Food and Drug Law Journal 2020 Symposium
This Teachable Moment: How COVID-19 Provides Lessons from FDA's Past and Present That Will Benefit Its Future Preparedness
November 12–13, 2020

6. How We Got Here: FDA Emergency Use Authorization from 9/11 to COVID-19

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Emergency use authorization (EUA) is a power granted by Congress to FDA to ensure the availability and distribution of medical countermeasures during public health emergencies. It permits FDA to authorize unapproved medical products or unapproved uses of approved medical products for emergency use. These products can be used to diagnose, treat, or prevent serious public health threats under certain statutory conditions. EUAs limit the informed consent process normally used by FDA for human research while requiring that patients be adequately informed to the fullest extent possible given the circumstances of a given emergency. EUAs also give FDA considerable discretion to regulate the distribution of EUA products.

EUAs are playing a critical role in responding to the current COVID-19 pandemic, a situation developing on a daily basis with near-daily emergency authorizations of medical countermeasures. In the past three months, FDA has issued an unprecedented number of EUAs for the use of protective equipment, diagnostic tests, and treatments that have yet to run the gauntlet of FDA's extensive ordinary approval process. However, we have yet to chronicle the evolution of this important power from its inception through its use against COVID-19, the most consequential public health emergency since the 1918 Spanish flu.

This paper reviews the history of FDA's EUA authority in order to better understand and anticipate EUAs' potential, risks, and limitations. The paper starts by considering four events that set the stage for the inception of EUAs: (i) the swine flu affair of 1976, (ii) FDA's response to the AIDS crisis in 1990, (iii) the controversy over administering the DryVax smallpox vaccine to first responders in 2001, and (iv) the SARS outbreak of 2002. The paper then details the establishment and early use of EUA authority in the wake of 9/11, focusing on its enactment under Project Bioshield in 2004 and enhancement by the PREP Act in 2005. The paper reviews early uses of EUAs—in particular, during the H1N1 crisis—before proceeding to EUAs in response to COVID-19. The paper concludes by reflecting on the history of EUAs and considers ethical questions relevant to their use in connection with COVID-19 (including a potential vaccine) and emergencies to come.

The history of EUAs reflects a gradual shift from counterterrorism in the post-9/11 period to naturally-occurring infectious diseases in the wake of the H1N1 crisis. There is reason to think that H1N1, as the first U.S. public health emergency since the emergence of EUA authority, altered the federal government's understanding of the framework of emergency laws that began with Project Bioshield. Equally interesting is how the emphasis on bioterrorism helped prepare the federal government, at least from a legal standpoint, to confront the current crisis over a decade later. At the same time, statutory developments and background deliberation across the federal government took influence, at least on occasion, from a community of health experts who consistently focused on infectious diseases—who warned that pandemics would arrive sooner or later, and that we ignore them at our peril.