

2023

## Trust the Science but Do Your Research: A Comment on the Unfortunate Revival of the Progressive Case for the Administrative State

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### Recommended Citation

Tushnet, Mark (2023) "Trust the Science but Do Your Research: A Comment on the Unfortunate Revival of the Progressive Case for the Administrative State," *Indiana Law Journal*: Vol. 98: Iss. 2, Article 1.

Available at: <https://www.repository.law.indiana.edu/ilj/vol98/iss2/1>

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# Trust the Science but Do Your Research: A Comment on the Unfortunate Revival of the Progressive Case for the Administrative State

MARK TUSHNET\*

*This Article offers a critique of one Progressive argument for the administrative state, that it would base policies on what disinterested scientific inquiries showed would best advance the public good and flexibly respond to rapidly changing technological, economic, and social conditions. The critique draws on recent scholarship in the field of Science and Technology Studies, which argues that what counts as a scientific fact is the product of complex social, political, and other processes. The critique is deployed in an analysis of the responses of the U.S. Centers for Disease Control and Food and Drug Administration to some important aspects of the COVID crisis in 2020.*

*The COVID virus had characteristics that made it difficult to develop policies to limit its spread until a vaccine was available, and some of those characteristics went directly to the claim that the administrative state could respond flexibly to rapidly changing conditions. The relevant administrative agencies were bureaucracies with scientific staff members, though, and what those bureaucracies regard as “the science” was shaped in part by bureaucratic and political considerations, and the parts that were so shaped were important components of the overall policy response.*

*Part II describes policy-relevant characteristics of knowledge about the COVID virus and explains why those characteristics made it quite difficult for more than a handful of democratic nations to adopt policies that would effectively limit its penetration of their populations. Part III begins with a short presentation of the aspects of the science and technology studies (STS) critique of claims about disinterested science that have some bearing on policy responses to the pandemic. It then provides an examination shaped by that critique of the structures of the Food and Drug Administration and the Centers for Disease Control, showing how those structural features contributed to policy failures. Part IV concludes by sketching how the STS critique might inform efforts to reconstruct—rather than deconstruct—the administrative state, proposing the creation of Citizen Advisory Panels in science-based agencies.*

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#### INTRODUCTION

Early in the Trump administration, Presidential Adviser Steven Bannon said that the administration would deconstruct the administrative state.<sup>1</sup> No one, probably not even Bannon, knew what specifically that would entail. Defenders of the administrative state responded to the Trump administration’s disruptions of settled patterns of practice in the administrative state by reviving, with modest qualifications, the classical Progressive arguments for having such a state.<sup>2</sup> According to Progressives, in contrast to a government in which only the traditional three branches could make policy, an administrative state would base policies on what disinterested, scientific inquiries showed would best advance the overall public

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1. Ryan T. Beckwith, *Read Steve Bannon and Reince Priebus’ Joint Interview at CPAC*, TIME (Feb. 23, 2017), <https://time.com/4681094/reince-priebus-steve-bannon-cpac-interview-transcript/> [<https://perma.cc/3VVE-WQDB>].

2. For examples of the revival, see Jody Freeman & Sharon Jacobs, *Structural Deregulation*, 135 HARV. L. REV. 585, 615–20 (2021) and Vicki C. Jackson, *Knowledge Institutions in Constitutional Democracies: Preliminary Reflections*, 7 CAN. J. COMPAR. & CONTEMP. L. 156 (2021).

good and flexibly respond to rapidly changing technological, economic, and social conditions.<sup>3</sup>

The revival of these components of the Progressive case, those referring to disinterested, scientific expertise and flexibility, is unfortunate because it is at least a speed bump, and perhaps more, in the path to a more adequate understanding of the administrative state. Over the course of the past half century, scholarship about science and government developed a critique of claims of disinterested expertise that might have infiltrated scholarship on the administrative state.<sup>4</sup> That critique, associated with academic fields with the labels “social studies of science” or “science and technology studies” (STS), was—to put it in grotesquely oversimplified terms—that the claim of disinterested, scientific expertise was itself a political claim, whose content was related to, though not precisely the same as, the content of politics in other venues.<sup>5</sup> Had this critique gained a foothold in the legal academy, we might have begun to see critiques of the administrative state that would have suggested tweaks to its use of scientific expertise combined with a more substantial reconstruction of the knowledge claims used to justify administrative policy.<sup>6</sup>

The Trump administration’s hostile stance toward the administrative state often took the form of direct political intervention, which could be understood with reference to an established critique of Progressive claims about the political independence of the administrative state.<sup>7</sup> Another component of that stance was a

3. For the classic expositions of the Progressive case, see FELIX FRANKFURTER, *THE PUBLIC AND ITS GOVERNMENT* (1930) and JAMES M. LANDIS, *THE ADMINISTRATIVE PROCESS* (1938). For a more detailed presentation of the Progressive case, see Mark Tushnet, *The Hughes Court: From Progressivism to Pluralism, 1930 to 1941*, in 11 OLIVER WENDELL HOLMES DEVISE HISTORY OF THE SUPREME COURT OF THE UNITED STATES 1, 423–31 (2022).

4. In my view, the only work on the administrative state that could be seen to have been influenced by these critiques has been done by Charles Sabel and his colleagues. See, e.g., Jeremy Kessler & Charles Sabel, *The Uncertain Future of Administrative Law*, 150(3) *DAEDALUS* 188 (2021) (discussing how the “provisional” nature of guidance documents can be capitalized upon to make the administrative state more flexible); Charles F. Sabel & William H. Simon, *Minimalism and Experimentalism in the Administrative State*, 100 *GEO. L.J.* 53 (2011) (defending experimentalist innovations in the development of administrative rules).

5. For a law-focused introduction to STS, see Sheila Jasanoff, *Serviceable Truths: Science for Action in Law and Policy*, 93 *TEX. L. REV.* 1723 (2015).

6. This Article is primarily a critique of the revival of the Progressive arguments about disinterested expertise, but in the Conclusion, I sketch some possibilities for reconstructing the administrative state that the critique of expertise might open up.

7. For Progressives, the administrative state would be structured to be mostly independent of political control so that its disinterested experts could develop and implement policies with an eye only to the public good and not to political necessity. By the 1970s, if not earlier, scholars of the administrative state, first in political science and then in law, had made it clear that the administrative state had become a venue for ordinary politics: pluralistic bargaining or gridlock and ossification, depending on how politics were being conducted in other venues. For an early and influential account in the legal literature, see Richard B. Stewart, *The Reformation of American Administrative Law*, 88 *HARV. L. REV.* 1667 (1975); for an account dealing with more recent developments, see Thomas O. McGarity, *Administrative Law as Blood Sport: Policy Erosion in a Highly Partisan Age*, 61 *DUKE L.J.* 1671 (2012). The politics of the administrative state were structurally the same as politics in

direct challenge to claims about disinterested expertise. For example, the administration dismantled, then rebuilt, advisory panels on environmental policy and attempted to limit the kinds of evidence that could be used to support administrative policies.<sup>8</sup>

The last year of the Trump administration was dominated by the COVID-19 pandemic.<sup>9</sup> With the important exception of Operation Warp Speed to develop an effective vaccine, which started early in 2020 and came to fruition only after the presidential election in November 2020, the Trump administration botched the policy response to the pandemic. The conventional story, I believe, is that the administration's policy failures show how political intervention and disregard of the expertise lodged in the administrative state vindicate the Progressive case for that state.<sup>10</sup> This Article uses policy failures during the first pandemic year (2020) as a vehicle for reexamining the Progressive case.<sup>11</sup>

A summary of the overall argument is this: almost every government botched the policy response to the pandemic in the sense that they failed to prevent widespread infection, serious illness, and death from COVID. The exceptions (Singapore, Japan, Korea, and New Zealand, primarily) have special characteristics not present in the

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other venues, though law and practice gave some participants more power and others less than they had in other venues. Cases on and scholarly claims about the president's unilateral power to remove at least high-level officers triggered a modest revival of the Progressive argument for political neutrality, chastened a bit by the new learning about the politics of administrative law. See, e.g., Gillian E. Metzger, *Foreword: 1930s Redux: The Administrative State Under Siege*, 131 HARV. L. REV. 1 (2017).

8. See Freeman & Jacobs, *supra* note 2, at 617, 619.

9. See Ryan Goodman & Danielle Schulkin, *Timelines of the Coronavirus Pandemic and U.S. Response*, JUST SEC. (Nov. 3, 2020), <https://www.justsecurity.org/69650/timeline-of-the-coronavirus-pandemic-and-u-s-response/> [<https://perma.cc/EE62-RXQG>].

10. The subtitle of Andy Slavitt's reasonably widely read book captures this conventional wisdom. See generally ANDY SLAVITT, *PREVENTABLE: THE INSIDE STORY OF HOW LEADERSHIP FAILURES, POLITICS, AND SELFISHNESS DOOMED THE U.S. CORONAVIRUS RESPONSE* (2021). As of February 23, 2021, the book was listed at #74 in Amazon's list of health policy books. See *Amazon Best Sellers*, AMAZON, [https://www.amazon.com/gp/bestsellers/books/227563/ref=pd\\_zg\\_hrsr\\_books](https://www.amazon.com/gp/bestsellers/books/227563/ref=pd_zg_hrsr_books) [<https://perma.cc/75WS-7ULA>].

11. The Article deals almost exclusively with policy in (roughly) 2020, between the arrival of COVID in the United States and the availability of vaccines. Policy failures thereafter seem to be driven primarily by the development of political and cultural divisions that blocked the implementation of policies that would otherwise have been effective. To that extent, those failures might not be attributable to "the administrative state" except insofar as a well-designed administrative state would have the resources to address or work around such political and cultural divisions. I note that focusing on 2020 might cause some difficulties in exposition. We have to think about the situation as it appeared to decision-makers at the time, disregarding what we know happened later (though taking into account the possibility that decision-makers could have anticipated later developments). Specifically, we should be careful to consider the possibility that some decisions that turned out to be wrong (or suboptimal) were ordinary mistakes of judgment that tell us little about the structure of decision-making in the administrative state, though they might tell us something about the personalities of the decision-makers and, on a more complete analysis, something about how people with those personalities get put in a position to make consequential decisions.

United States.<sup>12</sup> That fact alone cautions against attributing U.S. policy failures to distinctively Trumpian interventions.<sup>13</sup> The COVID virus had characteristics that made it exceptionally difficult to develop policies that would significantly limit its spread until a vaccine was available, and some of those characteristics went directly to the claim that the administrative state could respond flexibly to rapidly changing conditions.<sup>14</sup> But, and here is where the developing critique of claims about scientific expertise enters, the relevant administrative agencies were bureaucracies with scientific staff members, and what those bureaucracies regard as “the science” was shaped in part by bureaucratic and political considerations, and the parts that were so shaped were important components of the overall policy response.

To be clear, some quite substantial parts of the U.S. policy failures in responding to the pandemic did result from Trump administration misadventures. We shouldn’t overlook, though, the fact that another quite substantial part of those failures resulted from the fact that the administrative state functioned pretty much as well as it could, in light of the weaknesses of the Progressive case for policy making based on “the science.”<sup>15</sup>

There are two important qualifications at the outset. First, the STS critique is *not* that policy makers can’t go directly from the “is” of science to the “ought” of policy. The standard view, I believe, is that policy makers take the science they are given and insert it into some normative framework that generates a policy conclusion. Rather the STS critique is that the science policy makers receive is already infused with normative content. Simply inserting it into a normative framework will produce policies that might be inconsistent with the policy makers’ normative commitments. The STS critique is that they should examine the scientific “facts” to identify how values have entered into their construction and either adopt or purge those values as they move forward.<sup>16</sup>

Second, my argument is a reaction to developments in scholarship about administrative law in general. It’s well-known that “general” administrative law is almost always a distortion of the administrative law practiced in specific agencies. Food and drug lawyers know that about administrative law and, more importantly, know how the Food and Drug Administration isn’t the politically neutral and

12. See PETER BALDWIN, *FIGHTING THE FIRST WAVE: WHY CORONAVIRUS WAS TACKLED SO DIFFERENTLY ACROSS THE GLOBE* 123–25 (2021) (discussing “the advantages of insularity”).

13. That the policy failures continued into the Biden administration should induce a related caution, that the failures may be rooted in systemic features of the modern administrative state (and perhaps to some distinctive features of the public health system in the United States). Because my focus is on the initial policy responses in 2020 (and because policy continues to develop), I don’t explore these issues in this Article.

