Perspectives on COVID-19 Vaccine: The Incredible Success Versus the Incredible Failure

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Abstract: *»Perspektiven des COVID-19-Impfstoffs: Der unglaubliche Erfolg gegenüber dem unglaublichen Versagen«.* COVID-19 has been the deadliest pandemic since the Spanish flu of 1918–1920. While people in the twentieth century had to wait for the pandemic to run its course before life could return back to a pre-pandemic normal, COVID-19 saw the emergence of several effective vaccines within a year. This quick development is unprecedented. Usually, it takes many years for a vaccine to become applicable in real life, and it is the first time in human history that a vaccine has affected the cause of an ongoing pandemic. While a major scientific success, this situation has also created the unprecedented challenge of how to distribute vaccines at a time when existing stocks are far below what is required for global herd immunity. This paper explores vaccine globalism, nationalism, and commercialism, as the three major drivers underlying the worldwide provision with vaccines. It discusses ways in which they have contributed to vaccine development, production, and distribution and tries to draw lessons for the preparation and management of future pandemics.

Keywords: COVID-19, vaccines, vaccine globalism, vaccine nationalism, vaccine commercialism, COVAX.

1. Introduction

The Spanish flu of 1918–1920 is estimated to have killed between 17.4 million and 100 million people, which corresponds to between 1 and 5.4% of the world population of the time (Roser 2020). Similar percentages for the present world population would amount to between 79 million 426.6 million deaths. For a while, such a scenario could not have been ruled out for COVID-19. Though primarily affecting different age groups, the Spanish flu and COVID-19 seemed to have similar characteristics and similar overall mortality rates (Liang, Liang, and Rosen 2021). In March 2020, a team of researchers at the

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Imperial College in London famously modeled that a policy aimed at mere mitigation of the disease would result in 250,000 deaths in Britain and up to 1.2 million deaths in the US. They viewed as the only viable option a policy aimed at the suppression of the disease using a combination of measures such as social distancing, home isolation of cases, and school and university closures, all practiced intermittently with short periods of relaxation alternating with stringent implementation. They also commented that it was unclear if such a policy of suppression would succeed since there was no precedent of such disruptive measures continued for a long period and that the reactions of societies and populations was unpredictable (Ferguson et al. 2020). The outlook was enough to shock several governments into determined action. But existing public health options were painfully few and archaic: all variations of keeping people isolated and distanced to prevent transmission. Though such modern devices as mobile phones were useful, since they could help track people and provide health codes, in essence the policies were not much different from those used centuries ago. Consequently, the science reporter of the *New York Times* took inspiration from experiences in China and from the past and recommended authorities in the US to "go medieval" (McNeil 2020).

The aspect which radically differentiated COVID-19 from the Spanish flu and, indeed, from basically all other pandemics before, was the development of several effective vaccines in time to materially affect its development. As a result, people did not have to wait until the disease had run its course but, within less than a year, they received an instrument to change this course. This speed was unexpected. In the spring of 2020, even optimistic observers believed that the first prototypes could be expected sometime between April and October 2021 at the earliest (Schäferhoff, Yamey, and McDade 2020). In reality, vaccinations began in late 2020. By October 2021, the "biggest vaccination campaign in history" (Bloomberg 2021) had provided more than 6.55 billion doses in 184 countries. Then, almost half of the world population (47.7%) had received at least one dose of a COVID-19 vaccine, and the global vaccination process was advancing with 21.65 million vaccines administered every day. This record was spectacular, but it was also disheartening, since the distribution was extremely uneven, ranging from the United Arab Emirates (UAE), where 95% of all people have been vaccinated to Yemen, with a mere 1% of vaccinated population as of October 8, 2021. Overall, only 2.5% of people in low-income countries had been vaccinated at least once (Our World in Data 2021).

