

The COVID-19 Vaccine and the Role of the State A Talk with Professor Dorit Reiss

- Vaccine development process
 - Public Health Service Act of 1944
 - Vaccines are “biological products”
 - “The term ‘biological product’ means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.” 42 U.S.C. § 262(i).
 - Subject to this Act and the Federal Food, Drug, and Cosmetic Act. 42 U.S.C. § 262(j).
 - Typical timeline
 - Vaccine development typically takes over 5 years. Regulatory oversight increases as vaccine development moves through the stages.
 - Stages
 - Exploratory – laboratory research
 - Pre-clinical
 - Tissue culture and animal testing
 - Once vaccine is shown to trigger an immune response, the vaccine sponsor submits an Investigational New Drug application to the FDA. The application must be approved for the vaccine to proceed to clinical development.
 - Clinical development – 3 stages of clinical trials
 - Regulatory review and approval: Biologics License Application submitted upon successful completion of 3 stages of trials for FDA approval
 - Manufacturing
 - Quality control
 - Clinical trials
 - Phase I: small group of around 20 to 100 healthy patients.
 - Phase II: 200-300 randomized patients.
 - Phase III: thousands to tens of thousands of patients.
 - Oversight committees
 - Vaccines and Related Biological Products Advisory Committee (VRBPAC) under the FDA: reviews and evaluated data

- concerning the safety, effectiveness, and appropriate use of vaccines.¹
- Advisory Committee on Immunization Practices (ACIP) under the CDC: makes recommendations on the use of vaccines as public health guidance.²
 - Accelerating COVID-19 Therapeutic Interventions and Vaccines (ACTIV): develops a coordinated research strategy for prioritizing and speeding development of COVID-19 treatments and vaccines.³
- Pandemic response: accelerating the vaccine process⁴
 - Run stages of clinical trials concurrently
 - Prepare for large-scale manufacture of most promising vaccines during Phase III clinical trials
 - Plan for distribution infrastructure prior to vaccine approval
- Risks of accelerated vaccine development
 - Demands and pressure to expedite timeline can increase potential to cut corners in testing and monitoring of safety risks.
 - May increase potential for failures in manufacturing oversight.
 - E.g. Cutter Incident: over 100,000 doses of polio vaccine manufactured by Cutter Laboratories were not properly deactivated, leading to live polio virus. Over 250 children developed paralytic polio. Led to increased oversight and regulations.⁵
 - An unsafe vaccine prematurely pushed to market may undermine confidence and messaging.
 - Operation Warp Speed
 - Public-private partnership spearheaded by the federal government to accelerate the development, manufacturing, and distribution of COVID-19 vaccines and therapeutics.
 - Introduced in April 2020 under the Trump administration.
 - Multi-agency partnership to coordinate vaccine development with private enterprise.
 - Department of Health and Human Services (HHS)⁶
 - Centers for Disease Control and Prevent (CDC)
 - National Institutes of Health (NIH)

¹ FDA VRBPAC, <https://www.fda.gov/advisory-committees/blood-vaccines-and-other-biologics/vaccines-and-related-biological-products-advisory-committee>.

² CDC ACIP, <https://www.cdc.gov/vaccines/acip/index.html>.

³ NIH ACTIV, <https://www.nih.gov/research-training/medical-research-initiatives/activ>.

⁴ DoD Operation Warp Speed Accelerated Vaccine Process, <https://media.defense.gov/2020/Aug/13/2002476369/-1/-1/0/200813-D-ZZ999-100.JPG>.

⁵ CDC Historical Vaccine Safety Concerns, <https://www.cdc.gov/vaccinesafety/concerns/concerns-history.html>.

⁶ HHS Operation Warp Speed Fact Sheet, <https://www.hhs.gov/coronavirus/explaining-operation-warp-speed/index.html>.