14. For example, a person infected with the virus could transmit it to others before she experienced any symptoms and therefore before she had any reason to take precautions against infecting others. For a description of the difficulty, see BALDWIN, *supra* note 12, at 36.

15. In a preliminary version of this Article, I used the term “fundamental attribution error” to describe attributing policy failure to Trump administration choices rather than to structural features of the COVID virus and the existing administrative state. That term as used in social psychology isn’t applicable here, and I’ve decided to relegate its use to this footnote.

16. See *generally* Jasanoff, *supra* note 5.

technocratic bureaucracy envisioned by Progressives—and similarly for all other agencies.<sup>17</sup> My audience is scholars, of whom in my experience there are quite a few, who believe that the Progressive vision of the administrative state’s *technical* neutrality remains viable even as they acknowledge that the vision of that state’s political neutrality is not.

The remainder of this Article is structured as follows. Part I describes policy-relevant characteristics of knowledge about the COVID virus and explains why those characteristics made it quite difficult for more than a handful of democratic nations to adopt policies that would effectively limit its penetration of their populations.<sup>18</sup> Part II begins with a short presentation of the aspects of the STS critique of claims about disinterested science that have some bearing on policy responses to the pandemic. It then provides an examination shaped by that critique of the structures of the Food and Drug Administration and the Centers for Disease Control and Prevention, showing how those structural features contributed to policy failures. Part III concludes by sketching how the STS critique might inform efforts to reconstruct rather than deconstruct the administrative state.

#### I. POLICY-RELEVANT CHARACTERISTICS OF KNOWLEDGE ABOUT THE COVID VIRUS<sup>19</sup>

Good policy responds to knowledge—scientific knowledge in the case of public health policy to deal with a potentially serious infectious disease. Knowledge accumulates over time as scientists learn about the disease, and sometimes learning leads them to discard earlier accumulated knowledge (even though at the time it was acquired, the information satisfied scientific standards for accuracy). Making good policy entails updating policy choices in light of the best knowledge currently available. Such updating always takes time, of course, and as we will see, the COVID virus had characteristics that ensured that delays, sometimes even minor delays, in updating policy would have serious consequences.

Time matters too in determining periods in which the contours of policy choices would be quite different. For present purposes, I simplify the timeline. Given the virus’s characteristics, the first period is a relatively short one: from the virus’s first

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17. I emphasize that the “politics” associated with the routine activities of the FDA’s low-level employees (and that of similar employees at other agencies) isn’t partisan politics but is rather a distinctive politics of asserted expertise.

18. I confine my comments to democratic nations because some authoritarian nations—though not all—were able to adopt effective policies (effective at least in the short run) by imposing restrictions on citizen activity that would have been intolerable, and arguably unlawful, in most democratic nations.

19. I refrain from providing detailed citations to support every proposition about COVID’s characteristics because doing so would overburden the reader with citations to support what is now common knowledge. For accessible introductions to what we knew in real time as COVID spread and what we now know, see generally SCOTT GOTTLIEB, UNCONTROLLED SPREAD: WHY COVID-19 CRUSHED US AND HOW WE CAN DEFEAT THE NEXT PANDEMIC (2021), and SLAVITT, *supra* note 10. These books present views on the policy response to COVID that are influenced by their authors’ roles before and during the pandemic, and I refer to them here only for the basic information about COVID they provide.

appearance in a territory (a nation, in this case) and the beginning of “community spread,” that is, the transmission of the virus from a person who initially was infected by it in China to someone who had not been in China. Again, given the virus’s characteristics, the second period is also relatively short: from the first indications of community spread to uncontrolled community spread. The third period was longer (and but for some quite important contingencies could have been longer still): the time between uncontrolled community spread and the availability and widespread distribution of effective vaccines.<sup>20</sup> Finally, there is a fourth period, which we are now experiencing: the time after vaccines became widely available. Though I will make some brief comments about the relation between science and policy options during this period, the Article focus is on the first three.

In late 2019, Chinese authorities reported (and rumors circulated) about a novel coronavirus with serious flu-like symptoms. The Chinese authorities were parsimonious with information about the virus’s clinical characteristics.<sup>21</sup> They may well have assumed at the outset, and doctors outside China clearly did assume, that until further evidence accumulated, the virus was transmitted as most coronaviruses are, that is, through droplets in the air and the deposit of those droplets on surfaces (“fomite transmission”).<sup>22</sup>

The initial policies to inhibit transmission flowed from these assumptions. The first policy choice was obvious, and almost every nation with the capacity to do so made it: adopt a program for the rapid development of an effective vaccine.<sup>23</sup> What is there to do pending the arrival of a vaccine? Keeping away from other people—social distancing—would allow the droplets to fall to the ground before others could inhale them. Masks of pretty much any sort would block droplets from spreading, though surgical and other high-quality masks would of course do so better than lower quality masks (such as cloth masks).<sup>24</sup> But, pretty much everywhere, the supply of high-quality masks was limited and policy makers sensibly tried to reserve them for hospitals and other clinical settings.<sup>25</sup> And, of course, they urged people to wash their hands before and after touching surfaces on which droplets containing the virus might have fallen and to refrain as much as possible from bringing their hands in contact with their faces.<sup>26</sup>

20. We could subdivide this period by distinguishing between availability in principle and widespread distribution, but again because of my focus on 2020, doing so isn’t necessary in this Article.

21. See *COVID-19 and China: A Chronology of Events (December 2019–January 2020)*, EVERYCRSREPORT.COM (May 12, 2020), <https://www.everycrsreport.com/reports/R46354.html> [<https://perma.cc/XBX9-78V9>].

22. Relatively early, some scientists urged their colleagues and public health authorities to at least investigate the possibility that the virus was transmitted by aerosolized particles. That investigation did occur and rapidly revealed that COVID was indeed aerosolized. Still, basing initial policy on the default assumption that COVID was like other respiratory flu-like illnesses was probably the sounder choice, for reasons I describe in the text.

23. See BALDWIN, *supra* note 12, at 221–22 (describing rapid development efforts for a vaccine in the United States, China, and Russia).

24. See *id.* at 163–64 (describing the comparative utility of different types of masks depending upon the mode of COVID transmission).

25. *Id.* at 163 (describing supply shortages and allocation decisions).

26. Strikingly, the recommendations about handwashing have remained part of public



Soon enough it became clear that COVID was transmitted by aerosolized particles (that is, very small particles that remained suspended in the air for much longer than droplets do), and that other policies—such as the widespread use of high-quality masks (again, pending the arrival of an effective vaccine)—would be needed.<sup>27</sup> But, by then it was basically too late for the United States and many other nations. They moved almost directly from the virus’s initial appearance to the uncontrolled community spread, skipping the period in which it might have been possible to keep community spread under control.

Some nations were able to keep community spread under control, though, and it’s worth noting the policy choices they made—and why they were unavailable in practice in the United States as it was constituted in 2020.<sup>28</sup> First, they closed their borders quickly and tightly. This was easier for “island” (and island-like) nations such as Singapore, Japan, Taiwan, Australia, New Zealand, and South Korea and for some nations not part of the now-extensive system of worldwide trade.<sup>29</sup> Rapid and tight border closings weren’t possible for most other nations; the United States, for example, shut down flights from China in late January 2020 but did nothing to prevent inflows of people (and the virus) from other nations where they might have had contact with people who had become infected in China.<sup>30</sup>

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health messaging even though we now know that they do little to prevent COVID transmission. My best guess is that they persist partly to fulfill the public-health guideline that messages about public health should be consistent and partly because handwashing actually is effective in slowing the transmission of flus and the common cold. See *Handwashing in Communities: Clean Hands Save Lives*, CDC (Sept. 30, 2022), <https://www.cdc.gov/handwashing/index.html> [<https://perma.cc/9S32-ECC3>].

27. Cf. BALDWIN, *supra* note 12, at 138–39 (describing the sequential adoption of policies that proved ineffective).

28. Cf. *Pandemic Preparedness and COVID-19: An Exploratory Analysis of Infection and Fatality Rates, and Contextual Factors Associated with Preparedness in 177 Countries, from Jan 1, 2020, to Sept 30, 2021*, 399 THE LANCET 1489 (2022), [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(22\)00172-6/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(22)00172-6/fulltext) [<https://perma.cc/MV6E-DRQJ>] (concluding that the degree of trust citizens had in their governments and in each other provided the largest component of the explanation for variations in success). I note that the study is expressly exploratory, and I have the usual caution against relying on a single study, no matter how well-designed, to support strong conclusions. Cf. also Jay S. Kaufman, *Reaping What We Sow*, BOS. REV. (Dec. 8, 2021), [https://www.bostonreview.net/forum\\_response/reaping-what-we-sow/](https://www.bostonreview.net/forum_response/reaping-what-we-sow/) [<https://perma.cc/XWQ6-68C8>] (“The simple truth is that the United States has a weak ideological commitment to public health exactly because it is *public*. The U.S. Achilles’s heel . . . is a toxic social ideology rooted in a blind obsession with individual freedom.”); Zeynep Tufekci, *After a Pandemic Failure, the U.S. Needs a New Public Spirit*, N.Y. TIMES (Nov. 18, 2021), <https://www.nytimes.com/2021/11/18/opinion/covid-winter-risk.html> [<https://perma.cc/L3XA-ZLWW>] (“We need a new public spirit.”). I note that commentators, including the authors of the Lancet article, often suggest that we do not have good policy levers for building or rebuilding trust at least in the short run; for my mild disagreement, see *infra* note 43 and accompanying text for a discussion on political leadership.

29. See BALDWIN, *supra* note 12, at 131 (discussing the ability of some African nations to “impose[] severely restrictive measures”).

30. Among the first cases of community spread in the United States involved transmissions from people who had been in Italy and had there come into contact with people

Second, other nations deployed systems of contact tracing, sometimes using ones already available, sometimes setting up new ones.<sup>31</sup> Contact tracing was important because of another of the virus's characteristics. People infected with the virus were able to transmit it during a period of several days—perhaps up to a week—before they experienced any symptoms.<sup>32</sup> They were walking around feeling fine, conducting their ordinary activities, and spreading the virus to at least some other people with whom they came into contact. Contact tracing would prevent uncontrolled community spread as follows: once a person displayed symptoms, they could determine everyone with whom that person had been in contact within the prior several days and test them to see if they were infected.<sup>33</sup> Then place everyone who tested positive (or displayed symptoms, of course) into quarantine.<sup>34</sup>

In its classic form, contact tracing involves a public health person talking with the infected person to compile the list of contacts and then getting in touch with the people on the list. In that form, it is clearly quite resource intensive per person, which made it available in practice only for relatively small populations, either in the nation as a whole or in “bubbles” that could be isolated from the rest of the country. The latter possibility—localized lockdowns—was, again in practice, largely unavailable to many democratic nations with traditions of free movement that created political obstacles to adopting it.

Technology made another form of contact tracing possible. Tracking apps on cell phones could record where people were at any time.<sup>35</sup> Using an app to locate where an infected person had been and matching that information with similar information from everyone else's cellphone app enabled effective contact tracing.<sup>36</sup> Such apps were available and used in some nations, most notably South Korea.<sup>37</sup> Again, though, there were both technological and political difficulties in adopting technological contact tracing elsewhere. Sometimes not enough people had cell phones. Sometimes people didn't have the app and objected to acquiring it because of concerns about invasions of privacy and, perhaps more importantly, concerns that making the

who had become infected in China.

31. See BALDWIN, *supra* note 12, at 100–12 (discussing, inter alia, the use of contact tracing in Asia, Europe, and the United States).

32. See *id.* at 155–59 (discussing asymptomatic carriers and the problems of transmission control associated with them).

33. Notionally, contact tracing was connected to a policy of widespread testing of asymptomatic people. Such tests would identify infected people and contact tracing could then be used for them. As far as I know, no nation had enough good tests for COVID available in the pandemic's early days to determine whether the testing strategy was effective.