The vaccination of a population consists of several separate but inter-related steps: 1. The laboratory development of a vaccine (based on its scientific understanding); 2. Its production to scale; and 3. Its distribution to all susceptible people. For a successful vaccination process, all of these steps must work well. Every one of them is complicated and dependent on a variety of

contexts. Clearly, the existing system has performed well in development and production but failed in equitable distribution. But in the real world, those three elements cannot be considered in isolation: vaccines cannot be distributed in any meaningful sense unless a sufficient quantity has been produced, and no quantity can be produced unless at least one vaccine has been developed. On the other hand, as has often been pointed out, in a globalized world nobody is safe until and unless everybody is safe.

On one level, this outcome is of academic interest, as it is fascinating to explore how stake holders around the world have dealt with a situation that was both predicted and unprecedented. However, a mixture of population growth, increasing connectivity, and climate change have made disease outbreaks more frequent since at least the 2010s and, in the absence of major changes in these factors, it is all but certain that the world will face more pandemics in the future (Whiting 2020). It is therefore also of tangible practical interest to look at the experience gained with COVID-19 vaccines and to see what, if any, lessons can be drawn from them for the future. This paper reviews the record of vaccine policies almost two years into the COVID-19 pandemic, exploring its major drivers and discussing their contributions to potential future strategies.

2. Background

Work towards a vaccine began almost immediately. The early stage of the development of COVID-19 vaccines was much accelerated by the large body of relevant existing knowledge about coronaviruses. The similarity to SARS and MERS gave scientists a head start to understanding the virus and pointers to where to look for vaccines and therapeutics (Sharun 2020). In China, the Nasdaq-listed company Sinovac Biotech started a research program in late January, just days after Wuhan went into lockdown (Culver and Gan 2020). At around the same time in Germany, a small company in Mainz, BioNTech, initiated its project "Lightspeed" and in March they engaged in cooperation with the US company Pfizer and the Chinese company Fosun (Biontech, n.d.). By then, the scenery of vaccine development had virtually exploded. In April 2020, there were 115 candidates for vaccines, of which 78 were confirmed cases with publicly available information. Of the latter, 56 were being developed by industry, 22 by academia, the public sector, or other non-profit organizations. Thirty-six confirmed developers were situated in North America, 14 in China, 14 in other Asian countries and Australia, and 14 in Europe (Le 2020). By September, there were more than 300 candidates. The pressure of the ongoing pandemic threw usual processes into disarray. Many laboratories conducted phase I to III trials simultaneously while also beginning preparations for scaled-up production in parallel, before they had a functional

vaccine in hand or before they even knew if they would ever have one (O'Sullivan, Rutten, and Schatz 2020).

The Russian vaccine Sputnik V, produced by the Gamaleya National Center of Epidemiology and Microbiology, was the first vaccine to be publicly announced when President Putin broke the news in August 2020. At the time, it had only been tested on 38 people and phase III trials had not even begun (van Tulleken 2021). Apart from this outlier, international vaccines appeared on the scene in December 2020. The mRNA-based vaccine by Biontech-Pfizer was the first to receive emergency use listing (EUL) by the World Health Organization (WHO) as well as European Union (EU) approval (WHO 2021e; EMA 2020). Around the same time, the Chinese government announced the conditional approval of a vaccine based on dead virus, developed by a subsidiary of the state-owned conglomerate Sinopharm (Ma 2021a). By mid-August 2021, vaccines made by eight companies, using various techniques, had received WHO EUL or prequalification (PQ).[1] Eight further companies had submitted an official Expression of Interest, bringing the approval process underway (WHO 2021e). Some vaccines went into mass production without waiting for international approval. The Russian vaccine Sputnik V is a case in point. Its credibility was substantially boosted when, in February 2021, the prestigious medical journal *Lancet* published the results of trials that indicated an efficacy of over 90% and commented that the vaccine appeared safe and effective. Subsequently, researchers found disconcerting inconsistencies in the data and bemoaned the lack of rigor by *Lancet* and criticized a policy that effectively used scientific peer review as a proxy for a regulatory process for exports (van Tulleken 2021). Meanwhile, Cuba developed a total of four vaccine candidates, one of which (Abdala) received the approval of its national regulatory agency on 9 July 2021. According to national data, Abdala as well as a combination of two further vaccines are over 90% effective (Taylor 2021).

