# INTRODUCTION

According to longstanding scientific consensus, vaccines are widely regarded as playing a fundamental role in public health. Therefore, one would reasonably expect that the dynamics of vaccine production and distribution would place a premium on incentivizing robust levels of investment in vaccine development, with the allocation of resulting vaccine occurring in ways that reflect public health priorities. Yet, that is often not the case. This book examines this disjunction from the viewpoint of the laws, policies and other market-driven forces that shape the development and distribution of vaccines. Together, these mechanisms have long led to problems of under-investment in vaccine research and production, and inequitable allocation of limited vaccine supply in ways that recurrently disadvantage lower-income populations.

## Vaccines as Instruments of Public Health

The use of vaccines is among the most effective and affordable ways of preventing disease or lessening its burden on the health of populations across the globe.[[1]](#footnote-1) The development and use of many vaccines now labeled as “common” or “routine” has led to considerable decreases in morbidity and mortality.[[2]](#footnote-2) Some potentially lethal diseases, such as polio, have been eradicated in many countries through broad vaccination campaigns.

Scientists Stanley Plotkin and Edward Mortimer, two leading figures in vaccinology, have highlighted the public health value of vaccination by stating that “the impact of vaccination on the health of the world’s peoples is hard to exaggerate. With the exception of safe water, no other modality has had such a major effect on mortality reduction and population growth.”[[3]](#footnote-3)

From a public health perspective, vaccines are thus instrumental in enabling medical interventions with overwhelmingly positive effects in both the lower- and higher-income countries:

More children than ever before are being reached with immunization: over 100 million children a year in 2005–2007. And the benefits of immunization are increasingly being extended to adolescents and adults – providing protection against life-threatening diseases such as influenza, meningitis, and cancers that occur in adulthood.

In developing countries, more vaccines are available and more lives are being saved. For the first time in documented history the number of children dying every year has fallen below 10 million – the result of improved access to clean water and sanitation, increased immunization coverage, and the integrated delivery of essential health interventions.[[4]](#footnote-4)

In addition to their direct impact on the reduction of disease, disability and death, the use of vaccines is known to generate several other welfare-enhancing benefits that stretch well beyond the confines of public health. Through their preventative and disease-mitigating functions, vaccines help generate important economic savings to health systems.[[5]](#footnote-5) Their use also minimizes both temporary and permanent losses in the workforce and corresponding decreases in productivity, as well as in spending power by those foregoing wages. And, as illustrated by the COVID-19 pandemic, vaccination can help speed up the reopening of economies constrained by public health measures put in place to curb the uncontrolled spread of an infectious disease, or even avoid the adoption of these measures in the first place.

Robust levels of vaccination have also been linked to the lessening of inequalities between lower- and higher-income populations. The World Health Organization provides the following example:

The burden of infectious, including vaccine-preventable, diseases falls disproportionately on the disadvantaged. Vaccines have clear benefits for the disadvantaged. Pneumococcal immunization programmes in the USA have at least temporarily removed racial and socioeconomic disparities in invasive pneumococcal disease incidence, while in Bangladesh, measles vaccination has enhanced equity between high- and low-socioeconomic groups.[[6]](#footnote-6)

Relatedly, vaccination also contributes to the empowerment of women, especially in lower-income countries.

The vaccination of children has a great impact on the lives of women in developing countries. Protecting the lives of children through vaccination and through other PHC activities is a major strategy towards improving the lives of women. The opportunity and provision of vaccination empowers women to protect their own health and that of their children through their own actions, giving an added psychological feeling of control and empowerment in their lives.[[7]](#footnote-7)

The continued and future success of local, regional and global public health depends in considerable ways on the maintenance of robust levels of vaccination against known diseases. At the same time, new pathogens continue to emerge, posing renewed challenges to public health, as well as to those working to develop new vaccines against of backdrop of uncertainty as to which viruses or bacteria will cause the next outbreak. Coronaviruses like SARS-CoV-2, the pathogen that causes COVID-19, have long been part of an unfortunately long list of emerging pathogens identified by public health experts as likely to trigger severe public health crises in the near future.[[8]](#footnote-8) These lurking threats to human health are a powerful reminder of our collective need for the development of new vaccines, in addition to widespread distribution of existing ones.

