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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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1. History, Legislative Innovation, and Future Pandemics

Daniel A. Kracov[1]
Arnold & Porter LLP

In recent months we have seen reports of the development of sophisticated COVID-19 vaccines and treatments on the same pages as the President minimizing risks and suggesting consumption of disinfectants. Such dizzying contrasts between innovation and scandal have long been the rule rather than the exception in the history of public health in this country. However, in many cases, that history has ultimately led to legislative innovations providing powerful new frameworks and incentives for solving future problems. Given the uncertain attributes of future pandemic pathogens—as exemplified by the aerosol nature of SARS-CoV-2 transmission—a future pandemic (or bioterror) threat may place an even greater premium on the availability of effective diagnostics, prophylactics, and treatments—at large scale—at the earliest stage of a pandemic, before hundreds of thousands have died and our economy is devastated. Given our history, now is the time to consider whether we can address that gap through legislative innovation.

Problems in providing medical countermeasures for diseases emerged very early in our history. With the introduction of a rudimentary form of smallpox vaccine in the late 1700s, efforts were undertaken to ensure that this early technology could be delivered in a consistent way to communities where a smallpox epidemic was raging. In 1813, Congress enacted The Vaccine Act, a public health measure intended to subsidize the delivery of uncontaminated vaccine matter—cow-pox virus—by providing free postage privileges to the first National Vaccine Agent, Dr. James Smith. However, actual funding for the effort was left to private subscription efforts and state lotteries, and even this modest legislative effort to support a countermeasure dissolved in politics, death, and retreat. In 1821, instead of sending the local vaccine agent cow-pox as a smallpox vaccine, Smith's office sent scabs of actual smallpox—used in a more risky vaccination procedure called variolation—to Tarboro, North Carolina. By later that winter, sixty individuals had contracted smallpox, and ten had died in the widely reported "Tarboro Tragedy." Congress began inquiries, and allegations of negligence, conspiracies, and profiteering flew. By 1822, the Vaccine Act was repealed, and Dr. Smith died in obscurity in 1841.

Subsequent national public health measures were sporadic until the early 20th Century, when scandals associated with products such as adulterated diphtheria antitoxin and Elixir Sulfanilamide eventually drove the enactment of the central public health laws still in place today, such as the Public Health Service Act and Federal Food, Drug, and Cosmetic Act. While they were crucial achievements, even those measures initially failed to ensure safety and effectiveness and the development of a research-based biopharmaceutical industry. That awaited the subsequent enactment of the Kefauver-Harris Amendments in 1962, which finally moved the country beyond the era of fraudulent elixirs or "patent medicine" by requiring proof of efficacy for all drug products before marketing. Augmented by later legislation that provided powerful new incentives, such as the Orphan Drug Act for treatments for rare

[1] The views expressed in this abstract are those of the author, and do not necessarily reflect the views of Arnold & Porter or any client of the firm.

diseases, these legislative innovations have spurred decades of massive investments in research and development, saving and dramatically improving millions of lives.

Despite these advances, the COVID-19 crisis has revealed that even these measures may be inadequate to meet the public health demands of our age. While the U.S. government currently provides essential resources for research, capacity-building, and stockpiling, the problems emerging in the COVID-19 pandemic suggest that we need more powerful and customized incentives if we are to limit the impact of future threats via immediately deployable, broad-spectrum prophylactic and therapeutic anti-infectives, thermostable broad-spectrum vaccines, immune modulators, and diagnostics. To address this gap, this paper proposes a statutory framework that would offer bespoke "Incentive Models," tailored to clearly identified, high value public health countermeasure development and stockpiling goals and incorporating push and pull incentives. Such Incentive Models could be based on an economic and policy analysis of the relevant market, as well as scientific, infrastructure, and other impediments to achieving a specific, critical countermeasure goal. In addition to funding, such Incentive Models could draw from a rich history of legislative and academic proposals framing a variety of incentives, including, as appropriate:

- Mechanisms for strongly incentivizing voluntary, pre-competitive collaboration across life sciences companies, which could help optimize research and development of future pandemic treatments or tools and prevent siloed or duplicative research efforts.
- Awarding "wild card" or tradable exclusivity vouchers that can extend the existing patent life or exclusivity for a new product in return for successful efforts to develop important countermeasures for diseases of pandemic concern.
- Exclusivity incentives to spur research to demonstrate whether old drugs lacking intellectual property protections can be repurposed for emergent disease uses.
- Government program add-on payments and subscription approaches that may encourage the development and appropriate use of "dual use" products needed for conventional healthcare settings, with surge and stockpiling capacity for emergencies.
- Incentives for maintaining sufficient domestic advanced, on-demand, manufacturing capacity for key public health countermeasures, such as through sustained tax benefits.
- "Market entry rewards"—potentially in the billions—for drug, biologic or device developers that achieve approval of a novel product meeting an important pandemic preparedness need.

Finally, to the extent possible, such Incentive Models and associated activities should be ring-fenced from undue political interference and diversion of funding, including via relaxation of congressional "pay as you go" requirements.