Producing large quantities of these vaccines was the next big challenge. Bringing an existing vaccine up to scale for mass production is a complicated and expensive process. It involves handling sensitive live microorganisms in complex processes, which are often difficult to control, turning naturally variable biological processes and products into standardized products of high efficacy and safety. This requires not only specialized equipment but also the meticulously coordinated collaboration of numerous experts in planning, process development, equipment modifications, process adaptations, quality controls, and registration, easily amounting to hundreds of individual but interlocking actions. It requires that engineers, scientists, lab technicians, logistics organizers, maintenance crews, smart builders and overall leaders cooperate in ways that reflect scientific and technological requirements as well

[1] Biontech-Pfizer, AstraZeneca, Serum Institute of India (producing in license from AstraZeneca), Janssen, Moderna, Sinopharm, and Sinovac.

as patient needs. Even within the same company, bringing this process up and running requires a minimum of six months. Transfers from one company to another easily takes twice as much. In the case of COVID-19, many of the earliest vaccine producers were small companies faced with this challenge for the first time (O'Sullivan, Rutten, and Schatz 2020). How these processes were (not) implemented would be a major factor determining the global distribution of vaccines.

Overall, the relevant processes were shaped by three main drivers: vaccine globalism, vaccine nationalism, and vaccine commercialism. All affected the goal of achieving a timely, equitable vaccination of the world population in different, sometimes contradictory ways.

2.1 Vaccine Globalism

Initially, there was a remarkable degree of openness and cooperation of the early scientific work. On 3 January 2020, Professor Zhang Yongzhen at Shanghai Public Health Clinical Centre received a sample of the virus from a hospital in Wuhan and sequenced its genome within two days. Recognizing its similarly to SARS, he uploaded the result onto the UN National Center for Biotechnology Information and informed health authorities in Shanghai, Wuhan, and Beijing. On 11 January, he agreed to have it published on virological.org from where the news quickly spread to laboratories around the world. By 16 January, Professor Christian Drosten at the German Center for Infection Research at Charité, Berlin, had developed a diagnostic test, which he offered to WHO for free worldwide use (Charité 2020). During the next weeks, laboratory researchers around the world pushed aside options for publications and shared findings online in real time (Apuzzo and Kirkpatrick 2020). Meanwhile, the Gates Foundation, in cooperation with the Chan-Zuckerberg Foundation and the White House Office of Science and Technology Policy, published all known medical literature on coronaviruses in machine-readable form and Amazon offered its IT infrastructure (Chesbrough 2020). A consortium led by the National Institutes of Health and the National Institute of Allergy and Infectious Diseases produced maps of viral proteins (Zaitchik 2021).

In April 2020, a group of American and British researchers, scientists, academics, and lawyers launched an Open COVID Pledge, inviting organizations and companies holding patents or copyrights relevant to COVID-19 to share some or all of their intellectual property (IP) rights in the interest of accelerating the development of diagnostics, vaccines, therapeutics, equipment, and software solutions related to the pandemic. The initiative was supported by some illustrious commercial names such as Amazon, Facebook, and IBM, and, according to the organizers, "an estimated 500,000 patents and multiple

copyrights [had] been publicly pledged to the COVID-19 response" after one year (Open COVID Pledge 2021).

In May 2020, WHO acted on a Costa-Rican proposal and established a COVID-19 Technology Access Pool (C-TAP) as a platform for sharing information, knowledge, data, and other resources of intellectual property to prevent unnecessary duplication of efforts and accelerate the development of COVID-related products (WHO 2021a). However, the pharmaceutical industry showed little interest in this idea. More than a year later, by June 2021, the program had not received a single contribution from pharmaceutical companies (Mayta, Shailaja, and Nyong'o 2021). Vaccine research in the pharma industry unfolded in largely conventional ways.