## Vaccine Races and Innovation Policy

The twentieth and twenty-first centuries have been interspersed with vaccine races. As seen in chapter 3, the concept of vaccine races has become central to the way most modern vaccines come to market. In a temporal sense, vaccine races unfold whenever scientists attempt to develop new vaccine products against the backdrop of pressing public health crises, such as the recurring polio epidemics of the twentieth century or the recent COVID-19 pandemic.

Adding to the scientific and public health motivations behind vaccine races, there is a fear factor. Whether you choose to open David Oshinsky’s 2006 monography, *Polio: An American Story*, or to read Philip Roth’s account of the widespread fear of polio during summers in mid-twentieth century New Jersey in *Nemesis*, the extra-scientific impulses that have animated the quest for medicines addressing the outbreak of infectious diseases are palpable. Our more recent and quasi-global experience with COVID-19 has rekindled many of these sentiments, bringing vaccine races to the forefront of debates in public fora and around dinner tables, making them a touchstone of socio-economic policies at the domestic and international level, and stirring controversy about the adoption of emerging health goods – a type of controversy that is recurrent in the history of vaccines, and more broadly in the history of medicine, but that is often confined to very specific domains, from scientific scholarship and debate to segments of online discourse.

In addition to compressed timelines and motivating factors, there is yet another important dimension of vaccine races worth considering – one that attracted unusually strong levels of public attention during the COVID-19 pandemic. The concept of vaccine race also speaks to the research and development (R&D) format that prevails in contemporary vaccine development, outside epidemic or pandemic contexts: unless they are the sole sources of a vaccine, developers of vaccine technology compete with one another to be the first to market, in a process often structured around the prospect of obtaining intellectual property protection for their innovations. This protection, in the form of patents, contributes to R&D dynamics that emphasize expediency and secrecy as a norm over collaborative approaches to vaccine development. If R&D players succeed in obtaining one or more patents covering vaccine technology, the law grants them the ability to prevent others from commercializing or otherwise using those technologies for prolonged periods of time.

Intellectual property and adjacent areas of the law play therefore a key role in how the vaccine R&D ecosystem operates. These laws and policies were not designed or implemented with vaccines or other health goods in mind. Rather, they inform innovation processes in virtually all fields of science and technology, making no meaningful distinction between the underlying goods that R&D players are trying to invent, manufacture and distribute. This, in turn, subjects vaccine races – and, more broadly, the development and distribution of vaccines – to market-driven modes of production and allocation that, as seen throughout the book, are largely inadequate in light of the specific characteristics of vaccines.

These inadequacies are compounded by barriers beyond intellectual property. Contracts and other general-purpose legal tools allow two or more parties to buy and sell vaccines with almost no restrictions. The law regulates the purchasing process by focusing on the obligations of the parties vis-à-vis one another, but leaves them free to allocate the existing vaccine supply as they see fit. As a result, countries and vaccine suppliers transact in vaccines in ways that are scarcely distinguishable from the transnational commerce of steel or computer chips – by allocating them first to the most competitive payors, who are invariably the wealthiest countries on Earth. As seen in chapter 4, diverting the vaccine supply according to economic resources is bound to result in vaccine distribution patterns that hardly mirror transnational public health needs. This adds an additional layer to what the book calls “the commodification of vaccines,” the coalescence of different strands of law, policy and practices that make the production and distribution of vaccines predominantly driven by market forces, often to the detriment of public health.

Importantly, these practices are deemed consistent with current legal paradigms – both written domestic and international laws, and caselaw or other interpretive legal frameworks. If anything, laws have been consistently and deliberately engineered to preserve this status quo. The story told in this book is thus anchored on these sets of laws and the innovation policy precepts they help advance when applied to the production and distribution of goods as idiosyncratic as vaccines. The book employs the expression “innovation policy” to reference the interplay of legal and non-legal mechanisms (such as economically motivated decisions or social norms) that shape how vaccines are produced and distributed.[[9]](#footnote-9)

## The Case for Considering Vaccines from a Technological Angle

The fact that vaccines are subject to many of the same market forces that regulate other types of technology warrants examining the vaccine ecosystem through the lens of technology-centered law and policies. The legal and policy frameworks referenced in the previous section were not created in the petri dishes of public health law and policy. Intellectual property as commonly understood today is largely a byproduct of the technological developments brought about by the Industrial Revolution, and was implemented with the overarching utilitarian purpose of promoting innovation – which in the case of the patent system focuses specifically on scientific and technical innovation. Vaccines and other health goods join the ranks of innovations that qualify for patent protection, even though they are used in ways that are fundamentally different from other types of technologies.

