Introduction

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The three chapters in Part IV all deal with innovation in two senses: (1) the innovation ecosystem that gave us COVID-19 vaccines, diagnostics, and anti-virals; and (2) the innovation *in* the structures that produced those products. Behind the scenes of these chapters, I would argue, is a related but distinct conversation: Are these flaws in the legal system that the COVID-19 pandemic exposed or is this a story about how an exceptional "perfect storm" brought on by the COVID-19 vaccine foundered on the shoals of otherwise good regulatory structures?

In Chapter 15, "Innovation Law and COVID-19: Promoting Incentives and Access for New Health Care Technologies," Rachel Sachs, Lisa Larrimore Ouellette, W. Nicholson Price II, and Jacob Sherkow give a 10,000-foot view of the legal structures that led to these developments and what can be changed. They use the case of COVID-19 testing to show the way conflict and lack of coordination in the legal regimes of three sub-agencies of the Department of Health and Human Services – the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), and Centers for Medicare and Medicaid Services – led to problems in the production, approval, and quality of COVID-19 diagnostic tests in the first phase of the pandemic. While interagency problems are not perhaps unique to COVID-19, as more cooperation between agencies/sub-agencies would always be helpful, it is fair to characterize the contribution of this chapter as being about COVID-19's perfect storm, or maybe pandemics more generally, rather than a general critique of how these agencie/sub-agencies work together. The authors then examine the FDA's emergency use authorization (EUA) grants for several COVID-19 treatments, most notably hydroxychloroquine, remdesivir, and convalescent plasma. Here, the critique is more about how COVID-19 shines a spotlight on a deep, preexisting tension – the way in which faster approval or access programs, not just EUAs but the expanded access program, affect "the ability to generate high-quality clinical trial data to confirm or reject preliminary evidence of safety and efficacy" and the need for these programs to be designed with this tradeoff in mind. The final section of this chapter, which looks at government funding for vaccine development in COVID-19, falls between the two poles described here. On the

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one hand, the authors recognize that Operation Warp Speed's success was in part the result of an unusual configuration in medical research, where "public funding of COVID-19 vaccines focused more on covering the final stages of development and manufacturing costs, building on substantial private investments in early-stage research." On the other hand, some of what they discuss, such as advance purchase commitments as an innovation lever, could be more easily adapted for the next pandemic, which they ominously suggest is certain to come eventually.

In Chapter 16, "Addressing Exclusivity Issues During the COVID-19 Pandemic and Beyond," Dr. Michael Sinha, Sven Bostyn, and Timo Minssen focus on intellectual property rights related to COVID-19 vaccines and therapeutics with a particular focus on regulatory exclusivities. They describe, in general, the marketing authorization rules in Europe, especially the conditional marketing authorization process, and compare them with the EUA pathway in the United States. They then show how these pathways operated for vaccines and therapeutics. For vaccines they find a story in both places that is fairly exceptional. As they note, "[v]accine R&D over the last few decades has largely occurred within small and medium-sized companies" and successfully navigating clinical trials "is often dependent on additional federal funding or acquisition by larger firms," with many products languishing if "funding runs dry or large vaccine manufacturers decline to conduct further studies or pursue" authorization. The COVID-19 vaccine situation is very different. As in the previous chapter, the authors zero in on public funding and advance purchase commitments, but they also point to the intellectual property protection over mRNA vaccine platforms, patent libraries, and trade secrets as creating a much more secure environment for the pioneer companies here. But a quirk of how exclusivity periods run in the United States and Europe make a big difference for COVID-19 in comparing the two regimes: in Europe, the time-limited exclusivity period begins to run when conditional authorization is given, whereas in the United States the period is not triggered by the EUA, only by the Biologics Licensing Application (BLA), which they argue disincentivized the companies to rush to get a BLA approval (often thought of as a "full approval" by the public). They also review how voluntary sharing of technology and data, patent pools, and compulsory licensing have worked out in ensuring equitable vaccine access to poorer countries; the short answer, they conclude, is not very well. Here, it is hard to diagnose whether this represents a persistent problem baked into the system or one that is particularly bad for COVID-19 vaccines. The combination of large numbers of patents, the complexity of the technology and the trade secrets surrounding it, and the vaccine nationalism which prompted rich countries to make sure to secure their share first all made COVID-19 a bad if not worst-case scenario. Some of the changes they examine might be more palatable with respect to other global health needs or other technologies.

In Chapter 17, "Vulnerable Populations and Vaccine Injury Compensation: The Need for Legal Reform," Katharine Van Tassel and Sharona Hoffman examine the strange situation arising from the fact that the United States runs two distinct

programs relevant to vaccine injuries (a sad but inevitable result of even very safe vaccines administered to so many): (1) the National Vaccine Injury Compensation Program (VICP), which covers most vaccines given in the United States; and (2) the Countermeasures Injury Compensation Program (CICP), far less generous and more difficult to access, which applies when vaccines are administered as countermeasures. Importantly, during the period when vaccines in the United States were administered under an EUA status, as they were for much of the early months of vaccine availability, those injured could access compensation only under the CICP. The authors nicely show how the CICP coverage interfaced problematically with several – if not exceptional then at least fairly distinct – features of the COVID-19 vaccination scenario: high levels of vaccine hesitancy in poor and minority communities, and the fact that these same populations were both at high risk of COVID-19 infection and also the least financially able to withstand a vaccine-related injury.

The authors argue that an important innovation in policy is needed for future pandemics – a vaccine-specific carve-out (i.e., not drugs or devices) that would "establish that all vaccines that the FDA approves and the CDC recommends to ameliorate a [public health emergency] will be covered by the VICP, regardless of whether they are to be administered to pregnant women or children," thereby shifting all EUA-approved vaccines into the program.

The pandemic is not over, but it is entering a phase where the public is more interested in reviewing what has happened thus far. There is increasing talk in the United States of something like the 9/11 Commission, a full review of what we did and how it went. These chapters are an excellent guide to beginning that discussion. They also present the possibility of leveraging what went wrong with COVID-19, especially regarding access for the worst off globally, into more systemic changes to our innovation ecosystem.