34. See BALDWIN, *supra* note 12, at 39 (describing potential efficacy of targeted or universal quarantines).

35. See *id.* at 106 (describing use of AliPay and WeChat for contact tracing).

36. See *id.*

37. See *id.* at 106–07. These apps may actually have been of limited effectiveness in aiding contact tracing. For a summary of early studies, see Fabio Chiusi, *Digital Contact Tracing Apps: Do They Actually Work? A Review of Early Evidence*, ALGORITHM WATCH (July 8, 2021), <https://algorithmwatch.org/en/analysis-digital-contact-tracing-apps-2021/> [<https://perma.cc/GPR5-XJ89>].

information generated by the app available to the government would usher in a Big Brother world of universal real-time constant surveillance of the population.<sup>38</sup>

Finally, near-universal masking, even using low-quality masks, might slow transmission enough to keep the numbers of infected people low enough to make contact tracing possible.<sup>39</sup> Here, cultural and historical factors came into play. Masking was common in some nations, particularly in East Asia, where it had been adopted by people concerned about air pollution.<sup>40</sup> For them wearing masks wasn't an innovation. Many of the same nations had experienced serious localized coronavirus epidemics from severe acute respiratory syndrome (SARS), which emerged in 2002–2004, and Middle East respiratory syndrome (MERS), which emerged in 2012.<sup>41</sup> They had already lived through a period of intrusive public health regulation. For them, intrusive regulations to deal with COVID were again no innovation. Elsewhere, where masks were uncommon and SARS and MERS hadn't had serious effects, masking (and other intrusive policies) were politically difficult to “foist” upon the population.<sup>42</sup>

To summarize: COVID's easy transmissibility and the fact that people could transmit it even when they were asymptomatic meant that the window between the time COVID first landed in a territory and the period of uncontrolled community spread was quite narrow. In concept, policies were available to prevent uncontrolled community spread, but actually adopting them in large democratic nations with broad connections to the international economy was extremely difficult. Inspired political leadership might have been able to pull it off, but such leadership is a rare quality, and my assessment is that no large democratic nation had such leadership in early 2020.<sup>43</sup> Once the window had closed, the pandemic was going to have the kinds of serious human and economic consequences it did. We can call this a result of policy failure, and in some sense it was. But the policy failures during the initial period were pretty much foreordained—which is why they occurred almost everywhere.

What about policy choices after uncontrolled community spread? Here there were basically two: do nothing or impose substantial restrictions on previously ordinary economic, social, and cultural activities, the shorthand for which was “lockdowns.” Some nations, most notably Sweden, chose the “do nothing strategy” briefly, but it

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38. Cf. BALDWIN, *supra* note 12, at 107–08 (mentioning privacy concerns and “limited uptake” of phone apps in Australia).

39. *See id.* at 163 (referring to “a consensus” that masks of any sort “were . . . useful.”).

40. *Id.* at 162 (“In Asia, mask-wearing was as customary as hats had been in the West.”).

41. *See id.* at 85 (describing experiences with these diseases in Asian nations).

42. Cf. *id.* at 87 (asserting that in other nations “[t]he mistaken belief that pandemics were a problem of the past lulled authorities into a false sense of security”).

43. In my view, Jacinda Adern of New Zealand came the closest among well-known world leaders to providing such leadership, and she had the advantage of being prime minister of an island nation. Figures who come to mind in connection with other crises—Abraham Lincoln and the Southern rebellion, Winston Churchill and Franklin Delano Roosevelt and the rise of fascism—all had a decade or more to prepare for the crisis. Even they might have had difficulty providing transformative leadership in the roughly two months when such leadership might have helped dramatically change the COVID pandemic's course.

proved unsustainable for a combination of reasons, ultimately political.<sup>44</sup> The strategy led to large numbers of deaths and serious illness requiring hospitalization.<sup>45</sup> The latter meant that resources became unavailable to deal with other medical problems affecting non-COVID-infected people. And the former, of course, was a political liability.

The lockdown strategy had its own difficulties. It had enormous economic costs and created a variety of social and psychological stresses throughout the population.<sup>46</sup> Like the “do nothing strategy,” then, the lockdown strategy was difficult to sustain, though in practice it tended to last longer than the “do nothing” one. As the problems associated with lockdowns grew, the policy question basically became: How do we relax the lockdowns? What are the criteria for easing restrictions, and what behavioral recommendations or requirements should be adopted as lockdowns eased? These questions in turn required a combination of economic and public health analysis, the latter being characterized as questions of science in a way that the former were not (except among economists).

With this background, I now turn to an analysis of the performance of two major arms of the U.S. administrative state, the Food and Drug Administration and the Centers for Disease Control and Prevention, in light of STS critiques of science-based policy.

## II. WHAT SCIENCE AND TECHNOLOGY STUDIES CAN TELL US ABOUT THE U.S. ADMINISTRATIVE STATE’S PERFORMANCE DURING COVID

As I’ve already argued, evolving knowledge about the coronavirus’s characteristics was a major driver of COVID’s effect in the United States. Decisions within the administrative state did have effects on the margin. Some of those decisions were directly affected by departures from the Progressive ideal of a politically neutral administrative state, with interventions by the Trump administration into the development of science-based policy recommendations. Some, though, flowed from the ideal of scientific neutrality itself. I focus here on those because they help us understand how a critique of the Progressive ideal of a science-based administrative state can help us think about what a modern administrative state, chastened by critiques of both branches of the Progressive ideal, might look like. After sketching components of STS, I examine how the Centers for Disease Control and Prevention, the Food and Drug Administration, and Presidents Trump and Biden performed during the COVID pandemic. The focus of that examination is failure, not success.<sup>47</sup> Where did these agencies of the administrative

44. See BALDWIN, *supra* note 12, at 79–81 (describing the “Decline of the Swedish Model”).

45. *Id.* at 79 (asserting that Sweden had not avoided “the decimation of its elderly in the care homes” and “[f]or a week in mid-May, it suffered the highest per-capita mortality rate in the world”).

46. See *id.* at 55–56 (describing the “collateral damage” of lockdowns, including psychological effects and offering a preliminary assessment of the economic effects of lockdowns).

47. As I’ve noted, governments around the world got one very large thing right. From the beginning, they pushed for and invested in the rapid development of effective vaccines and

state go wrong, and why? In particular, did they go wrong because political agendas overwhelmed the politically neutral administrative state, or—as I argue—did they go wrong because, given COVID’s characteristics as discussed in Part I, it wasn’t possible to follow a science that was independent of politics, culture, and economics?

*A. A Sketch of Relevant Aspects of Science and Technology Studies*

The tagline of STS is now almost anodyne: science is a social construct.<sup>48</sup> Some elaborations of that tagline are equally anodyne: at any moment what counts as a science is a social construct (phrenology—yes at one time, no now; psychoanalysis—yes at one time, maybe no now; homeopathy—maybe yes in the past, maybe no now).<sup>49</sup> For present purposes, though, one claim in STS is non-obvious, troubling, and relevant to assessing the role of science in the administrative state. That claim is that what counts as a scientific fact is also a social construct.<sup>50</sup>

The claim that what counts as a scientific fact can be given a relatively uncontroversial form. Suppose someone asserts that she has used a novel technique to create a material that works as a superconductor at room temperatures. Others attempt to replicate her experiment. Some replications produce the results she claimed to have had, others do not. With enough replications in hand, we apply statistical tests of significance and conclude that, using conventional standards for assessing likelihood, the chances are pretty good that she did (or didn’t) produce what she said she did.<sup>51</sup> One way of describing this process is that a consensus emerges over time about the scientific facts. How that consensus is produced is a social process involving, among other things, the prestige of those doing the replications. A high-prestige investigator failing to replicate will count more in determining whether there’s a consensus than a low-prestige one replicating it. For example, successful replications by employees of corporations with an interest in producing room-temperature superconductors will count less than successful or unsuccessful ones by scientists supported by competitive government grants.

How should we think about her claim *before* the consensus emerges? And, in our specific context, can we say that policy predicated on that or similarly not yet

(mostly) did a good job of making such vaccines available to those who wanted them.

48. Barry Barnes, David Bloor, and John Henry offer what they call a “normal version” of the claim: “knowledge . . . was the possession of the members of a culture or subculture, transmitted from generation to generation as a part of their tradition, and dependent for its credibility on their collective authority.” BARRY BARNES, DAVID BLOOR & JOHN HENRY, *SCIENTIFIC KNOWLEDGE: A SOCIOLOGICAL ANALYSIS* 111 (1996). They then extend and qualify this version, *see id.* at 111–39.

49. For descriptions of how the demarcation between science and non-science has been drawn historically, *see id.* at 140–54; *see also* MICHAEL D. GORDIN, *ON THE FRINGE: WHERE SCIENCE MEETS PSEUDOSCIENCE* (2021).

50. For an introduction to the arguments for and against treating scientific facts as a social construct, *see generally* BARNES, BLOOR & HENRY, *supra* note 48.

51. Even here, of course, some degree of social construction is apparent on the surface. What counts as a statistically significant result is a matter of convention. And, especially in policy-relevant contexts, people can disagree about whether it makes sense to move forward with a project if one of the factual predicates is thought to be accurate at a .01, .05, or .10 level of statistical significance.

“confirmed” claims “follows the science”? Consider in this connection a study of a group of “exercising healthy subjects to approximate the impact of ozone on specially sensitive populations, such as asthmatics . . . [where the scientists] were not satisfied that subjective symptoms of discomfort (chest pain, congestion, cough) amounted to evidence of adverse health effects.”<sup>52</sup> Ultimately regulators decided to “label as an ‘adverse health effect’ changes that were much less severe than clinical disease symptoms . . . [a conclusion that was not supported] by a medical or scientific consensus.”<sup>53</sup>

The determination that a specific chemical used to kill spider mites that affect stone fruits depended upon an examination of slides of cells affected by the chemical. Scientists employed by the regulator read the slides as showing damage that could eventually become cancerous. A company that made the chemical hired three well-credentialed scientists to look at the same slides. “Applying allegedly more up-to-date diagnostic criteria than those employed by [the regulator’s scientists], the panel asserted that the effects observed . . . were ‘non-neoplastic nodules’ which did not progress into either benign or malignant tumors.”<sup>54</sup>

In another instance, the Environmental Protection Agency based its assessment of cancer risks from an environmental contaminant by combining benign tumors with malignant ones “unless the benign tumors are not considered to have the potential to progress to the associated malignancies of the same histogenic origin,” and the Office of Management and Budget proposed to combine such tumors “to the extent that they are expected to develop into associated malignancies of the same histogenic origin.”<sup>55</sup>

Finally, and of particular relevance to this Article, questions about the statistical power of epidemiological studies regularly arise. Such questions occur when we think about whether the population studied was large enough to detect what we’re worried about: increases in mortality or the incidence of side effects. For example, studies of drugs to treat cardiac arrhythmias (irregularities in heart beats) chose subjects

primarily on the basis of the nature of the arrhythmia rather than the characteristics of the patient in whom the arrhythmia occurred. Because of their toxic side-effects, however, most drugs of this type were believed likely to work only for particular subpopulations of patients, . . . [but] the testing . . . was obviously not sensitive enough to produce the data [thought necessary to provide good guidance on using the drugs].<sup>56</sup>

Of course, we can explain some of these disagreements: scientists employed by regulators chose criteria for identifying what counted as a fact that supported regulation, while those hired by manufacturers chose criteria that didn’t. Which

52. SHEILA JASANOFF, *THE FIFTH BRANCH: SCIENCE ADVISERS AS POLICYMAKERS* 108 (1990).

53. *Id.* at 109.

54. *Id.* at 139.

55. *Id.* at 192–93.

56. *Id.* at 162.

scientists were right?<sup>57</sup> Do we look at formal credentials? Maybe the scientists employed by regulators are generally a bit less competent than those hired by manufacturers. Do we discount for biases? There might be biases both ways.

More important here, these controversies might go away over time.<sup>58</sup> If more and more slides of mouse tissue are taken and examined, a consensus might emerge that they do or don't show growths that could become cancerous. As we study more and more benign tumors, we might be able to figure out which ones actually do have the potential to become malignant. At the outset, though, probably the best we can say is that there's really no established scientific fact for us to "follow." We might be able to make some guesses educated by a rough sense of what might turn out to be the case. Whether only scientific experts are well-positioned to do so can, I think, reasonably be questioned.

This perspective offers at least some cautions against accepting a key part of the Progressive case for the administrative state. As noted earlier, for Progressives, the administrative state could respond nimbly to rapidly changing circumstances because of its political neutrality and reliance on science rather than politics. The intrusion of ordinary politics into the administrative state reduced some of its nimbleness. But even where elements of the administrative state could respond rapidly to a novel development squarely within the domain of science—the topic of this Article—the STS critique of science suggests that the administrative state *can't* be driven by science.<sup>59</sup> At the outset of inquiries, which is to say precisely when the administrative state acts nimbly, claims about what the science shows are of course made. However, the STS critique proposes that such claims are supported by social, political, economic, and cultural forces rather than by the force of a science that will emerge, if at all, only after some time.<sup>60</sup>

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57. It's sometimes suggested that using the precautionary principle—regulating when there's some chance that regulation will prevent some serious harms from occurring—can elide these difficulties. Perhaps it can to some extent, but, as is widely known, the precautionary principle comes with attendant (unnecessary) costs when regulation in fact won't have that effect.