Further back in time, contract law developed mechanisms to regulate the provision of goods. Unlike intellectual property, these early developments took place long before vaccines were created, as the Sumerians traded in cloth and the citizens of Ancient Rome transacted in glassware. Modern contractual mechanisms allow a country, or a restricted number of countries, to use contracts to exhaust the global supply of vaccines just as a wealthy Sumerian or Roman could appropriate all cloth or glassware. Yet, vaccines are markedly different from these commodities, and used for non-commodifiable purposes. Even the emergence of international law, which regulates relationships between sovereign or quasi-sovereign actors, has yet to find a way to limit the exclusionary effects that contracts and patents combine to produce in vaccine markets. The book therefore interrogates these legal frameworks and the policies they generate, and searches for solutions within existing laws to mitigate long-lasting inequalities in vaccine production and distribution.

A second reason for the vaccines-as-technology approach adopted in the book relates to the nature of vaccines themselves: they are products of biotechnology, the engineering of a blend of living and non-living materials with goal of creating a product that does not exist in nature. As such, they are especially complex forms of technology. As seen in chapters 1 and 3, modern vaccines consist of an amalgamation of technologies, from the substance that prompts the body to trigger an immune response (the antigen) to stabilizers, to the delivery mechanism. Moreover, vaccines are a subset of pharmaceutical products known as biologics, which are known for being especially hard to replicate. The particular technological characteristics of vaccines set them apart from other goods – including several other health goods. This means that the process to bring a new vaccine to market is subject to different regulations than those applicable to most other goods, as seen in chapter 2. Their technological specificities also mean that some corrective interventions that are successful with regard to other technologies, and even other types of pharmaceutical products, might not work if a vaccine is at stake. For instance, if a less complex product is scarce, policymakers may direct competitors to make and distribute copies, even if the original manufacturer opposes the measure and refuses to collaborate. This policy may be successful if the product is a mask or structurally small drug, such as many of the drugs sold over the counter in pill format. But if scarcity involves a vaccine – as it did during the COVID-19 pandemic – the same measure might not be enough to overcome lack of cooperation from patent holders and to meet the heightened logistic standards required by vaccine manufacturing. A study of the specificities of vaccines as technologies is therefore necessary to inform innovation policy as applicable to vaccine R&D, manufacturing and distribution.

A third reason for the book’s technology-centric approach is tied to the fact that the discovery, development and delivery of vaccines is becoming increasingly dependent on the application of technologies from fields that are not related to biotechnology or health. In providing a glimpse into the future of vaccines in chapter 6, the book describes emerging uses of 3D printing technology and artificial intelligence in different areas of vaccinology. The ways in which exogenous technologies help push the boundaries of vaccine R&D and distribution have been hailed as promising. At the same time, their use makes the vaccine ecosystem to some extent dependent on innovation policies set in connection with non-vaccine technologies. For instance, if early-stage research using artificial intelligence incorporates racial or socioeconomic biases – as it often does in a myriad of non-vaccine contexts[[10]](#footnote-10) – these biases are bound to affect the ultimate vaccine product, further tilting vaccine R&D and production in benefit of patients belonging to dominant racial and socioeconomic groups.

By introducing and using this vaccines-as-technology framework, the book makes three main contributions. First, it draws attention to the intertwining laws, policies and other structures that determine and shape the development and distribution of vaccines. Second, the book shows that excessive reliance on market-driven forces – including but not limited to patent-centric modes of vaccine development – produces results that are largely antithetical to public health and systemically disadvantage lower-income populations, especially those located in the Global South. And third, operating within existing legal and policy tools, the book examines possible solutions to mitigate the most acute consequences of this reliance on markets instead of public health needs.

