



## 10. Regulatory Reactivity: FDA and the Response to COVID-19

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Public health-oriented agencies have a critical role to play in pandemic preparedness and response. Challenges in determining how to prepare for pandemic risks without knowing the nature of the risk or when and where it will emerge, along with difficulties in reallocating funding away from current known health risks and priorities, have led to a heavy administrative reliance on mechanisms of response in emergency contexts. Decision making under emergency conditions is inevitably subject to a variety of political and public pressures and time constraints that stress existing modes of administrative analysis and decision making in ways that may lead to imperfect regulatory responses.

Using FDA's response to COVID-19 as a case study, this Article examines the challenges of administrative decision-making in a situation of unexpected public health emergency, identifying the implications of applying standard agency procedures and agency responses under what we term "reactive modes" of decision making. We contrast this with what we refer to as a "responsive mode," which is characterized by explicit *ex ante* tailoring of regulatory decision making to emergency contexts. We draw from work on regulatory resilience that has emerged in other contexts, such as financial regulation in the wake of financial crashes, to suggest how to increase the regulatory resilience of the FDA in response to pandemic threats. While we utilize COVID-19 as a lens through which to examine reactive regulatory responses to public health crises, the article anchors its analysis in a study of broader trends characterizing FDA's response to previous large-scale crises, such as the rush to develop treatments and vaccines for Ebola and Zika. We conclude with suggestions to increase regulatory resiliency, providing a set of principles designed to capitalize on and enhance the FDA's role both as a standard-setter in public health preparedness and as a critical responder to future epidemics.