mean fashioning procedural manifestations for recognized substantive protections.

IV. Regulatory Approvals Need to Be Faster and More Flexible in a Pandemic

In addition to laws affecting information flows and laws affecting decisionmaking over public health measures, another crucial area where law influences infection and death tallies is regulation concerning the approval of drugs, vaccines, and diagnostics.

Government bureaucracy is notorious for moving slowly. Some of this criticism is overblown, but in general, it is true that regulatory agencies resist moving hastily and tend toward extreme deliberateness. Most of the time, that is probably a good thing. Indeed, the longstanding better-safe-than-sorry process the FDA has used for approving new drugs and other medical products has been a venerable one. It has kept Americans safe and fostered trust in the healthcare system while ensuring that a steady stream of innovation reaches the market. But in the midst of a pandemic, bureaucratic slowness can be deadly.

The U.S. Food and Drug Administration (FDA), as the approver of drugs, vaccines, diagnostic tests, and other medical products, is at the center of the regulatory aspect of the coronavirus pandemic. The FDA has considerable flexibility to change how it regulates. And, of course, Congress can compel regulatory shifts with legislation.

In the early phase of the coronavirus pandemic, we saw the FDA itself take substantial initiative on its own to decrease regulatory burdening. A simple and early example involves diagnostic kits. In early March 2020, federal agencies were criticized for not doing more to approve diagnostic kits to allow for quicker, more widespread testing.[32] Quickly thereafter, the FDA began issuing emergency-use authorizations for testing kits.[33] On March 13, 2020, FDA Commissioner Dr. Stephen M. Hahn said such actions showed the FDA's "dedication to working around the clock" to review and approve COVID-19 diagnostics.[34] Then just a few days later, on March 16, the FDA seemed to deem its own sped-up processes to be too slow. The FDA announced it was

31. *See, e.g.*, LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 428-30 (2016) (stating that under the Court's strict scrutiny analysis, "only persons who pose a significant risk of transmission can be confined" and "courts could require the state to demonstrate that confinement is the least restrictive alternative to achieve its state objective").

32. *See, e.g.*, Lauren Stanforth, *Cuomo Slams CDC Preparations*, THE TIMES-UNION (Albany, N.Y.), Mar. 9, 2020 at A1.

33. *See, e.g.*, Press Release, FDA, Coronavirus (COVID-19) Update: FDA Issues Emergency Use Authorization to Thermo Fisher (Mar. 13, 2020), https://perma.cc/M3GN-KGZJ.

34. *Id.*

permitting private firms to start directly marketing testing kits to the public without pre-approval.[35] Under this new scheme, companies would be required to send data to the FDA so the agency could review testing accuracy on a retroactive basis.[36]

The loosening of regulatory approvals was not without risk. A substantial number of testing kits proved unreliable in the field.[37] Nevertheless, the FDA's intentionally flexible approach seems to us to have been a good thing. If we want regulatory fleet-footedness, we must expect stumbles. And when the FDA finds it has gone too far or in the wrong direction in loosening regulatory reigns, the agency can and should readjust. Regulatory flexibility is a key administrative agency virtue if regulations are to follow emerging data and evidence in a time frame effectively commensurate with the rapidity of a pandemic such as COVID-19. And the fact remains that even with the FDA's intentional course of regulatory relaxation, as of late April 2020 there was still a deficit of testing capacity—although that deficit may have been largely a function of federal government managerial failures in procurement and coordination.[38]

An area where legacy regulatory structures have shown more stickiness is with vaccines. This is crucial, because with the virus seeded widely throughout the United States, any successful resolution to the pandemic almost certainly means a vaccination program. The alternative of letting COVID-19 work its way through the population until herd immunity is obtained would be an abject policy failure, as it would entail hundreds of thousands of additional deaths and unquantifiable suffering.

Candidate vaccines were developed very quickly in the course of the pandemic, but because of the need for safety and efficacy testing, the U.S. public health leadership stated that in the best-case scenario, a vaccine was likely more than a year and a half away from reaching the market.[39] Such a time frame comes from the pre-pandemic FDA regulatory structure for vaccine approval—

35. Thomas M. Burton, *FDA Allows Test Kits to Be Sold to Public*, WALL ST. J., (Mar. 17, 2020, 9:04 AM), https://perma.cc/R9WL-N4T6.