Efforts to globalize distribution have had a similarly mixed record. In late April 2020, a large group of organizations, including the WHO, the Bill & Melinda Gates Foundation, the Coalition for Epidemic Preparedness Innovations (CEPI), the Wellcome Trust, the Global Alliance for Vaccines and Immunizations (GAVI), and the World Bank, established the Access to COVID-19 Tools (ACT) Accelerator, self-described as "a groundbreaking global collaboration to accelerate the development, production and equitable access to COVID-19 diagnostics, treatments and vaccines" (WHO 2021b). This initiative stayed within conventional forms by keeping intellectual property intact (which has been criticized by an anti-IP hardliner; Zaitchik 2021) but it represented an innovative concept of the distribution of COVID-related material as a global responsibility instead of a function of individual national and commercial transactions. As its center it created COVAX whose stated goal was to provide access to at least 2 billion doses of safe and effective COVID-19 vaccines to the most vulnerable in all participating societies, both high- and low-income countries, by the end of 2021 (COVAX 2020, 5). Its design was a combination of commercial trade and donations: most countries would buy vaccines through this facility while 92 low-income countries should receive vaccines for free though the COVAX Vaccine Advance Market Commitment (AMC), financed through donor contributions. This way, priority would be given to high-risk people in all countries instead of citizens of any one country. Such a mechanism was unprecedented, and hopes were high.

However, disillusionment soon set in. By the time COVAX got underway, individual countries had already begun negotiating bilateral agreements with pharmaceutical companies, and since no government was willing to cancel existing deals which promised to provide it with vaccines at an early date, COVAX became something of an additional bidder for contracts with vaccine manufacturers instead of the central coordinating institution. Long before effective vaccines existed, AstraZeneca took the lead in June 2020 by doing a $750 million agreement for over 300 million doses of the vaccine (which, they claimed, was at no profit). They also reached a licensing agreement with the Serum Institute of India to supply one billion doses to low- and middle-

income countries (AstraZeneca 2020). Biotech-Pfizer and Sanofi and Johnson followed suit, but these efforts suffered a severe setback in September 2020, when US President Trump announced that the US would not join COVAX because of its ties to the WHO and its supposedly overly friendly attitudes towards China (Rauhala and Abutaleb 2020). At that time, the pledged funding amounted to a mere $2.5 billion, a far cry from the $31.5 billion considered necessary to fulfill its plan (WHO 2021d).

Nevertheless, the organizers demonstrated optimism. By December 2020, CEPI, on behalf of COVAX, had invested in ten vaccine candidates, of which nine were in development and seven still in clinical trials. Proudly, it

> announced that it had arrangements in place to access nearly two billion doses of COVID-19 vaccine candidates, on behalf of 190 participating economies. [...] This includes delivering at least 1.3 billion donor-funded doses of approved vaccines in 2021 to the 92 low- and middle-income economies eligible for the COVAX AMC. (WHO 2020c)

Indeed, the situation improved markedly when the new US President Biden changed course and announced US support for COVAX, including substantial financial donations (Rauhala, Cunningham, and Taylor 2021). In late September 2021, $18.3 billion had been pledged to COVAX, much improved from a year earlier, but still far below the sum envisaged. In a dramatic shift from the year before, the largest donor, by far, was the United States providing more than $6 billion, followed by Germany with roughly $2.7 billion and Japan with approximately $1.2 billion (WHO 2021d). However, the biggest challenge was not financing but vaccines, and here the record of COVAX has been disillusioning, as many countries opted for vaccine nationalism rather than globalism. At the time of writing, early October 2021, COVAX had declared having shipped over 341 million COVID-19 vaccines to 144 participants (Gavi 2021). Two billion by the end of the year are clearly out of reach.

In short: globalism helped jump-start the development of vaccines but, so far, the globalist dimension of vaccine distribution has been limited, though it appears to be growing and the final record remains to be seen. Globalism has been flatly unhelpful at getting large amounts of funding channeled into the processes of later vaccine development and large-scale production.

2.2 Vaccine Nationalism

Vaccine nationalism has been blamed for concentrating access to vaccines in high-income countries and preventing a fair distribution, including to people in low-income countries. However, a more comprehensive evaluation, taking into account all three stages of vaccine provision, provides a more ambiguous picture. If nothing else, nationalism appears the driving force behind much of the finances of vaccine developments and production.