## Limitations of the Book

The book focuses predominantly on vaccines against emerging pathogens. These pathogens have caused some of the greatest public health crises in history – including in recent history; consider the severe outbreaks of COVID-19, Zika and Ebola that occurred in less than a decade (2014–21, the time of writing). While there is great public health need for vaccines in other areas – for instance, cancer vaccines – vaccines against emerging pathogens fall prey to a particular paradox. When an outbreak takes place, scientists are often able to adapt existing technology and quickly create a new vaccine. Unlike cancer vaccinology, this is an area in which the underlying pathogens are simpler to understand, and innovation processes often work by adapting an existing vaccine targeting a similar pathogen. While relatively unencumbered from a scientific and technical perspective, work on vaccines targeting emerging pathogens remains chronically underfunded, compromising public health preparedness for pandemics and epidemics. The assessment of the World Health Organization on the R&D landscape before the large 2014–16 Ebola outbreak was dire: “there were no vaccines, no treatments, few diagnostics, and insufficient medical teams and trained responders.”[[11]](#footnote-11) Yet, as seen in chapter 3, there was a successful vaccine candidate developed in the early 2000s, which was ready to enter clinical trials and start the admittedly time- and resource-consuming process of obtaining market approval from drug regulators. There was however no market interest in this vaccine before the outbreak. By the time it was rushed to clinical trials in 2014, the outbreak was beginning to wane. The vaccine eventually came to market in late 2019, with several other fatal outbreaks occurring the meantime.

Many other vaccine-preventable diseases lack a commercially available vaccine. Data from 2015 revealed that there were forty-seven vaccine-preventable diseases and infections for which there were either no approved vaccines or only partially effective vaccines. [[12]](#footnote-12) By contrast, there were only twenty-two vaccine-preventable diseases with “commonly used vaccines” and two (adenovirus types 4 and 7, and anthrax) for which there were “limited-use vaccines.”

The book thus focuses on systemic problems that affect a large subset of vaccines – and one in which market-driven modes of production result in losses to public health preparedness.

Although one of the main themes of the book is the disparity in vaccine access by lower-income populations – including populations in the Global South as well as pockets of the Global North – a second limitation of the book is that it does not focus on vaccine development and production in countries of the Global South. Many of these countries are major players in the vaccine ecosystem. India, for instance, is home to the Serum Institute, which manufactures vaccines for 170 countries.[[13]](#footnote-13) The book, however, focuses on how decisions made in the Global North, where the bulk of resources for vaccine R&D is concentrated, affect access to vaccines across the world. These decisions take the form of policies, laws and market-driven behaviors that actors in the Global North control in disproportionate ways. The critiques offered by the book are thus aimed at this facet of the vaccine ecosystem.

Relatedly, several segments of the book are written with reference to the United States. For instance, when chapter 2 describes the process used by drug regulators to evaluate new vaccines, it does so by using the Food and Drug Administration and US regulations as an example. Similarly, when explaining how the patent system works, chapter 3 employs terminology derived from US law to illustrate how international intellectual property rules have been adopted at the domestic level. In these specific cases, the book takes this approach because both vaccine regulation and patents are regulated in largely similar ways throughout the world. National-level drug regulators make decisions based on scientific principles related to vaccine safety and efficacy, and have similar processes for determining whether vaccine meet these criteria.[[14]](#footnote-14) And because they derive from international law, modern domestic patent laws are said to be “harmonized,” with the criteria for obtaining a patent being the same in virtually every country.[[15]](#footnote-15) Of course, illustrative approaches are inherently limited, and do not capture variability at the national level. Wherever possible – for instance, by providing data on vaccine-related patent applications across the world – the book provides information on relevant distinctions or country-level actions that are especially salient.

A final limitation of the book is that, although critical of strong market-driven models of vaccine R&D and distribution, it does not discuss at length solutions that would rely on alternative modes of production. Rather, it locates solutions available under current legal regimes, however imperfect they might be. In this sense the book takes a pragmatic approach. As legal scholar Rochelle Cooper Dreyfuss put it when discussing how intellectual property systems often lead to the production of sub-optimal results, “intellectual property rights will not soon disappear” and therefore there is a need for corrective interventions within the sphere of intellectual property law itself.[[16]](#footnote-16) The same can be said of overly permissive contractual frameworks and the weak reach of international laws and policies affecting the allocation of vaccines. The prescriptive portion of the book therefore considers tools available under current legal frameworks. A discussion of solutions entailing a significant overhaul of current legal and economic regimes has an urgency of its own, but is outside the scope of this work.