36. *Id.*

37. *See, e.g.*, Jeremy Schwartz, *Laredo ER Spent $500,000 on Coronavirus Tests That Didn't Work*, TEX. TRIB. (Apr. 10, 2020), https://perma.cc/E3U9-C33M.

38. *See* Alexandra Sternlicht & Jack Brewster, *Governors From Both Parties Slam Trump's Claims About Testing*, FORBES (Apr. 20, 2020), https://perma.cc/UQF4-RZV4; Shane Harris, Felicia Sonmez & Mike DeBonis, *Trump Says Government Will Step Up Coronavirus Testing Efforts, After Governors Blast Federal Inaction*, WASH. POST (Apr. 19, 2020), https://perma.cc/QL92-JT9C.

39. *See Fiscal 2021 Budget Request for The National Institute of Heath: Hearing Before the H. Appropriations Subcomm. on Lab., Health & Human Serv's. & Educ.*, 116th Cong. (Mar. 4, 2020) (statement of Dr. Anthony Fauci, Dir., National Institute of Allergy and Infectious Diseases), https://perma.cc/7FGU-B64X (describing a period of a year and a half or more of testing and development before having a SARS-CoV-2 vaccine ready for the American population).

one that involves a cautious series of sequentially staged clinical trials with increasingly enlarged pools of volunteer testing subjects.[40]

Some pushback to this way of doing things emerged in late March and early April 2020. In late March, an early version of this Essay argued that this process of making safety and efficacy findings for a vaccine was too slow.[41] And we argued the same point in a *Washington Post* opinion piece in early April.[42] Our reasoning was that, given the overwhelming social need in the pandemic context, it would be ethical to overlap or combine trial phases in a way that does not compromise scientific standards for demonstrating safety and efficacy, but that does expose more individuals to uncertain risk beyond what is conventionally tolerated. As we noted, what is at issue is a risk-risk tradeoff, because the status quo path was to leave the general global population exposed to a bureaucratically protracted period of pandemic risk without medical mitigation. Also in late March, a group of public health scholars—Nir Eyal, Marc Lipsitch, and Peter G. Smith—published a detailed study in the *Journal of Infectious Diseases* showing how human challenge trials—where test subjects are purposefully exposed to the virus—could accelerate vaccine approval by months.[43] Impressively, that group of researchers showed how a thoughtful study design could keep net mortality and morbidity low or even negative for participants.[44] This approach gained some notice on Capitol Hill. In April 2020, 35 members of Congress, led by Representatives Bill Foster and Donna Shalala, wrote to Secretary of Health and Human Services Alex M. Azar II and FDA Commissioner Stephen Hahn. Their letter asked Azar and Hahn to consider more rapid approval and deployment processes for a vaccine, pointing to the promise of human challenge testing in particular.[45] While it was gratifying to see some conversation about reimagining safety and efficacy testing for vaccines, the lack of progress on this front has been disappointing and will stand as a lost opportunity to bring the crisis to a swifter conclusion.

Looking over the first months of the pandemic, it is clear that a key want has been congressional attention to the issue of regulatory flexibility and streamlining. When the FDA has proven overcautious in the past, Congress has repeatedly stepped in to grease the wheels. In 1984, the Drug Price Competition and Patent Term Restoration Act, better known as the Hatch-

40. *See* 21 C.F.R § 312.21 (2019).

41. Eric E. Johnson & Theodore C. Bailey, *Urgent Legal Lessons from a Very Fast Problem: COVID-19*, 73 STAN. L. REV. ONLINE (Apr. 3, 2020) (prepublication manuscript), https://perma.cc/7LVK-HNGP.

42. *See* Eric E. Johnson & Theodore C. Bailey, *Speed Up the FDA's Vaccine-Approval Process*, WASH. POST (Apr. 8, 2020), https://perma.cc/V6FG-7NN9.

43. Nir Eyal, Marc Lipsitch & Peter G. Smith, *Human Challenge Studies to Accelerate Coronavirus Vaccine Licensure*, 221 J. INFECTIOUS DISEASES 1752, 1752 (2020).

44. *Id.* at 1754-55.

45. Letter from Rep. Bill Foster and Rep. Donna Shalala, Members of Cong., to Alex M. Azar II, Sec'y of Health & Human Serv's., and Stephen Hahn, FDA Comm'r (Apr. 20, 2020), https://perma.cc/DVD8-DCLJ.