Most is known about the US effort, entitled *Operation Warp Speed*, a mechanism that coordinated the cooperation between private companies and various governmental bodies (Baker and Koons 2020). Announced on 15 May, the concept was to invest massive funds (originally $10 billion, later increased to $18 billion) with the stated goal of providing 300 million doses of safe and effective vaccine to the American people by January 2021. The program took into account that it would presumably fund some attempts that would eventually fail but that, in total, it would dramatically speed up the overall process of vaccine development and production (Cohen 2020).

At least 13 manufacturers signed onto the program until the end of 2020 and received funds for research, scaled-up production of materials, specialized equipment, and contract development (Anderson 2020). Part of the funds took the form of advance-purchases of hundreds of millions of doses of (potential) vaccines and options for future purchases (Rauhala 2021). It was essentially a nationalist program: though non-US companies could take part, vaccine candidates from China were excluded, and the advance-purchases were unapologetically reserved for Americans. More important to President Trump, he hoped to be able to announce a US breakthrough in vaccine production before the presidential election on 3 November (Baker and Coons 2020). The $18 billion probably made Operation Warp Speed the largest funding program.

Not quite nationalism but a form of regionalism was operated by the EU. The EU tried to avoid the bitter and embarrassing situation during the early stages of the pandemic when individual EU countries had engaged in a free-for-all scramble for protective gear and competed against each other in global markets, which provoked justifiable criticism of lack of solidarity (Michalopoulos 2020). Leading politicians were determined not to make the same mistake again and insisted on a common approach in which all member countries should work together, buy vaccines collectively, and distribute it equitably among member states according to population size. After what appears to have been complicated negotiations between 27 member states, the EU provided €2.7 billion for negotiations with six companies whose vaccine candidates looked promising (AstraZeneca, Sanofi-GlaxoSmithKline, Johnson&Johnson, BioNTech-Pfizer, CureVac, Moderna, Novavax, and Valneva). While the process took longer than for individual countries, notably the US and UK, the EU commission achieved favorable conditions regarding pricing and product liability for a mixed portfolio of – not-yet existing – drugs, a total of 2.3 billion doses of potential vaccine for a population of approximately 450 million people. The approach practiced solidarity within the EU but not between the EU and the rest of the world (Lehne 2021).

Comparatively less is known about developments outside of North America and Europe. A large program took place in China. By August 2020, 13 Chinese companies were working on vaccine development, of which nine were

conducting human trials, more than in any other country (Culver and Gan 2020). Chinese researchers faced the enviable problem that infection rates in their country were too low to allow phase III trials, so they reached agreements with Brazil, Indonesia, and the UAE to conduct trials there. As the first country, China began vaccinating its population in the late fall, before phase III trials had been finished (Citroner 2020). By mid-February 2021, Chinese authorities had approved three vaccines developed by Chinese companies: the state-owned Sinopharm, the private company Sinovac, and the vaccine manufacturer CanSino Biologics (Lew, Zuo, and McCarthy 2021). In early May/June 2020, the Sinopharm and Sinovac vaccines received the WHO EUL making them eligible to be used by COVAX (UN 2021; WHO 2021f). Without doubt, substantial Chinese government funds went into these processes, but the sums are unknown. The same is true for Russian and the Cuban programs (Borowy 2021).

There is no doubt that these national programs activated immense sums of money. No global program came even close. CEPI could spend a "mere" $1.4 billion in support of vaccine development (Lancet Commission on COVID-19 Vaccines and Therapeutics 2021). A fundraiser, organized by the European Commission for the global Coronavirus response on 4 May 2020, resulted in pledges of $8 billion (Cohen 2020), about half of Operation Warp Speed for the US alone. It is questionable whether this nationalist form of research funding is the most efficient research format. Some scientists have criticized national funding programs, arguing that it would make scientists compete with each other instead of with the virus and engage in wasteful duplication and that investing those sums into a multilateral system like COVAX would bring better results (Cohen 2021). It is, however, also questionable whether governments could be moved to spend remotely similar sums without such nationalist motivation.