## A Note on the Side Effects of Vaccines

As with the use of pharmaceutical products in general, the use of vaccines presents some risks. In most cases, the side effects that may arise in connection with the administration of a vaccine are relatively minor.[[17]](#footnote-17) Common effects include soreness or redness at the injection site, and low fever. Sporadically, severe side effects do occur. An extensive body of scientific studies note that the frequency of severe side effects is “extremely rare.” To put this frequency in context, the US Department of Health and Human Services explains in its informational webpage on the side effects of vaccines, that “if 1 million doses of a vaccine are given, 1 to 2 people may have a severe allergic reaction.”[[18]](#footnote-18) This does not render vaccines unsafe, nor particularly different from other pharmaceutical products. As seen in chapter 2, scientific precepts and the laws that mirror them prevent drug regulators across the world from authorizing the commercialization of a given vaccine unless they determine that, according to the application of current scientific knowledge, it meets the regulatory standards for safety.

In a very limited number of cases, detrimental effects to the health of an individual do occur. This trade-off has long been regarded as tolerable from a public health and societal perspective, not just with regard to vaccines but health goods in general. Regulators and society have chosen to tolerate small amounts of risk – in this and many other areas – in exchange for the availability of technologies that, on balance, are overwhelmingly beneficial. While acknowledging the inherent risks posed by vaccines, the departing point of the book is informed by the scientific consensus that vaccines are welfare-enhancing, societally desirable instruments of public health.

## Structure of the Book

The book is divided into six chapters. Chapter 1 provides background information on the spread of infectious diseases, emerging pathogens and the history of vaccines. It also introduces the topic of technological heterogeneity in vaccinology, surveying different types of vaccine technology currently in use.

Chapter 2 describes the regulatory processes in place to bring new vaccines to market and introduces the main players in the vaccine R&D ecosystem. In so doing, it highlights the centrality of clinical trials to the process of generating data used by drug regulators across the world to evaluate the safety and efficacy of vaccines, as well the shortcomings that affect the production of vaccine clinical trial data.

Chapter 3 shifts the narrative to the role of intellectual property in vaccine R&D, arguing that the race-to-patent format adopted in recent decades has contributed to an undesirable commodification of vaccines under market-driven dynamics. The chapter first theorizes the application of intellectual property to the development of vaccines against emerging pathogens, and then provides several case studies on vaccine R&D.

Chapter 4 continues exploring the effects of the adoption of market-driven modes of vaccine production and distribution, now emphasizing the allocative imbalances that these modes are bound to create. It explains how contractual frameworks recurrently used in international transactions give rise to “vaccine nationalism”– the inequitable channeling of vaccine doses in situations of scarcity towards to a restricted number of countries, irrespective of epidemiological factors.

Chapter 5 argues that policymakers and lawmakers should make greater use of existing mechanisms available under current domestic and international law to start remedying some of the problems diagnosed in the previous chapter. Each proposal made here is informed by notions of technology specificity, proactive adoption, permanency and formalization – the idea that innovation policy affecting the production and distribution of vaccines requires ad hoc measures factoring in both the specific characteristics of vaccines and public health imperatives; that those measures should be negotiated and adopted before outbreaks occur, as opposed to the current practice of negotiating and creating mechanisms to promote vaccine R&D and distribution as public health crises unfold; that, as a consequence, these measures should lead to the creation of permanent agreements and structures; and that resulting collaborations between players in the vaccine ecosystem should be regulated by binding agreements, instead of relying on informal relationships and spur-of-the-moment collaborations.

Chapter 6 crosses the vaccines-as-technology idea with reflections on the growing number of non-health technologies that influence the vaccine ecosystem. It begins by exploring cases in which the use of technology contributes to hinder the reception of vaccine technology, by facilitating the propagation of vaccine misinformation and disinformation. It then turns to instances in which disparate technologies, such as 3D printing and artificial intelligence, are pushing vaccine R&D in new directions – with the implication that technology policy in non-vaccine domains is likely to become increasingly relevant for the vaccine ecosystem.