Waxman Act, facilitated the speedier approval of generic equivalents for brand-name drugs already on the market.[46] In 1997, the Food and Drug Administration Modernization Act sought to smooth the way for faster approval of treatments for the AIDS pandemic.[47] And in 2016, the 21st Century Cures Act aimed to quicken the time-to-market for new products by encouraging new trial designs and the use of real-world evidence.[48]

The lack of congressional attention in this area is likely to stand out as a key missed opportunity. Consider that a simple law could give the FDA wide discretion to suspend longstanding rules for approving treatments relevant to COVID-19. Such legislation could direct the FDA to navigate according to the developed good judgment of its experts, encouraging the public servants at the FDA to think creatively in designing case-by-case approval procedures for vaccines, therapeutic biologics, and small-molecule drugs for combatting COVID-19. Legislation along these lines would put the force of law behind the sentiments expressed in the Foster-Shalala letter. And if such a law does not emerge in the midst of the pandemic, then the post-pandemic legislative agenda should surely include designing administrative mechanisms that can spur regulatory innovation in a pandemic crisis.

Another lesson going forward is the missed opportunities arising from thinking about risk that has been stuck in a pre-pandemic mode. We continue to believe, as we argued in the earlier version of this Essay, that when it comes to safety and efficacy testing, we should respect the will of selfless individuals to knowingly take on additional uncertain risk as an act of service in times of pandemics. While we admire the work of Eyal, Lipsitch, and Smith in charting the course for a human challenge vaccine trial that could reduce overall risk to study participants, we see some danger in holding on to a pre-pandemic aversion to elevated levels of risk to human subjects. Indeed, the Eyal group's article shows conformance with conventional attitudes toward human subject testing, stating, "Importantly, challenge studies are conducted against the background of competent volunteers' informed consent, minimization of study risks, and high baseline risks of infection for participants. They do not violate participants' individual rights on the altar of emergency response, but heed both individual rights and the global public health emergency."[49] There should be no

46. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355). The provision for abbreviated approval for generic versions of previously approved drugs is at 21 U.S.C. § 355(j).

47. *See* Eleanor D. Kinney, *21st Century Cures Act and Medical Device Regulation: Departure from Principles or Catching the Wave*, 44 AM. J. L. & MED. 269, 273 (2018); Lewis A. Grossman, *AIDS Activists, FDA Regulation, and the Amendment of America's Drug Constitution*, 42 AM. J. L. & MED. 687, 735 (2016); Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 (codified as amended in scattered sections of 21 U.S.C.).

48. 21st Century Cures Act of 2016, Pub. L. No. 114-255, 130 Stat. 1033 (codified in scattered sections of 21 and 42 U.S.C.).

49. Eyal, et al., *supra* note 43, at 1755.

compromise on individual rights and informed consent. But altar sacrifice is, we think, the wrong analogy. In the context of a fast-moving, social-order-wrecking, novel viral pandemic, pre-pandemic norms categorically prioritizing the minimization of study risks bear re-evaluation.

The categorical prioritization of minimizing study risks appears to overlook the fact that decisions about study design are always decisions about the relative allocation of risks between two groups. The first group is the subjects in a particular clinical study—who have the benefit of well-established safeguards for the protection of their informed autonomy with respect to study-related risks. The second group is the general human population—which lacks similar protections of informed autonomy with respect to the risks of the disease under study. If autonomy and risk minimization are indeed appropriate guiding ethical values for research design—and we share the prevailing view that they are—then a more nuanced view is in order. Where the risk for the general population is very high, as it has been with COVID-19, then subjects in the study should be permitted to take on heightened levels of study-related risks.

In March, we noted that many writers have aptly analogized the coronavirus pandemic to war. We continue to believe that, just as in war, a country allows heroes to risk their lives for the sake of others, we should stand ready to honor the choice of volunteer testing subjects to do the same in the face of COVID-19.

Conclusion

Scientists and health professionals tend to take the law as a fixed constraint on their work—even as they attempt to bend chemistry and biology to their will in the battle against disease. The pandemic context, however, demands a more expansive perspective. We must think searchingly about how the law may exacerbate or ameliorate the pandemic, and we must consider how changing the law could save lives. Reflecting on the law's role in the very fast problem of COVID-19 points to the value of building formal pandemic provisions and contingencies into the law. Such an effort could facilitate the innovation and collective action we will need to grapple with pandemics yet to come.