Indeed, the nationalist element in vaccine development is clear enough, even in the names: The Soviet vaccine, Sputnik V, relives the moment during the Cold War when the Soviet Union beat the US in sending a satellite into space. One Cuban vaccine, Abdala, bears the name of a poem by its national hero José Martí, and another, Soberana 2, means "sovereign." The US government Operation Warp Speed was named after the fictitious speed of the Star Trek movies, the series of US popular culture fame.

But beyond symbolism, vaccines have also been about political prestige. In Western democracies, this has emphatically been driven by the urge to get vaccines to their own populations as fast as possible. This was most clearly expressed by the degree to which public funding has frequently been connected with pre-purchase agreements. These have been the object of criticism and indignation because they often involved reserving more potential doses of vaccine than there were even people in the country. As one voice among a chorus, a Washington Post columnist complained that "wealthy

nations gobble up more than their fair share of available doses" (Attiah 2021). Similarly, the People's Vaccine Alliance, a coalition of NGOs including Oxfam, Amnesty International, and Global Justice Now, pointed out in December 2020 that rich countries had secured enough vaccines to vaccinate their populations several times over. This was true for the US, the UK, Australia, Japan, and the EU but they were all topped by Canada, which had bought "enough vaccines to vaccinate each Canadian five times" so that the commentator denounced it as "the biggest hoarder of COVID-19 vaccine preorders in First World" (Win 2020).

However, a full evaluation is more complex. At the time, the Canadian government made its pre-purchase decisions, no vaccine had yet been approved. Canadian policy makers decided to buy options from six manufacturers, without knowing whether all, some, or none of them would eventually produce effective vaccines. As of October 2021, four (AstraZeneca, Biontech/Pfizer, Moderna, and Janssen) are producing vaccines that have received WHO EUL. Another, Sanofi, had to admit that its candidate produced insufficient immune response, then partnered with another company whose vaccine efforts had also been unlucky, to develop an improved version and submitted a new approval application. Another, Novavax, hit production problems and also went through a delayed trial and approval process (EMA 2021, WHO 2021e). Other manufacturers such as Curevac or Valneva have similarly pre-sold parts of their potential production but have still to come up with a single dose of approved vaccine.

Strictly speaking therefore, pre-purchasing is not accurately described as hoarding. Instead, it forms a process of self-interested and risky investment into R&D of vaccines, which people all around the world urgently need. Henrietta Fore, Executive Director of UNICEF, acknowledged the essentially beneficial nature of these early orders, explaining that "initially, 'over-contracting' was justified because countries were investing much-needed capital into promising research and development" (Fore 2021). At that point, the pre-ordering had the effect of accelerating the process of making these vaccines come into existence, a crucial – though not sufficient – precondition for a global vaccination success.

But while early pre-purchasing had a beneficial effect for boosting production, it came with the obvious effect of supplying vaccines first to those living in societies that could pay for it, rather than those who most needed it around the world. Given the special responsibility governments have for their own populations, this arrangement is ethically defensible up to a point, but from that point onwards such monopolization seems no longer justifiable and calls for sharing have become deafening (Emanuel et al. 2021). This raises the question of when this point is reached, and which form this sharing should take.

The most painless method would be that high-income countries provide vaccines to others once their own needs have been filled. This measure has repeatedly been suggested, among others by UNICEF Executive Director Henrietta Fore (Fore 2021). A sympathetic rationalization of this strategy was put forth by a US government official in May 2020 by comparing it to familiar directions during plane flights. He called it the "oxygen mask approach," explaining, "we want to get our oxygen mask on first and then we're going to help the people around us" (Cohen 2020). A less charitable view is that of the rich gobbling up life-saving drugs leaving nothing for the poor for months – or possibly years – to come. Besides, vaccinating the people of the world according to nationality or financial status instead of vulnerability or infectious potential risks prolonging the pandemic, increasing the risk of mutations which may or may not be preventable by the vaccines and may, therefore, jeopardize the vaccination success in already vaccinated population in high-income countries (Borowy 2021).