58. As historian of science Peter Galison puts it, an experiment ends "[when it] stand[s] up in court" (and not, implicitly, when the experimenter initially publishes her results [even after peer review]). PETER GALISON, *HOW EXPERIMENTS END* 276–77 (1987).

59. Sociologist Gil Eyal uses this metaphor: basic science proceeds down the right-hand (slow) lane of a three-lane highway; policy making proceeds down the left-hand (fast) lane; administrative agencies using "regulatory science" are in the middle lane and have to figure out how to get some of the right lane stuff together with some of the left lane stuff. He suggests that quite often there's a crash, or at least blaring horns, in the middle lane. GIL EYAL, *THE CRISIS OF EXPERTISE* 7 (2019). Another version of the point is this: experts are people you go to when you have to solve an urgent problem, but if they actually knew what the answer was, the problem would already have been solved. So, when you go to them, they offer you informed guesses about what further inquiries, which neither they nor you have time to conduct, will show. *Cf. id.* at 25 (epigraph quoting Niklas Luhmann: "An expert is a specialist to whom one can put questions that he is unable to answer.").

60. For a general discussion of how scientists interpret their observation as a result of their commitments to contingent local traditions (which, on my reading of the argument, would include bureaucratic cultures), see BARNES, BLOOR & HENRY, *supra* note 48, at 18–45.

*B. Developing and Applying Science Within the Administrative State*

## 1. The Centers for Disease Control and Prevention

## a. Structure

The Centers for Disease Control and Prevention's (CDC) structure has several features that affected its performance during the first year of the COVID pandemic. (i) The "s" at the end of the organization's name mattered. The CDC consists of a number of centers, each with a specialized mission.<sup>61</sup> Funding flows to the centers and then to projects within each center. When a new problem arises, it has to be slotted into one of the centers. In one sense that was easy for COVID; choosing between the Center for Emerging and Zoonotic Infectious Diseases and the Center for Surveillance, Epidemiology, and Laboratory Services probably took about five seconds. Once there, though, funding has to follow. Getting new funding takes some time, although "reprogramming" existing funds from one project to another is in principle available. Reprogramming can face bureaucratic resistance as the new investigation cannibalizes ongoing work.<sup>62</sup>

(ii) The CDC depends crucially on information it receives from state and local public health officials. The quality and even the form of that information varies wildly. Some state and local public health officials are highly trained and well-resourced; others are orphans within state and local bureaucracies.<sup>63</sup> There's no uniform template for providing information. Some information is sent to the CDC in the form of simple notes and hand-filled-out spreadsheets; some is sent via fax and regular mail.<sup>64</sup> Whether COVID could have been contained depended in significant part on where it landed. There was some possibility that community spread could have been stopped or slowed in well-provisioned Washington, a smaller possibility than if COVID had landed in rural California. In addition, the CDC's computer systems for dealing with information were outdated and couldn't process the information the agency received in a coordinated manner.<sup>65</sup>

(iii) The CDC is primarily an information-gathering and information-processing organization, not a regulatory one.<sup>66</sup> The science it uses is epidemiology, inferring

61. Jeneen Interlandi, *Covid Proved the C.D.C. is Broken. Can it Be Fixed?*, N.Y. TIMES MAG. (June 16, 2021), <https://www.nytimes.com/2021/06/16/magazine/cdc-covid-response.html> [<https://perma.cc/VK6K-5QTA>] (providing an overview of the CDC's structure and operations).

62. *See id.* ("Each of [these] line items is protected by a fierce constituency that fought to get it there in the first place.")

63. Despite what seems to me to have been the author's intention, this is a major takeaway from MICHAEL LEWIS, *THE PREMONITION: A PANDEMIC STORY* (2021).

64. Interlandi, *supra* note 61 (referring to "data" in the form of "handwritten notes, manual spreadsheets, fax machines and snail mail").

65. *Id.* (referring to CDC's "more than 100 separate disease-specific computer systems . . . many [of which] . . . can't interface with one another").

66. The CDC issued a regulatory order barring evictions during the pandemic, relying upon a statute that, as implemented, authority it to



from data about infectious diseases, how they are likely to spread, and what measures are likely to halt or slow the spread. Rather than regulations, the CDC issues “guidance” recommendations to other officials—national but also state and local—about what measures, in its judgment, the epidemiological evidence suggests would be effective.<sup>67</sup> Here, the science it uses is knowledge about how people can effectively communicate often-complex information and advice to other people. It may be worth noting that neither epidemiology nor “public communication” are considered hard sciences, though their effective practice does require the kind of expertise that Progressives associate with the administrative state.

#### b. Testing

The CDC produced tests that were supposed to detect communicable diseases. It failed in doing so. What went wrong? One failure attracted a lot of attention. The tests the CDC produced itself were defective as a result of contamination in the production facility.<sup>68</sup> Scott Gottlieb, former head of the Food and Drug Administration (FDA), details the events.<sup>69</sup> The CDC’s test kits had three components.<sup>70</sup> The first two were specific to COVID; positive results would signal infection. The third component would identify non-COVID SARS-like infections and COVID mutations if they occurred.<sup>71</sup> According to one of Gottlieb’s sources, the third component was important in reducing the number of false positive results.<sup>72</sup> Before shipping the kits, the CDC did a quality check, which indicated that the third

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make and enforce such regulations as . . . are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. For purposes of carrying out and enforcing such regulations, the [CDC] may provide for such inspection, fumigation, disinfection, sanitation, pest extermination, destruction of animals or articles found to be so infected or contaminated as to be sources of dangerous infection to human beings, and other measures, as in his judgment may be necessary.

Ala. Ass’n Realtors v. Dep’t Health & Hum. Serv., 141 S. Ct. 2485, 2487–90 (2021) (holding that this statute, enacted in 1944, almost certainly did not authorize the eviction moratorium).

67. I mention the following to avoid the unlikely possibility of confusion: CDC guidance is directed at (roughly speaking) the public unlike the “guidance documents” directed at agency employees that have been the subject of attention in recent scholarship on administrative law. For an example of the latter, see Christopher J. Walker, *Constraining Bureaucracy Beyond Judicial Review*, 150 (3) DÆDALUS 155 (2021).

68. As far as I know, the source of the contamination has never been precisely identified beyond the generic “sloppy practices at the facility.” GOTTIEB, *supra* note 19, at 111 (stating that the contamination of the tests was “perhaps related to contamination at the CDC site that was making the kits”).

69. *Id.* at 107–16. I note that Gottlieb writes with a rather clear anti-CDC, pro-FDA bias.

70. *Id.* at 107.

71. *Id.*

72. *Id.* at 108.

component might be producing false positive results.<sup>73</sup> The CDC distributed the kits to state and local public health agencies on February 3, 2020.<sup>74</sup> Many of those agencies themselves conducted a standard quality check, using sterile water—obviously not carrying any virus—and systematically got results showing infection.<sup>75</sup> The source of the difficulty appeared to be in the third component. Back-and-forth conversations between the CDC and the FDA led the CDC to double down on producing the three-component test even though the third component wasn't essential.<sup>76</sup> By February 16, “contingency plans” about what to do were floating around: raise the criterion for saying that the test showed the virus's presence (with the effect of producing more false negatives), drop the third component, or advise public health authorities to discard the kits (leaving them with no testing capacity at all).<sup>77</sup> On February 25, 2020, the CDC told the FDA that it was going to tell public health officials that they couldn't use the test with only the first two components.<sup>78</sup> The FDA objected and the CDC changed its policy. The next day, it told public health facilities to use the kits but omit the third component. Just short of one month passed before the CDC's tests could be widely used. By that time, the window for effective use of testing to prevent community spread had basically closed.<sup>79</sup>

The CDC's failure in producing the test kits was the product of neither political interference nor an absence of expertise. As far as anyone knows, it was ordinary sloppiness that could have occurred anywhere. In contrast, its fumbling over what to do once the problem was identified was a failure of expertise. Rather than adapting quickly to unexpected developments, the CDC dithered.

#### c. Guidance on Non-pharmaceutical Interventions (NPIs)—Masks and Social Distancing

Experts say that effective guidance must be clear, consistent, and readily understandable by its non-expert audiences. Where the information is technical, devising an effective message is difficult. Where the underlying phenomenon changes rapidly, maintaining a consistent message becomes extremely challenging, though not impossible. The CDC's guidance on masks and social distancing suffered because its experts in communication operated within a bureaucratic culture that wasn't well-suited for the COVID pandemic.<sup>80</sup>

73. *Id.* at 109.

74. *Id.*

75. *Id.* at 109–10.

76. Other nations' health authorities allowed test kits without the third component. *See id.* at 110.

77. *Id.* at 112.

78. *Id.* at 115.

79. In the meantime, additional difficulties had emerged when contamination apparently affected the first two components in some kits, notably those distributed to New York, where community spread was quite likely. *Id.* at 116.

80. *See Interlandi, supra* note 61 (“Agency officials were exceedingly slow to update guidelines, and then conservative, awkward and confusing when they did . . . . [The] agency's director . . . undermined [advice on resuming international travel] almost immediately by saying that personally, she advised against it.”). I note that the international-travel example

As noted above, in the earliest days, prior flus were the model for COVID.<sup>81</sup> Such flus were transmitted by droplets and on surfaces. Masks and social distancing are reasonably effective against droplet transmission because the droplets fall to the ground relatively quickly. Masks block the droplets from getting more than a short distance from the infected person. High-quality masks are of course better than lower-quality ones, but pretty much any mask will have some effect against droplet transmission.<sup>82</sup>

Further, the effectiveness of a mask depends in part upon the transmissibility of the virus. Masks reduce the possibility that an infected but asymptomatic person (or an infected person who doesn't yet realize that her symptoms flow from COVID rather than an ordinary flu or cold) will transmit the virus. No matter how good they are, masks aren't perfect, and some virus will escape. A less transmissible virus that escapes a mask poses a smaller risk than a highly transmissible one, of course. So, low-quality masks might be acceptable where the virus isn't highly transmissible but almost useless where it is. Early estimates of COVID's transmissibility put it in the range, as I would put it, of "troublingly transmissible but not extremely so." Low-quality masks probably would have done a fair bit to cut down on transmission, though again, not as much as high-quality ones would.

The CDC's initial guidance on NPIs was shaped by this early understanding, with one important qualification: it recommended social distancing and handwashing but didn't strongly urge people to wear masks.<sup>83</sup> The reason appears to be a concern that a mask recommendation would lead people to search out high-quality masks, which were in short supply, and thereby limit the availability of such masks for use in hospitals and other high-risk settings. Either the CDC didn't consider the possibility of recommending the use of low-quality masks or it concluded that the public wouldn't get the message clearly and would use up the high-quality masks anyway. In retrospect, this appears to have been a serious error. And, in some sense, it was an error *within* "science" (here, either a mistake about low-quality masks or an assessment of the behavioral science dealing with public responses to messages), serving as a caution against following the science generated by the CDC.<sup>84</sup>

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comes from a later period than the one on which I focus.

81. See *supra* notes 22–26 and accompanying text.

82. For a discussion of masks, see *supra* notes 24–25 and accompanying text.

83. A report from the CDC published on February 5, 2020, describing CDC's initial actions included this phrase: "everyday preventive actions such as washing your hands, covering your cough, and staying home when you are ill." Anita Patel & Daniel B. Jernigan, *Initial Public Health Response and Interim Clinical Guidance for the 2019 Novel Coronavirus Outbreak — United States, December 31, 2019–February 4, 2020*, CDC (Feb. 5, 2022), <https://www.cdc.gov/mmwr/volumes/69/wr/mm6905e1.htm> [https://perma.cc/N9WA-EBNW].

84. Politics in the ordinary sense interacted with these bureaucratic difficulties. The Trump administration, as any White House would have, created a working group in Washington. Messages coming from that group sometimes conflicted with—and sometimes were substantively better than—the messages coming from the CDC in Atlanta.

## d. Guidance on Emerging from Lockdowns

As described earlier, for all policy-relevant purposes only two strategies existed once uncontrolled community spread occurred. You could do nothing, allow the infection to spread “at will,” and hope that so many people would become infected that the virus wouldn’t be able to find hosts who hadn’t acquired immunity as a result of prior infections (“herd immunity”<sup>85</sup>). Or you could lock things down until effective vaccines were available, subject to modest exceptions where NPIs might substantially limit the virus’s spread.