- Biomedical Advanced Research and Development Authority (BARDA)
 - Department of Defense (DoD)⁷
- COVID-19 vaccine mandates
 - Federal
 - Federal government may not set universal mandates.
 - May condition on activities that touch interstate commerce
 - E.g. truck drivers, getting on an airplane, etc.
 - May condition getting a passport, travelling internationally, or other similar activity
 - The federal government already requires vaccinations for immigrants. USCIS requires vaccinations for foreign nationals applying for a visa or seeking to adjust status to a permanent resident in the U.S.⁸
 - Certain vaccines are already required for travel to certain countries.⁹
 - State plenary power to regulate for the public health
 - Court upholds state vaccine mandate: *Jacobson v. Massachusetts*, 197 U.S. 11 (1905).
 - A Massachusetts statute allowed cities to mandate smallpox vaccinations for its residents over the age of 21 with a criminal penalty of \$5 for noncompliance. Subsequently, Cambridge adopted a regulation requiring smallpox vaccinations. Jacobson refused vaccination.
 - The Supreme Court held that the vaccine mandate was a legitimate exercise of the state’s police power to protect for the public health. The Court noted, “[T]he liberty secured by the Constitution of the United States... does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good” (197 U.S. at 26). In this case, the Court found that the Cambridge regulation was not arbitrary, unreasonable, or beyond what was reasonably required.
 - Though states have imposed local universal mandates in the past, state mandates with narrowed goals are more likely to succeed in today’s political climate.

⁷ DoD Operation Warp Speed, <https://www.defense.gov/Explore/Spotlight/Coronavirus/Operation-Warp-Speed/>.

⁸ USCIS vaccination requirements, <https://www.uscis.gov/tools/designated-civil-surgeons/vaccination-requirements>.

⁹ CDC Travelers’ Health, Destinations for Travelers, <https://wwwnc.cdc.gov/travel/destinations/list>.

- E.g. healthcare professionals. Many states already mandate vaccinations for healthcare workers.
- E.g. meat-plant workers and other high-risk essential workers
- E.g. schools. All 50 states already require certain vaccines to attend schools. Whether school mandates will hold may depend on the risk profile of the vaccine because COVID-19 has been shown to be a lower risk to children than the other diseases against which they're already required to be immunized.
- Employers
 - Employers have broad latitude to require vaccines, subject to certain laws or collective bargaining agreements in unionized workplaces.
 - Accommodations required under anti-discrimination laws
 - Accommodations may include minimizing contact with other employees or the public by working remotely, being reassigned to other jobs, being physically separated by screens and other measures. Reasonable accommodations will vary based on job functions and nature of the work.
 - Americans with Disabilities Act (ADA)
 - Prohibits discrimination on the basis of disability.¹⁰
 - Requires “reasonable accommodations,” unless employer can demonstrate that it would “impose an undue hardship.” 42 U.S.C. § 12112(b)(5)(A).
 - “Undue hardship” means “significant difficulty or expense.” 42 U.S.C. § 12111(10).
 - Defense to a charge of discrimination includes a showing that an individual would pose a “direct threat to the health and safety” of other people. 42 U.S.C. § 12113(b).
 - Title VII of the Civil Rights Act of 1964
 - Protects employees with sincerely-held religious beliefs.
 - Employers may deny accommodation if it poses an “undue hardship,” with a showing of “more than de minimis cost.”¹¹ 29 CFR § 1605.2(e).

Additional Resource

- Reiss, Dorit Rubinstein, The COVID-19 Vaccine Dilemma (June 29, 2020). 6 Admin. L. Rev. Accord (Nov. 2020, Forthcoming), Available at SSRN: <https://ssrn.com/abstract=3638623> or <http://dx.doi.org/10.2139/ssrn.3638623>

¹⁰ Americans with Disabilities Act of 1990 (ADA), 42 U.S.C. §§ 12101.

¹¹ EEOC Title VII Religious Discrimination guidance, https://www.eeoc.gov/laws/guidance/section-12-religious-discrimination#_Toc203359523