Another nationalist instinct has been to use vaccine exports as a form of soft power. Early on, Russia, India, and China adopted vaccine diplomacy as a form of ostentatiously doing good and gaining political advantages over Western countries and their apparent selfish policy of monopolizing vaccines while those in low-income countries were left behind. This was especially true for China, whose leadership saw a strategy of visible solidarity and a way of improving its global image, which had suffered during the early phase of the pandemic. For India, home of the Serum Institute of India, the largest vaccine producer of the world, it was a major opportunity to compete with China in an area of strength. The quantities have been substantial. In August 2021, the Chinese Foreign Ministry announced that China had "provided more than 750 million doses and concentrates to over 100 countries and international organizations [...] more doses to developing countries than anyone else" and that, supported by the Chinese government, Chinese vaccine companies had engaged joint production in many countries (Jingxi 2021). Relatively wealthy countries, like Brazil and the UAE, have paid for the deliveries, but reportedly a sizable proportion of transfers has been donations (MacKinnon and York 2021; Zhu 2021). According to Bridge Consulting, a Beijing-based research company, China had actually sold 952 million doses and donated merely 33 million doses worldwide (Wee 2021). As a rule, these transfers were bilateral rather than to COVAX. Meanwhile, by September 2021, Sputnik V was authorized in 70 countries worldwide and doses had been ordered in many of them, including an order of 250 million doses by India (Statista 2021).

This order reflected the special situation in India, which was both the site of the largest vaccine manufacture in the world and of a major outbreak of a new variant. India exported over 66 million doses of vaccine to 90 countries at a time when just two percent of its population had been vaccinated. When

it was hit by a severe wave of the delta variant of COVID-19 in the spring of 2021, which infected more than 33 million and killed approximately 450,000 people, it suspended its exports. This decision was understandable but threw plans for vaccination programs in neighboring countries as well as COVAX into disarray. In the following months, the already substantial vaccine production capacity was further ramped up so that daily production was doubled (Vohra 2021). In late September, when 62% of the Indian population had been vaccinated once, and 22% twice, the Indian government announced it would resume vaccine exports again (Associated Press 2021). Even relatively small manufacturers, like those in Cuba, entered the international vaccine trade. In this context, Cuba could build on a basis a strong healthcare sector and of health forming an important part of its foreign policy. It exports various vaccines to about 40 countries in the world and an Iranian laboratory had begun producing it under license (Taylor 2021).

Collectively, the impact of these bilateral policies has been enormous. Early in 2020, as Western countries were concentrating on vaccinating their own populations, India, Russia, and China began shipping vaccines to low-income countries around the world, mostly as exports but partly as donations. They could contrast their own generosity to the "hoarding" of Western countries (MacKinnon and York 2020). India's large pharmaceutical industry provided a strong position, but it suspended exports when the delta variant struck with devastating effects in the country. Consequently, by mid-October 2021, the Chinese vaccines by Sinovac and Sinopharm accounted for almost half of all vaccines administered worldwide of which, in turn, about half had been used in China and the rest in other countries, above all in Indonesia, Brazil, Pakistan, and Turkey (Mallapaty 2021).

Irked by the political successes of the vaccine diplomacy of India, China, and Russia (and probably by the scathing criticism of international organizations and NGOs),Western countries, especially the US, began massively increasing their commitment to COVAX in the second part of 2021. Then, a majority of Americans had been vaccinated and the US government, which had, so far, strictly limited its policy to providing for US citizens, began opening up and exporting or donating vaccines to other countries. The result was a sort of vaccine race. In several announcements between June and September, President Biden pledged the donation of a total of 1.1 billion doses of Pfizer-Biontech vaccines, partly through COVAX (Smith 2021). Similarly, in August 2021, President Xi Jinping promised that China would provide a total of 2 billion doses of COVID-19 vaccines as well as donating $100 million to COVAX (Jingxi 2021). It remains to be seen how these dynamics will play out. The US promise is for donations of what appears to be the best vaccine on the market, while, so far, Chinese supplies have been overwhelmingly sold with only a fraction being donated. However, the US shipments have started late and have been slow to get off the ground, partly due to the logistical challenges of

the low temperatures required to maintain the Pfizer-Biontech vaccine, and in October 2021, only 176 million doses had been shipped (Ma 2021b).