Sweden tried the first strategy, which proved to be unsustainable in human and political terms.<sup>86</sup> Too many people died or suffered severe disease that overburdened the healthcare system for policy makers (and politicians) to sustain the policy.<sup>87</sup> Elsewhere, some policy makers and politicians toyed with the idea of adopting the Swedish strategy, but almost all converged rather quickly on the alternative lockdown strategy.<sup>88</sup>

The problem with lockdowns is that people get tired of them. They want to get back to the pre-lockdown normal, or at least get closer to it. And, of course, the lockdowns can’t ever be complete. “Essential workers” have to do their jobs of picking up trash, taking care of the ill, and delivering food. The CDC issued guidance to essential workers and, eventually, people emerging from lockdown on the NPIs they should use.<sup>89</sup> But, conditions outside lockdown varied a great deal: essential workers in hospitals faced different conditions from those collecting trash, which were in turn different from those facing workers in meat-processing plants. And, lockdowns were more effective in some communities than in others,<sup>90</sup> which meant that communities could emerge—gradually—from lockdown at different rates.

The effect of these conditions was simple; communication about what to do outside of lockdown was inevitably complicated. Variables included the rates of infection, hospitalization, and death; whether indoor venues were well-ventilated; how long people typically stayed inside; and more.<sup>91</sup> You could come up with color-coded stages, but they were going to be rough, and like all classifications, both under- and over-inclusive in ways that might jar with common sense. Perhaps more importantly, the conditions they identify could change rapidly: you might be in code

85. *Herd Immunity and COVID-19: What You Need to Know*, MAYO CLINIC (Sept. 27, 2022), <https://www.mayoclinic.org/diseases-conditions/coronavirus/in-depth/herd-immunity-and-coronavirus/art-20486808> [<https://perma.cc/26DM-Z3YK>].

86. For a discussion of the Swedish strategy and its failure, see BALDWIN, *supra* note 12, at 60–67.

87. *See id.* at 67, 80.

88. *See id.* at 53.

89. The CDC has posted a timeline of its actions, which includes the identification of the dates on which versions of its guidance were issued. *See CDC Museum COVID-19 Timeline*, CDC (Aug. 16, 2022), <https://www.cdc.gov/museum/timeline/covid19.html> [<https://perma.cc/A949-C5MW>].

90. *See* BALDWIN, *supra* note 12, at 109–10 (providing examples, some from the United States, of variations in the scope of lockdowns).

91. *See* Tandon v. Newsom, 141 S. Ct. 1294, 1298 (2021) (Kagan, J., dissenting) (describing some of the variables).

yellow today but code red a week later. Again, extremely well-designed messages might deal with these challenges but, again, the expertise lodged in the CDC wasn't up to the challenge.<sup>92</sup> One hopes that CDC officials have learned from the communicational difficulties in the pandemic that they should upgrade their communications capacity.<sup>93</sup> One might also suspect that such efforts will regularly be subordinated to upgrading the agency's capacities in other domains such as epidemiology, particularly in light of the funding problems the agency has regularly faced.

In all these domains, then, the CDC used the science it had on hand to develop policy. As the STS critique of science suggests, that science was itself conditioned by the network of relations between the CDC and state and local public health authorities, by the way in which the CDC was financed, and by ordinary bureaucratic policy. Whether policy makers *could* "follow the science" is unclear; whether doing so would improve on "use your common sense informed by the rough judgments the experts have sent you" is even less clear.

## 2. The Food and Drug Administration

### a. Structure

The FDA is often described as the second oldest administrative agency in the United States.<sup>94</sup> Created in 1906, the FDA is an executive agency now located within the Department of Health and Human Services with a senate-confirmed head.<sup>95</sup> Its mission includes ensuring that medications and medical devices, including tests used to guide medical choices, are safe and effective when used as intended.<sup>96</sup> As political scientist Daniel Carpenter has shown, the FDA has carefully cultivated a reputation for reliability and accuracy.<sup>97</sup> It has heralded its own triumphs such as staff scientist

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92. The communications difficulties were compounded by ordinary politics rather than the politics of knowledge production that STS attends to. Not surprisingly, the Trump administration set up a task force to deal with the pandemic. One prominent member, Dr. Deborah Birks, was a public health specialist seeking to maintain some influence on administration policy. Dr. Birks sometimes made statements inconsistent with or questioning the guidance coming from the CDC. *See, e.g.*, SLAVITT, *supra* note 10.

93. I emphasize that my concern here is not with the content of CDC's messages, which was transparently value-laden (how risky would it be to relax one or another restriction under what circumstances?), but with the way in which the messages were affected by the considerations STS directs our attention to—and, to that extent, not by expertise in messaging.

94. *Cf. FDA History*, U.S. FOOD & DRUG ADMIN. (June 29, 2018), <https://www.fda.gov/about-fda/fda-history> [<https://perma.cc/W7TK-K3BB>] (describing the FDA as the "oldest comprehensive consumer protection agency").

95. For general information about the FDA's structure, see *Food and Drug Administration*, WIKIPEDIA, [https://en.wikipedia.org/wiki/Food\\_and\\_Drug\\_Administration#Organizational\\_structure](https://en.wikipedia.org/wiki/Food_and_Drug_Administration#Organizational_structure) [<https://perma.cc/F3A4-5F8Q>].

96. *See* Michelle Meadows, *Promoting Safe & Effective Drugs for 100 Years*, FDA (Apr. 23, 2019), <https://www.fda.gov/about-fda/histories-product-regulation/promoting-safe-effective-drugs-100-years> [<https://perma.cc/7C4T-XLPL>].

97. DANIEL CARPENTER, *REPUTATION AND POWER: ORGANIZATIONAL IMAGE AND PHARMACEUTICAL REGULATION AT THE FDA* (2010).

Frances Kelsey's insistence that thalidomide not be approved for distribution in the United States,<sup>98</sup> and it has overcome disasters such as its approval of Vioxx as a treatment for pain, where the drug had effects on cardiac function that were fatal to a large number of users.<sup>99</sup> These and similar events led the FDA to delegate substantial authority to its scientists, with higher-level officials constrained by agency culture from challenging the conclusions the staff scientists drew.<sup>100</sup>

The events also produced a culture of caution within the FDA—a culture that is an important element in sustaining its reputation and influence. Caution means that the FDA focuses on avoiding “Type I” errors—approval of medications that aren't safe enough given their actual effectiveness, where one component of effectiveness is an assessment of how important it is to treat the condition for which the drug works.<sup>101</sup> Large numbers of serious side effects might be acceptable if the drug addresses a really serious problem and unacceptable if, as in the case of Vioxx, it simply helps to alleviate pain better than some available alternative. The cost of avoiding Type I errors is making “Type II” errors—failure to approve medications that would be safe enough in treating the conditions for which they are designed.

There are structural reasons for preferring to avoid Type I errors even when one knows that more Type II errors will occur: Type I errors are visible (people die from side effects, as with Vioxx), whereas Type II errors are typically invisible because (overstating the point) we can't identify any individual who would have benefited had the FDA approved the drug.<sup>102</sup> Notably, those charged with approving medications for distribution in other nations, especially Europe, are less risk-averse than the FDA.<sup>103</sup> The result is that drugs are available elsewhere that aren't available in the United States, and the FDA's critics can point to their use in Europe without disasters ensuing as a criticism of the FDA's functioning.

One implication of the FDA's culture of caution is that it typically requires more evidence of safety and effectiveness than other drug regulators do, evidence that comes from running larger, more costly, and longer trials for proposed medications.<sup>104</sup> In the COVID context, it's not that the FDA didn't approve effective medications, both treatments and vaccines, but that it might have done so more

98. See GERALD M. POMPER, *ORDINARY HEROES AND AMERICAN DEMOCRACY* 134–58 (2004) (describing Kelsey's work).

99. See THOMAS J. NESI, *POISON PILLS: THE UNTOLD STORY OF THE VIOXX DRUG SCANDAL* (2008) (recounting the events leading to the manufacturer's 2005 withdrawal of the drug from the market); EYAL, *supra* note 59, at 130–31 (describing a “recursive dynamic, whereby attack, criticism, and accusation end up strengthening the position of the accused”).

100. CARPENTER, *supra* note 97, at 477.

101. *Id.* at 480–81 (describing the FDA's caution in connection with approval of medications).

102. Cf. Jerusalem Demsas, *Is the FDA Too Cautious?*, VOX (Feb. 10, 2022, 7:10 AM), <https://www.vox.com/22893078/fda-covid-19-too-cautious-tests-vaccines> [<https://perma.cc/A7HK-D2LF>] (quoting a former FDA employee: “‘If anything goes wrong,’ he argued, ‘think how bad it will look that we approved the drug so quickly.’”).

103. See Boris Hauray, *From Regulatory Knowledge to Regulatory Decisions: The European Evaluation of Medicines*, 55 MINERVA 187 (2017) (describing the European approach using an STS framework).

104. For an overview of differences between the U.S. and European approaches, see CARPENTER, *supra* note 97, at 709–12.

quickly, on the basis of less evidence than it actually required, and thereby saved some additional lives.<sup>105</sup>

#### b. Developing Vaccines

The FDA's process for approving medications as safe and effective is presumably a model of science's use in the Progressive vision of the administrative state. The protocols for doing randomized controlled trials (RCTs) are well-developed and essentially uniformly accepted, as are the appropriate statistical tests for determining when and to what degree an RCT establishes safety and efficacy. On the modest version of STS, these are as close to scientific processes as we will ever come.<sup>106</sup> And, manufacturers know better than to submit fraudulent or manipulated data to the FDA because the costs to them of doing so would be enormous, so issues of research fraud that are a theme in scholarship about publications in scientific journals don't arise.

And yet—actually carrying out RCTs and drawing conclusions from them about safety and efficacy are shot through with social judgments, just as the STS critique would have it. The effect, as I argue, is that the FDA-based science that we are asked to follow answers some, but not all, of the questions we might put before developing policy. At least with respect to those overlooked questions, the science at best gives us a basis for making some educated guesses about what good policy would be.

RCTs take various forms, but they all have the same underlying structure. I use the “test-negative” form used in the RCTs on COVID vaccines. Because the goal was to find a vaccine for a new disease for which none were already available, the RCT consisted of coming up with two “populations,” one of which would get the vaccine, the other a placebo (an injection of water with salt dissolved in it). Based on the way in which the putative vaccines were expected to work (their “mechanisms of action”), the vaccines' designers basically guessed about how much should be in each shot, and in the COVID tests whether to give that amount in a single shot or in two.<sup>107</sup>

The RCTs then set a target number of COVID infections for the group receiving the placebo: when one hundred (say) people in that group got COVID, the testers would look at the vaccinated group to find out how many COVID infections *they*

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105. The FDA moved with undeniable rapidity in getting vaccines tested, but given the pandemic's scope, even intervals of a week or two had significant consequences for severe illness and death.

106. Cf. EYAL, *supra* note 59, at 116–27 (describing the FDA's reliance on the “mechanical objectivity” of RCTs as a “legitimation strategy”).

107. The guess about the proper dosage may have been mistaken. After the two-shot dosage was administered, the experts concluded that a third “booster” shot would enhance the vaccine's ability to prevent severe consequences of infection. And, it may have been that the third shot was better understood as delivering the optimal total dosage rather than, for example, elevating (“boosting”) a decline in immunity over time. This error, if it was one, was an ordinary mistake in designing the RCT, which can happen because the vaccine's designers really had no basis other than an informed sense about what dosage would “work.” Such mistakes don't play a significant role in the STS critique of science.

had.<sup>108</sup> If the vaccine were really effective, only a few of the people in the vaccinated group would have become infected; the less effective, the more people in that group would be infected. There are standard statistical measures to pin a number on effectiveness given the two numbers. Those measures get more accurate the larger the target number: you can be more confident about your conclusion about effectiveness if your target was two hundred than if it had been one hundred. And, if the target number is too small and the vaccine is reasonably effective, you might not have enough vaccinated-but-infected people to support statistically valid conclusions. But, of course, you'll hit the target number sooner the smaller it is. The test designer, and ultimately the FDA, have to make some judgment about how urgent it is to come up with an answer when it sets (and approves) the target number.

The possibility that you're interested in whether the vaccine is more or less effective for subpopulations introduces complications. Standard examples are gender and race, though the COVID vaccines' mechanisms of action almost certainly wouldn't vary among those groups. They might vary, though, on the basis of the recipients' age. And if, as appears to be true for COVID, the disease's severity varies depending upon age, you're going to want the RCT to have enough older people. Doing so will increase your confidence that when you compare infection rates, you can draw statistically defensible conclusions about the effectiveness for the subpopulations.