A brief conclusion links the topics explored throughout the book with larger questions, including the shortcomings of market-driven models of production of health goods; shared similarities between vaccines and other areas in public health also subject to these models, including rare diseases and antimicrobial resistance; and the ultimate incompatibility between nationalistic or otherwise sovereignty-asserting behaviors and the borderless nature of public health interventions.

1. Mark Doherty et al., “Vaccine Impact: Benefits for Human Health” (2016) 34 *Vaccine* 6707–14 (calling vaccines “one of the cheapest and most effective forms of medical intervention”). [↑](#footnote-ref-1)
2. See e.g. US Centers for Disease Control and Prevention, “Routine Vaccines,” https://wwwnc.cdc.gov/travel/page/routine-vaccines. [↑](#footnote-ref-2)
3. Stanley A. Plotkin & Edward A. Mortimer, *Vaccines* (1988). [↑](#footnote-ref-3)
4. World Health Organization, *State of the World’s Vaccines and Immunization* (3rd edition, 2009). [↑](#footnote-ref-4)
5. Francis E. André et al., “Vaccination Greatly Reduces Disease, Disability, Death and Inequity Worldwide” (2008) 86 *Bulletin of the World Health Organization* 81–160. [↑](#footnote-ref-5)
6. André et al., note 5. [↑](#footnote-ref-6)
7. A. E. Shearley, “The Societal Value of Vaccination in Developing Countries” (1999) *Vaccine* 17 Suppl 3:S109–12. [↑](#footnote-ref-7)
8. World Health Organization, “An R&D Blueprint for Action to Prevent Epidemics” (2016), https://www.who.int/blueprint/about/r\_d\_blueprint\_plan\_of\_action.pdf. [↑](#footnote-ref-8)
9. See e.g. Jakob Edler & Jan Fagerberg, “Innovation Policy: What, Why, and How” (2017) 33 *Oxford Review of Economic Policy* 2–23. See also European Parliament, “Innovation Policy” (defining innovation policy in general as “the interface between research and technological development policy and industrial policy and aims to create a conducive framework for bringing ideas to market”), https://www.europarl.europa.eu/factsheets/en/sheet/67/innovation-policy. [↑](#footnote-ref-9)
10. See e.g. Sharona Hoffman & Andy Podgurski, “Artificial Intelligence and Discrimination in Health Care” (2020) 19 *Yale Journal of Health Policy, Law & Ethics*; Cathy O’Neil, *Weapons of Math Destruction: How Big Data Increases Inequality and Threatens Democracy* (2017). [↑](#footnote-ref-10)
11. World Health Organization, “R&D Blueprint,” note 8, at 6. [↑](#footnote-ref-11)
12. See Stanley A. Plotkin et al., “Establishing a Global Vaccine-Development Fund” (2015) 373 *New England Journal of Medicine* 297. [↑](#footnote-ref-12)
13. Serum Institute, https://www.seruminstitute.com/about\_us.php. [↑](#footnote-ref-13)
14. World Health Organization, “Vaccine Regulation,” https://www.who.int/immunization\_standards/vaccine\_regulation/en/. [↑](#footnote-ref-14)
15. See e.g. Peter K. Yu, “Currents and Crosscurrents in the International Intellectual Property Regime” (2004) 38 *Loyola Los Angeles Law Review* 323. [↑](#footnote-ref-15)
16. Rochelle Cooper Dreyfuss, “Does IP Need IP? Accommodating Intellectual Production Outside the Intellectual Property Paradigm” (2010) 31 *Cardozo Law Review* 1437, 1439. [↑](#footnote-ref-16)
17. US Centers for Disease Control and Prevention, “Possible Side effects from Vaccines,” https://www.cdc.gov/vaccines/vac-gen/side-effects.htm. [↑](#footnote-ref-17)
18. US Department of Health and Human Services, “Vaccine Side Effects,” https://www.hhs.gov/immunization/basics/safety/side-effects/index.html. [↑](#footnote-ref-18)