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This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present That Will Benefit Its Future Preparedness
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4. Vaccine-Related Liability: Past Approaches, Current Challenges, and Proposals for Encouraging Future Innovation

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As scientists, governments, and pharmaceutical companies race to develop a vaccine to treat COVID-19, they face significant challenges to global adoption of the vaccines ultimately developed. Chief among these challenges are public fear of vaccine-related injury and manufacturers' fear of liability arising from those injuries. Through the lens of the COVID-19 pandemic, we explore potential solutions to these challenges. Part I provides a historical overview of how vaccine-related liability has discouraged pharmaceutical companies from developing vaccines and how various countries have mitigated this risk and spurred innovation by establishing vaccine injury compensation programs. The United States has utilized a Vaccine Injury Compensation Program to compensate people injured by vaccines. Other countries have established no-fault vaccine compensation programs, but such programs exist in less than fifteen percent of the World Health Organization member states. Moreover, because the specifics of processing claims and receiving compensation vary from country-to-country, these systems provide only limited protections.

Against this historical backdrop, Part II summarizes and critiques the steps taken to address liability related to the development and release of a potential COVID-19 vaccine. In the United States, federal authorities have invoked the Public Readiness and Emergency Preparedness Act ("PREP") to provide immunity to COVID-19 vaccine manufacturers. Although PREP provides expansive immunity, it does not prevent litigants from bringing suit, and those invoking PREP as a defense will have to litigate their entitlement to its protections. Europe has no comparable immunity scheme. Instead, the European Commission's Product Liability Directive ("PLD") holds producers liable for damage caused by their "defective" products—even those developed to address a public health crisis. But the PLD does provide producers with a defense if it was not "scientifically possible" to discover the defect when the product was brought to market.

Part III offers recommendations aimed at establishing a more effective injury compensation regime designed to encourage innovation and swift adoption of vaccines and other pandemic responses. First, we propose three strategies for establishing a global vaccine-injury compensation scheme to assuage the public's fears of new vaccines by ensuring that anyone suffering a vaccine-related injury will receive just compensation. Each of the proposed schemes will provide "no fault" compensation to those injured by vaccines, provide immunity to manufacturers and those who administer vaccines, and require injured parties to exhaust administrative remedies before suing. Second, to ensure the prompt adoption of effective vaccines so as to achieve "herd immunity," we recommend developing enforceable and near-mandatory vaccination requirements. Third, we propose strategies for addressing two related hurdles that have previously stymied vaccine development and pandemic preparedness: global amnesia, which describes the collective forgetting of key details of a public health crisis once a situation has resolved, and hindsight bias, which describes the tendency to misjudge, after-the-fact, the challenges and uncertainties experienced during a crisis.