Yet another complication: you can "reverse engineer" the target number depending on how effective you think the vaccine will be. That is, if you think (before you start the RCT) that the vaccine's likely to be quite effective, you can choose a smaller target number than you would if you thought that the vaccine would be moderately effective. In practice, the RCT designers say, in effect, the vaccine will be good enough if it reduces the incidence of the disease by 40%, 50%, or some specified amount. Given that number, they can choose a target number of COVID infections large enough to support a statistically valid conclusion about the degree of effectiveness, but no larger than that so that they can end the trial as soon as they get a defensible result.

The takeaway here is that a well-designed RCT has quite a few guesses built into it. Only the guesses about the vaccines' mechanisms of action operate within the

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108. I simplify the description of the test-negative approach for clarity. For a more complete presentation, see Natalie E. Dean, Joseph W. Hogan & Mireille E. Schnitzer, *Covid-19 Vaccine Effectiveness and the Test-Negative Design*, *NEW ENG. J. MED.* (Sept. 8, 2021), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8451180/> [<https://perma.cc/C7NZ-CVS7>]. An analytically equivalent test-negative form would set a target number of *vaccinated* people becoming infected, and when that target was hit, find out how many people receiving the placebo had become infected. If the vaccine is quite effective, though, reaching the target might take quite a bit of time. When the test-negative approach is used in connection with medications to treat existing illness, sometimes the test is ended before the target is reached. Ordinarily, the test protocol discourages that to avoid the possibility of terminating the process prematurely if you get encouraging results early. But if the results are extremely dramatic, with nearly everyone protected or nearly no one, the testing process will be stopped and the medication will be accepted or rejected immediately.



domain of “science”; the others—about seriousness, subpopulations of interest, and the like—come from politics, social pressures, and culture.<sup>109</sup>

The foregoing structure of analysis is replicated when we turn from efficacy to safety, with the size of the population in the test taking the leading role.<sup>110</sup> We want to set the number of participants so that we’re going to be able to detect adverse side effects. Here we have to distinguish among adverse side effects along dimensions of severity and frequency. We would worry a lot about serious side effects that occurred in lots of vaccine recipients, though the worry might not lead us to block the vaccine’s use if preventing the person from getting COVID was really important. We wouldn’t worry much about minor side effects that were quite common.

A well-designed RCT will almost inevitably have enough participants to reveal common adverse side effects whether minor or serious (and we certainly don’t care about rare minor side effects). The kicker comes with rare and serious side effects. The vaccine’s mechanism of action might suggest the possibility of some such rare side effects, and others might emerge as the RCT proceeds. In the former case, the RCT has to have a large number of participants for the rare side effect to appear often enough to support valid conclusions about its prevalence; in the latter case, the RCT’s designers might have to extend the study (for example, by upping the target number of COVID infections in the vaccinated population).<sup>111</sup>

Here, the “nonscientific” judgments deal with how serious the rare side effect has to be before we regard it as something that has to be disclosed to vaccine recipients, but that does not justify blocking the vaccine’s use altogether.<sup>112</sup>

### c. Polymerase Chain Reaction (PCR) and Rapid Tests

Testing was important in the pandemic’s first stages because widespread testing could identify people who were infected with COVID so that they could be isolated and their contacts could be traced. The FDA had to decide what tests would be adequate, knowing that the number of tests on hand was clearly inadequate to do truly widespread testing. Tests are always imperfect. They fail to identify some infected people (false negatives) and they say that some people are infected who actually are not (false positives).<sup>113</sup> Both kinds of errors are worrisome. If the

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109. See EYAL, *supra* note 59, at 118–19 (noting that “[FDA] judgments about efficacy and safety inevitably involve balancing perceived benefits against estimated risks, and therefore contain an irreducible political calculation”).

110. For a useful presentation of the point that the size of the study population affects its ability to reveal rare and less rare but practically important effects, see Paul Romer, *Burden-of-Proof Games*, REALCLEAR MARKETS (Sept. 22, 2021), [https://www.realclearmarkets.com/2021/09/22/burden-of-proof\\_games\\_795385.html#!](https://www.realclearmarkets.com/2021/09/22/burden-of-proof_games_795385.html#!) [<https://perma.cc/UX32-8VAB>].

111. The situation becomes even worse if the rare side effect seems to occur only in specific subpopulations.

112. Although I don’t develop the analysis here, it’s clear that a parallel argument can be made with respect to the studies underlying EPA determinations about levels of exposure to hazardous substances (to various populations) that are consistent with statutory requirements.

113. A test’s *sensitivity* measures the proportion of people actually infected that the test detects. A test’s *specificity* measures the proportion of uninfected people who the test says are indeed uninfected. You want both measures to be high.

infection is highly contagious, a false negative means that someone will be walking around in the community spreading the infection. A false positive means that people are going to be required to quarantine themselves and their contacts traced. And, worse, if the infection is rare—as it was early in 2020 in the United States—even a very good test administered to a large population will produce a fairly large number of false positives.<sup>114</sup> In light false positives would rapidly overwhelm the public health system. Both false negatives and false positives, that is, were likely to produce community spread.

There are two common types of COVID tests. PCR tests detect the presence of fragments of COVID in the body.<sup>115</sup> A positive result means that you are or have recently been infected. That in turn, means that you might be currently transmitting the infection (in short, infectious), though you might not be because the fragments persist in the body after the period of transmissibility has passed. The technology underlying PCR tests available in the early days of the COVID pandemic meant that results could be obtained only after (at a minimum, absent extraordinary efforts) two days.<sup>116</sup>

In contrast, rapid antigen tests return results within minutes.<sup>117</sup> These tests detect evidence that your body is producing an immune response to the virus.<sup>118</sup> With COVID, that means that you are rather likely not only to be infected, but to be infectious as well. Rapid antigen tests are less sensitive than PCR tests. This means that an FDA-approved PCR test detects infection at a very high rate: used on a group of infected people, the FDA standard in 2020 required that the test find the virus in at least 90% of the people tested who actually were infected; in contrast, when rapid antigen tests were used on a population they detect the presence of an immune response of (say) 75–80%.<sup>119</sup> But, importantly, these two populations actually differ

114. Bill Casselman, *Does He Have It?: Sensitivity, Specificity, and COVID-19 Testing*, AM. MATHEMATICAL SOC'Y, <https://www-ams-org.ezp-prod1.hul.harvard.edu/public-outreach/feature-column/fc-2020-09> [<https://perma.cc/X9UG-CPYR>], offers the following example. Suppose a test has 90% sensitivity (detects 90% of those infected) and 95% selectivity (accurately identifies 95% of those uninfected). The test is administered to one thousand people in connection with an infection whose rate is 1%. Ten people will be infected, and the test will identify nine of them. Nine hundred ninety people will be uninfected, and it will accurately tell us that 902 (rounded) of them are indeed uninfected. But it will also tell us erroneously that another 48 are infected. So, we'll have to isolate and contact-trace 49 people.

115. GOTTLIEB, *supra* note 19, at 62–66 (describing the characteristics of PCR tests).

116. See *COVID-19 and PCR Testing*, CLEVELAND CLINIC (Aug. 24, 2021), <https://my.clevelandclinic.org/health/diagnostics/21462-covid-19-and-pcr-testing> [<https://perma.cc/GH6P-E3JT>] (“You should receive your test results as early as 24 hours after sample collection, but sometimes it can take a few days, depending on how long it takes the sample to reach the laboratory.”).

117. See *What are COVID-19 Rapid Antigen Tests (RATs) and Where Can I buy Them*, HEALTHDIRECT (Dec. 15, 2021), <https://www.healthdirect.gov.au/blog/what-are-covid-19-rapid-antigen-tests> [<https://perma.cc/7GS8-9V69>] (“RATs are quick — returning a result within 10 to 20 minutes.”).

118. *Id.* (“Rapid antigen tests can detect whether proteins of the COVID-19 coronavirus are present in your body.”).

119. Katie Faley, *PCR vs. Rapid COVID-19 Test: What's the Difference*, OSF HEALTHCARE (Feb. 9, 2022), <https://www.osfhealthcare.org/blog/pcr-vs-rapid-covid-19-test->

in a consequential way: the PCR-positive population is less likely to be infectious than the rapid-antigen-positive population.<sup>120</sup> Or, as Rochelle Walensky, appointed by President Biden to head the CDC, put it in 2020 when she was the chief of infectious disease at Massachusetts General Hospital, “P.C.R.-based nasal swab[s] . . . do[] a great job determining if you are infected but [they do] a rotten job of zooming in on whether you are infectious.”<sup>121</sup>

The FDA initially decided that it would approve rapid antigen tests only if they were nearly as good as PCR tests.<sup>122</sup> That might have been defensible in early 2020 when all we knew was that COVID was highly transmissible and didn’t have good information on how long it remained so. In addition, testing of any sort wouldn’t have done much to ease the pandemic after uncontrolled community spread. Testing might aid, though, in helping policy makers decide how to ease lockdowns, particularly in designing advice to individuals about when they could venture forth with appropriate precautions. For those purposes, rapid antigen tests were better than the more accurate PCR tests because getting results from the latter usually took at least two, and sometimes up to five, days. The FDA worried, though, that false negatives in rapid antigen tests would give false confidence to people; with a negative result in hand, they might start resuming contact with other people even though (because the negative test result was in error) they were still infectious.<sup>123</sup>

The difficulty in obtaining approval for rapid antigen tests wasn’t merely that the FDA had set a high standard for assessing test results. Some FDA requirements about the data stood in the way of approval. The agency wouldn’t accept studies that included results from the tests used in Europe and India because it wasn’t confident in the quality of such evidence (even though regulators in Europe relied on the same evidence).<sup>124</sup> And, as with the CDC, the FDA’s methods of handling information hadn’t adapted enough to modern technologies of data compilation.

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whats-the-difference/ [<https://perma.cc/QK76-TV4C>] (describing the different sensitivities of the two types of tests).

120. The reason is (roughly) that a positive rapid antigen test means that you have a fair amount of the virus in you, which in turns means that you’re more likely to transmit it, whereas the more sensitive PCR test can be positive because you have a little of the virus left in your body, not enough to make you highly infectious.

121. Zeynep Tufekci, *The C.D.C. is Hoping That You’ll Figure COVID Out on Your Own*, N.Y. TIMES (Jan. 5, 2022), <https://www.nytimes.com/2022/01/05/opinion/omicron-covid-testing-cdc.html> [<https://perma.cc/4AWB-LFDV>].

122. For an overview of the FDA’s actions, see Lydia DePillis, *This Scientist Created a Rapid Test Just Weeks into the Pandemic. Here’s Why You Still Can’t Get It*, PROPUBLICA (Dec. 21, 2021), <https://www.propublica.org/article/this-scientist-created-a-rapid-test-just-weeks-into-the-pandemic-heres-why-you-still-cant-get-it> [<https://perma.cc/KF3W-D3WM>]. The FDA required that rapid antigen tests “pick up nine out of ten positive tests that a PCR identified.” *Id.*

123. Cf. Giorgia Gugliemi, *Fast Coronavirus Tests Are Coming*, 585 NATURE 496, 498 (2020) (quoting a consultant to the World Health Organization: “There’s a big risk that the moment these tests become widely available, people will just use them and say, ‘It’s negative, so I’m clear . . .’”). The concern was compounded by the possibility that private developers would put tests on the market that satisfied threshold requirements but actually varied in accuracy.

124. Lydia DePillis & Eric Umansky, *Here’s Why Rapid COVID Tests Are So Expensive*

Further, the FDA’s concern that negative results from rapid antigen tests would give people false confidence wasn’t anything like the judgments it routinely makes in assessing RCT design. If the concern is scientific at all, it is in the domain of the behavioral rather than the physical sciences, and FDA scientists had no particular expertise in that domain.<sup>125</sup> What might have happened is that the culture of caution within the FDA got extended to a matter on which the FDA staff were pretty much like the rest of us, churning out hypotheses that seemed a matter of common sense. Whether that extension was justified seems not to have become a focus of attention within the FDA.

#### d. Approving Medications for Treating COVID

No medications specifically designed (or tested) to treat COVID could have been available in the pandemic’s first year or so. Doctors turned to medications already approved for other uses to see whether they were any help in treating COVID.<sup>126</sup> The FDA had no formal role here because medications approved for specific conditions can be used “off label,” that is, to treat other conditions.<sup>127</sup>

Off-label uses are tricky, though. Medications used on-label are safe and effective when used as intended, which means that the risks of adverse effects are outweighed by the benefits with respect to the condition for which the use is approved. Note that if the condition is a really serious one, “safe” might mean a real risk of a serious adverse effect that on balance is worth taking given the benefits in treating the condition. We can’t confidently say that about off-label uses, at least if our confidence must rest on well-conducted studies rather than clinical experience. But, if the risks of serious adverse effects are small or if the ones that do occur with some frequency aren’t all that serious, it might be worth trying an off-label use if nothing else is available.

That’s what happened with two medications: hydroxychloroquine, a medication approved for use in treating malaria, and ivermectin, approved basically for deworming—large doses when used to deworm animals, smaller ones for humans.<sup>128</sup> Their mechanisms of action suggested to some doctors that they might help treat COVID. Some initial, experimental off-label uses resulted in published studies,

*and Hard to Find*, PROPUBLICA (Nov. 4, 2021, 6:00 AM), <https://www.propublica.org/article/heres-why-rapid-covid-tests-are-so-expensive-and-hard-to-find> [<https://perma.cc/8W36-QD7Y>].

125. The FDA does make behavioral guesses in determining, for example, whether a medication can be made available over the counter rather than exclusively by prescription. These guesses, though, are supported primarily by common-sense judgments rather than, for example, surveys or observation of consumer behavior.

126. See GOTTLIEB, *supra* note 19, at 290.

127. The FDA traditionally policed pharmaceutical companies that *promoted* off-label use even though it couldn’t prohibit such uses but abandoned efforts to directly enforce the ban on promoting off-label uses after *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012), held that doing so violated the First Amendment.

128. See *Ivermectin*, DRUGS.COM, <https://www.drugs.com/ivermectin.html> [<https://perma.cc/GB5X-N9MF>] (describing ivermectin as “an anti-parasite medication”) (May 23, 2022).

suggesting that the two medications would indeed help (this was problematic but probably not grossly defective on its face). There were of course skeptics, and as some of the examples provided in describing STS indicated, the results of a single study can't really tell us what the "science" is. But, pending further studies, it wasn't irrational for people who "did their own research" by looking for off-label uses that might work to try hydroxychloroquine and ivermectin. The only thing that people who relied on the FDA could say is that there wasn't enough solid evidence that the medications were safe and effective for treating COVID.

In the end, it turned out that hydroxychloroquine has some positive effects when used to treat COVID (and carries non-trivial risks of causing serious adverse effects on patients' hearts), but the positive effects weren't large enough to displace COVID-specific medications once they became available.<sup>129</sup> Ivermectin, in contrast, wasn't an effective COVID treatment when the dosage safe for humans was used. Some early studies accurately reported positive effects on the study populations, but the populations consisted of large numbers of people with parasitic worms (a "comorbidity"). Ivermectin killed the worms, allowing the populations' natural immunity to kick in, thereby alleviating COVID's effects.<sup>130</sup> The people who did their own research were indeed following the science as it then was—even though it wasn't the "official" science endorsed by the FDA's approval of the medications for on-label uses.

### 3. Conclusion

Perhaps we can understand the CDC and FDA's performance—successes and failures—through the lenses of politics and bureaucracy alone, without drawing upon STS. The STS critique, though, is that the expertise deployed by administrative agencies and the science that emerges from them are shaped in important ways by politics and bureaucracy. What the science is turns out to be conditioned by politics and bureaucracy. That in turn, weakens the Progressive case for treating administrative expertise and knowledge as neutral and removed from politics.

The CDC and FDA produce something for policy makers to follow, and we can fairly call that something "science" as long as we understand the way the conditions

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129. *FDA Cautions Against Use of Hydroxychloroquine or Chloroquine for COVID-19 Outside of the Hospital Setting or a Clinical Trial Due to Risk of Heart Rhythm Problems*, U.S. FOOD & DRUG ADMIN. (July 1, 2020), <https://www.fda.gov/drugs/drug-safety-and-availability/fda-cautions-against-use-hydroxychloroquine-or-chloroquine-covid-19-outside-hospital-setting-or> [<https://perma.cc/9CX7-GAKX>].

130. *Ivermectin May Help Covid-19 Patients, but Only Those with Worms*, THE ECONOMIST (Nov. 18, 2021), <https://www.economist.com/graphic-detail/2021/11/18/ivermectin-may-help-covid-19-patients-but-only-those-with-worms> [<https://perma.cc/TF8S-85ZT>]. Apparently, the study populations didn't have enough people who didn't have worms for "no worms" to be used as one of the control variables. For an overview of trials using ivermectin and concluding that there was "very low certainty of evidence" of ivermectin's effectiveness as a COVID treatment, see Luis I. Garegnani, Eva Madrid & Nicolás Meza, *Misleading Clinical Evidence and Systematic Reviews on Ivermectin for COVID-19*, BMJ EVIDENCE-BASED MED. (2022), <https://ebm.bmj.com/content/ebmed/27/3/156.full.pdf> [<https://perma.cc/9U4D-AEZJ>].

under which it was produced affect the content of the information the policy makers receive. How then should the ultimate policy makers—in this case we can call them “chief executives” such as mayors and governors—follow the science?

*C. Follow the Science to Where? Developing “Science”-Based Policies*

Suppose a bit counterfactually that the CDC and the FDA transmitted clear conclusions to chief executives about what to do in the face of uncontrolled community spread. The CDC might have offered a metric along the lines of, “You should impose substantial restrictions on ordinary business operations until the infection rate gets below seven per thousand.” A chief executive would follow the science by adopting a policy of imposing such restrictions subject to that condition.

What might a chief executive who *rejected* the science say? Maybe they would say that the seven per thousand number reflects a solid judgment about the point where the public health benefits of the restrictions get small enough to ignore. “I have to worry about the economic, social, and psychological consequences of the restrictions as well as the public health ones. And, in my judgment we ought to relax the restrictions quite a bit more quickly.”

If such a chief executive wanted to, she might invoke another science in support: economics. Some economists present themselves as master scientists with regard to public policy through cost-benefit analysis. They might advise the chief executive to place a monetary value on the incremental public health benefit of maintaining the restrictions and place monetary values on the economic, social, and psychological costs (and benefits, though this tended to be ignored in economists’ discussions of pandemic policy) of maintaining the policy; come up with a bottom-line on the net of costs and benefits; then do the same for the policy offered to replace the existing one; then compare the bottom lines and choose the policy whose bottom line number is greater.

Our hypothetical chief executive who wanted to ignore the public health science might hope that the science of economics would support her decision. And, it might well do so, often enough. The technology for placing monetary values on human goods not traded in markets is notoriously fuzzy, not infrequently generating quite a wide range of plausible bottom lines.<sup>131</sup> Occasionally, it will be evident that the bottom line of a proposed action is clearly worse than keeping restrictions in place; that appears to have been the case, for example, of President Trump’s never-implemented hope that all restrictions on business activity could be eliminated by Easter 2020.<sup>132</sup> Less extreme examples of more sensible bottom line guesses are

131. My personal favorite example comes from Cass R. Sunstein, *The Arithmetic of Arsenic*, 90 GEO. L.J. 2255, 2255 (2002) (estimating that the monetized benefits of a proposed regulation of arsenic in drinking water might range from \$0 to \$560 million). Cf. Elizabeth Popp Berman, *Let’s Politicize Cost-Benefit Analysis*, LPE PROJECT (Oct. 5, 2021), <https://lpeproject.org/blog/lets-politicize-cost-benefit-analysis/> [https://perma.cc/F8GM-674Y] (“Our actual estimates of costs and benefits are often lucky to be correct within an order of magnitude.”).

132. Annie Karni & Donald G. McNeil, Jr., *Trump Wants U.S. ‘Opened Up’ by Easter, Despite Health Officials’ Warnings*, N.Y. TIMES (March 24, 2020), <https://www.nytimes.com/2020/03/24/us/politics/trump-coronavirus-easter.html> [https://perma.cc/NVT4-AFBL].

abundant, particularly when the proposed relaxation of restrictions was to be done in stages.

Perhaps, then, following the economic science can lead to ignoring the public health science. An observation by political scientist Martin Shapiro seems pertinent here. According to Shapiro, the “traditional solution [of] having the experts ‘on tap but not on top,’ does not work very well. Given one set of people who know something and another who do not . . . the experts supposedly on tap are likely in reality to end up on top.”<sup>133</sup> Here, the economist-experts would be tapped by chief executives and end up on top of the public health experts.

Often though, the chief executives who ignored the public health science didn’t invoke anything close to a formal cost-benefit analysis. They relied upon a seat-of-the-pants or common-sense judgment that overall life would get better if restrictions were relaxed (or at least that they would benefit politically from acting upon that view). And in doing so, they weren’t departing dramatically from the reasoning methods the STS critique says pervade decision-making in science itself.<sup>134</sup>

With this background, we can now understand what chief executives who “followed the [public health] science” did. They said in effect that they and their constituents prioritized good public health outcomes over the economic, social, and psychological outcomes that flowed from following the public health science, in light of the already existing and potentially available supports to policies to address the problems given a lower priority. No less than chief executives who refused to follow the science, they made a choice that can best be understood with reference to politics in the first instance, culture and other social characteristics ultimately (because such characteristics shape politics).

#### *D. Conclusion: What Do These Failures of the Administrative State Tell Us?*

The CDC’s fumbles on giving guidance about masks, both early and late in the pandemic, and its early botching of the task of distributing COVID tests might not have been terribly consequential. As I’ve suggested, the COVID virus’s characteristics, coupled with the organization of public health in the United States, the nation’s cultural characteristics, and practical politics probably meant that uncontrolled community spread was inevitable. Similarly, for the FDA’s pace of approving emergency and permanent use authorizations of vaccines for different segments of the population, quicker approvals would of course have saved lives but resistance to getting vaccinated, not the unavailability of vaccines to some subpopulations, meant that many lives would be lost even after vaccines were widely available.

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133. Nor, according to Shapiro, will “soliciting rival expertise,” because that “will render the policy discourse more elaborately technical.” Martin Shapiro, “*Deliberative, “Independent” Technocracy v. Democratic Politics: Will the Globe Echo the E.U.*,” 68 LAW & CONTEMP. PROBS., 341, 343 (2005).

134. Cf. Josh Marshall, *Do We Need a Wartime CDC?*, TPM (Dec. 30, 2021), <https://talkingpointsmemo.com/edblogger/do-we-need-a-wartime-cdc> [<https://perma.cc/L4VE-F5UJ>] (“Will supporting boosters make people doubt the efficacy of vaccines? . . . I doubt it. But an immunologist doesn’t have any more insight of that question than I do.”).

One might think that the COVID crisis exposed a narrow difficulty in the theory of the administrative state. Even an incredibly nimble agency might find it impossible to effectively address a crisis whose timeline gave the agency windows of two or three days, or even two or three weeks, to act in ways that would forestall disaster. Perhaps so, but we should also understand that temporality is, so to speak, indexed to the nature of the problem at hand. Doing something in a few weeks would be quick action on COVID; doing something over the course of two years might be quick action on climate change. The way the CDC and FDA dealt with scientific facts during COVID might well be (I think it has been) reproduced in the Environmental Protection Agency and others tasked with addressing the climate crisis. If that's correct, the STS critique of agency science would have broad purchase.

The failures we observed during 2020 are instructive about the actual functioning of the modern administrative state. The science on which regulators rely consists of educated guesses. Ordinary people can't make even educated guesses about the science, so the advice "trust the science" makes sense. But so does the advice "do your research,"<sup>135</sup> when it is interpreted to mean, as it usually does, "if you feel like it, look around to see if there are other well-credentialed scientists whose guesses are different from the regulators."<sup>136</sup> If there are,<sup>137</sup> we ordinary citizens face a conflict of epistemic authorities—and resolving that conflict is a matter not of science but of politics and culture.<sup>138</sup> In the COVID context, many people who did their own research wandered into byways with dead ends. What should we say about them? In

135. For an interesting example of a group of climate skeptics who indeed did their own research, see EYAL, *supra* note 59, at 137–39: Believing that temperature measurements taken at official stations might be distorted by local conditions such as the presence of a hot asphalt street or a shady tree, the group went out and did their own measurements. *Id.* Apparently their hypothesis was disconfirmed, and the group became inactive. *Id.*

136. I note that a willingness to do your own research can make sense quite independent of sometimes justified skepticism about the disinterestedness of the scientific advisory committees and other institutions designed to enhance the credibility of claims made by agency scientists. *Cf. Id.* at 106 (observing that "[t]o a skeptical observer they can appear as an arrangement in which the political and scientific establishments band together and close ranks against renegade, iconoclastic scientists").

137. Throughout the COVID episode, there have often been such scientists, some of whom proved to be right (those who argued early on that COVID transmission was aerosolized), others wrong (those who found—accurately for the population they studied—that ivermectin was an effective treatment for COVID). Once again, time matters: ordinary people who relied on the ivermectin study weren't rejecting the science; they were choosing, for reasons that could be subjected to examination, one set of educated guesses over another.

138. For a related discussion of that proposition, see Mark Tushnet, *Epistemic Disagreement, Institutional Analysis, and the First Amendment Status of Lies*, 22-09 KNIGHT FIRST AMEND. INST. (Oct. 19, 2022), <https://knightcolumbia.org/content/epistemic-disagreement-institutional-analysis-and-the-first-amendment-status-of-lies> [<https://perma.cc/W8WT-YFFC>]. *Cf. Jasanoff, supra* note 5, at 1747 (suggesting the possibility of "epistemic subsidiarity," which "would allow subordinate segments of a polity, such as states in a federal union . . . to hold on to their own ways of knowing and their own collective knowledge on contested issues.").



part that they forgot the first injunction, to trust the science (to some degree), but more important, I think, that they were politically but not epistemically mistaken.<sup>139</sup>

### III. RECONSTRUCTING THE ADMINISTRATIVE STATE

The critiques of the two branches of the Progressive theory of the administrative state don't mean that the administrative state has to be deconstructed in the sense of "dismantled." A significant amount of literature addresses the critique of the political branch, offering a wide range of solutions.<sup>140</sup> The revival of the "trust the science" branch is unfortunate to the extent that it slows consideration of possible revisions in the administrative state's structure that would respond to the STS and similar critiques. In this section I sketch some ideas about how the STS critique of the "expertise" branch of the Progressive theory might lead to a modestly or substantially reconstructed administrative state.

The FDA's concern that widespread use of insufficiently accurate rapid antigen tests provides a convenient point of entry. Were they to address the issue, one thing behavioral scientists would do is simple: do a survey that tries to inform people that negative test results are sometimes inaccurate and asks respondents what they would do if they got a negative test result.<sup>141</sup> The pharmacologists and epidemiologists at the FDA didn't think to ask because, as the STS critique suggests, they were embedded in a culture that directed their attention elsewhere.

So, perhaps we could augment the "science"-oriented components of the administrative state. One possibility would be to deepen its scientific capacity by attaching experts in other fields to each science-based agency—a behavioral sciences unit within the FDA, for example. Or, such supplementation might occur outside the agency, when chief executives take the information they receive from the science-based agencies and develop policy based upon it and supplemented, in this scenario, by information from the behavioral sciences unit.<sup>142</sup> As I suggested in connection with the attempt by economists to present a cost-benefit analysis as a master science, this strategy might simply substitute one set of experts for another—and the science

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139. I thank Gil Eyal for pressing me to clarify this point. Eyal also suggests that doing your own research might systematically undermine trust in mainstream science, which might be true but not obviously a bad thing. See EYAL, *supra* note 59.

140. For examples from a large literature, see Metzger, *supra* note 7, at 77–95; Nicholas Bagley, *The Procedure Fetish*, 118 MICH. L. REV. 345, 400–01 (2019); Freeman & Jacobs, *supra* note 2, at 652–64.

141. Obviously, this is an extremely crude formulation of the survey, and I offer it only as an entry point for the discussion to follow. I note that looking at revealed preferences isn't possible where, as here, the vaccine isn't available.

142. The Obama administration created the Social and Behavioral Science Team as a subcommittee of the National Science and Technology Council. See *About SBST*, SBST, <https://sbst.gov/> [<https://perma.cc/3LES-LD3X>]. The Trump administration disbanded it. The British government once had a Behavioural Insights Team, which it eventually transferred to private ownership. See *Who We Are*, BEHAV. INSIGHTS TEAM, <https://www.bi.team/about-us/who-we-are/> [<https://perma.cc/7ZEX-GWLX>]. Neither appears to have performed the role suggested in this Article, but their creation suggests that similar innovations aren't entirely in the realm of fantasy.

done by the newly “on top” experts would be subject to STS critiques targeted at their science.

What might be done that wouldn’t face an STS-type critique? Perhaps modifying the Progressive commitment to expert or science-based decision-making. The FDA and the EPA have science advisory panels consisting of experts in the relevant fields who comment on proposed regulatory actions.<sup>143</sup> In practice, as Sheila Jasanoff shows, these advisory panels have something close to a veto power.<sup>144</sup>

Suppose we constituted citizen advisory panels in each science-related agency.<sup>145</sup> The FDA panel might be given the kinds of background material that science advisory panels get and asked its opinion on whether ordinary people would get a false sense of security from negative test results. To move to other examples, the citizen advisory panel might be given a list of possible side effects and asked how serious they are in connection with COVID (or, of course, other problems for which the FDA is examining medications), which subpopulations are of particular concern in light of the fact that obtaining statistically reliable results about some such populations would extend the RCT by some period—in short, all the aspects of scientific decision-making that lie outside the agency’s core scientific expertise. The EPA citizen advisory panel would be charged with similar tasks. For example, one persistent issue in risk regulation is a disjuncture between experts’ assessments of risks, particularly cancer risks, and citizen assessment.<sup>146</sup> The EPA citizen advisory panel could be asked to provide non-expert views (or, as I suggest below, views derived from the members’ life experience understood as a source of citizen expertise).<sup>147</sup>

This hypothetical EPA example raises an important question about how citizen advisory panels might be incorporated into science-oriented agencies. Science advisory panels have been influential within these agencies because they speak the same language as the agency scientists. Citizen advisory panels wouldn’t be expected to do that, although they might “go native” and start doing so.<sup>148</sup> Were these advisory panels to be merely advisory, the scientists in the agency might disregard their input

143. See generally JASANOFF, *supra* note 52 (detailing a study of FDA and EPA advisory panels in the late twentieth century).

144. *Id.*

145. I forgo providing detailed discussion of many obvious design issues there are associated with this proposal (how to select members of the panels, how long they serve, how they are compensated, and much more) to focus on their role in acting as a counter to the scientists’ embeddedness in their communities.

146. See Nancy Kraus, Torbjörn Malmfors & Paul Slovic, *Intuitive Toxicology: Expert and Lay Judgments of Chemical Risks*, 12 RISK ANALYSIS 215 (1992).

147. For a proposal that operates in roughly the same conceptual space but relies more heavily on deliberative polling’s results as inputs into policy choice, see Zachary Liscow & Daniel Markovits, *Democratizing Behavioral Economics*, YALE J. ON REGUL. (forthcoming), <https://ssrn.com/abstract=4012996> [<https://perma.cc/FQ3W-928N>]; see also Wendy E. Wagner, *No One Solution to the “New Demarcation Problem”?: A View from the Trenches*, 92 STUDS. HIST. & PHIL. SCIENCE 177, 181 (2022) (describing “‘collaborative’ decision-making, where the public stakeholders work iteratively or alongside the scientists to resolves social problems”).

148. For a related example of “going native,” see EYAL, *supra* note 59, at 106. (I’m not fond of the term “going native,” but Eyal uses it and I know of no handy substitute.)

as insufficiently well informed. Perhaps, then, citizen advisory panels should be given a formal veto power over agency proposals (or, in our example, agency-approved research designs).<sup>149</sup>

I believe that citizen advisory panels can be accommodated with a chastened Progressive vision of the administrative state. Scholars in many fields have shown that ordinary people have “expertise” derived not from training or participation in a community of experts but from their daily lives.<sup>150</sup> Political scientist James Scott’s classic analysis in *Seeing Like a State*, for example, shows how central decision-makers implementing “knowledge-based” plans often go wrong because they aren’t familiar with the characteristics of the locations where their policies will be implemented.<sup>151</sup> Ordinary people on the ground can bring local knowledge to bear, thereby improving performance. Similarly, studies of workplace safety have shown, as one author puts it, that “labour possesses vital, tacit, shop floor knowledge regarding health and safety, knowledge that is imperative for reducing accident rates.”<sup>152</sup>

Consider here the observation above that the conditions associated with relaxing lockdowns varied enormously. Leaving lockdown for largely outdoor jobs or activities was different from leaving it to do jobs or activities indoors. People in some communities might know that their neighbors were particularly responsible (or irresponsible) people. Social sanctions for ignoring NPIs might be strong in some places and weak in others. These are precisely the conditions under which local knowledge comes into play. Local decision-making bodies could implement CDC guidance more flexibly and with greater net social benefits than bodies with larger jurisdiction could.

Some philosophical pragmatists offer a theory of knowledge—about facts in the world, including scientific facts—that supports reliance upon local, shop floor, ordinary knowledge in developing public policy (and understanding the world generally). Philosopher Derrick Darby refers to W. E. B. Du Bois’s invocation of “sage souls” as a justification for universal suffrage, for example, and to John Dewey’s pragmatic account of knowledge.<sup>153</sup> Ordinary people, to these pragmatists, are experts in their own right. The Progressive account of the administrative state

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149. This would be at least compatible with Eyal’s thought in the concluding lines of his book that “[t]he republic of trans-science would need to be one where ‘bringing the bad news,’ teaching others how to recognize ‘inconvenient facts,’ is established as a routine yet honorable and well-regard vocation.” *Id.* at 149.

150. For a compilation of studies premised upon the view that ordinary people can bring their own expertise to decision-making tasks, see *HANDBOOK OF DEMOCRATIC INNOVATION AND GOVERNANCE* (Stephen Elstub & Olive Escobar eds. 2019).

151. See generally JAMES C. SCOTT, *SEEING LIKE A STATE: HOW CERTAIN SCHEMES TO IMPROVE THE HUMAN CONDITION HAVE FAILED* (1998).

152. Adam Seth Litwin, *Trade Unions and Industrial Injury in Great Britain*, *CTR. FOR ECON. PERFORMANCE* (2000), [https://cep.lse.ac.uk/\\_NEW/PUBLICATIONS/abstract.asp?index=468](https://cep.lse.ac.uk/_NEW/PUBLICATIONS/abstract.asp?index=468) [<https://perma.cc/UVL6-LLXK>].

153. Derrick Darby, *Du Bois’s Defense of Democracy*, in *DEMOCRATIC FAILURE* 207, 230 (Melissa Schwartzberg & Daniel Viehoff eds., 2020).

could bring them into its structure without surrendering its commitment to expert decision-making.<sup>154</sup>

Experience, common knowledge, and philosophy support institutional innovation to address weaknesses in the Progressive advice to “trust the science.” Though I have suggested citizen advisory panels as such an innovation, recognizing that innovation is needed is more important than coming up with concrete policy proposals.

Indeed, the political economy of institutional innovation in the administrative state suggests that committing to any specific proposal for such innovation would be a mistake. The political economy associated with the critique of the “political neutrality” strand in the Progressive defense of the administrative state is straightforward. Ossification serves no one’s interests. People who want to deregulate find themselves unable take old regulations off the books, and people who think that new regulations are desirable or even imperative find themselves unable to get them adopted. At some point both groups will come to understand that something has to be done.

What of the political economy is associated with the critique of the “expertise” strand? In the end, the institutional innovations would have to occur within the administrative state. That state’s commitment to expertise will initially block efforts to do so. But, unlike the innovations needed to unjam the political gears, innovations with respect to knowledge can occur outside the administrative state. NGOs can devise their favored innovations and use them as a sort of “shadow” government—an NGO-sponsored citizen advisory panel to the FDA (indeed, one, two, or many such panels, sponsored by different NGOs). People can see what they say, decide which ones seem to work well and which do not, and then bring pressure on politicians to adapt the administrative state.<sup>155</sup>

#### CONCLUSION

The COVID crisis showed how the administrative state actually operates in the face of rapid change—not well. The Trump administration’s political interventions didn’t help, but the difficulties run deeper. Attributing everything to political interference and calling for a restoration of the Progressive vision of a politically neutral and expert administrative state is, I have argued, the wrong way to go. We should indeed trust the science, but we should also do our own research.

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154. For what it’s worth, my view is that pragmatism provides the best response to some versions of STS that rely on extremely strong positions offered by skeptical philosophers of science. For one prominent example of such skepticism, see PAUL FEYERABEND, *AGAINST METHOD: OUTLINE OF AN ANARCHISTIC THEORY OF KNOWLEDGE* (1978). Also, for what it’s worth, my view is that Feyerabend ultimately is committed to the pragmatic account of knowledge.

155. See SCOTT, *supra* note 151, in which a fair number of the innovations that are described originated with NGOs and then were taken up by governments. These include deliberative polling and citizen assemblies. *Id.*