The obvious benefit of these policies is that they succeeded in getting roughly half of the world population vaccinated. There can be little doubt that nationalist goals, both with regard to domestic and foreign policy, have been the leading force behind most vaccinations. There may be a trade-off between national egotism and international cooperation. Nationalism can be counterproductive when it causes countries to monopolize vaccines beyond a reasonable care for their own populations, which, admittedly, may be difficult to define. But it can also have a positive effect when it takes governments into a competition about the fastest or best vaccine and most benevolent foreign policy. This is not to suggest that concerns about people's welfare never plays a role, but it is difficult to imagine that similar sums of money would have been generated and similar levels of vaccine diplomacy activated without considerations about national (or even personal) prestige.

However, the disadvantages are also clear: the distribution is determined not by need but by geo-strategic consideration so that this process, again, is not ideal and may prolong the pandemic compared to a more scientifically grounded one. Thus, the record of vaccine nationalism seems positive for development and production and contradictory for distribution. Besides, these national interests are deeply intertwined with commercial interests, which come with their own set of problems.

2.3 Vaccine Commercialism

While national governments have contributed funding as well as political support and though some public laboratories have contributed research (such as Oxford University to the AstraZeneca vaccine), most R&D and production has been done by private companies. The importance of individual companies becomes clear when looking at the manufacturers of all vaccines produced until October 2021. Rather than a fairly even distribution among the literally hundreds of companies that worked on vaccines development, fewer than twenty had produced any vaccines by then and the vast majority by just four companies, Sinovac, Sinopharm, Pfizer-Biontech, and AstraZeneca. Of these, the mRNA-based vaccine by Pfizer-Biontech had an efficacy of over 90% while the others share similar efficacies of between 65 and 75% (Mallapaty 2021). Clearly, vaccine production is not something easily achieved, and even some experienced and otherwise successful companies have failed. On a global scale, getting a vaccine fast during a pandemic may inevitably involve having many laboratories try and fail so that a few may prevail.

But if individual companies earned the success as major actors, they also earned the blame for the unequal distribution. A Washington Post commentator argued that "the greed of naked capitalism will be the major obstacle to

keep the world safe from the virus and its political and economic shockwaves" (Attiah 2021). Some critics have considered the mixture between the need for life-saving drugs, on the one hand, and company profits, on the other, unethical in itself. As early as December 2020, even before the first Western vaccines had been approved, Amnesty International declared, "all pharmaceutical corporations and research institutions working on a vaccine must share the science, technological know-how, and intellectual property behind their vaccine so enough safe and effective doses can be produced. Governments must also ensure that the pharmaceutical industry puts people's lives before profits" (Amnesty International 2020). Similar demands have been repeated many times since.

While understandable at a time of a global pandemic which is killing millions of people, the argument is also problematic. Private companies are commercial entities which have to generate profits in order to survive. Those that do not will fail (and no longer produce vaccines). In normal times, the development of drugs, including and especially vaccines, is risky business. Developing a vaccine typically takes more than ten years and costs up to $500 million. It also typically involves many unsuccessful attempts, with over 90% of efforts failing between animal studies and the registration of a final product (Broom 2020). Even successful efforts may turn out to be economic failures if the demand evaporates with a decline of the disease. In the past, companies have repeatedly engaged in vaccine development at their own peril. For example, several companies undertook research for a vaccine against Ebola after the outbreak of the disease in West Africa in 2014. They all took major losses on their investments. The first vaccine, originally developed by a Canadian government laboratory and produced by Merck, was approved in 2019, years after Ebola and any interest in a vaccine had died down (Apuzzo and Kirkpatrick 2020). In a market system, therefore, profits are necessary not only to cover the R&D costs for actually marketed drugs, but also the costs of potentially numerous and expensive failed attempts. These considerations are real, but at the same time they do not eliminate the question of how much profit is ethical and how much constitutes greed.

The most tangible and most pressing demand discussed in this context has been to put an end – or at least to suspend – pharmaceutical companies' intellectual property rights. For instance, the People's Vaccine Alliance demands in passionate terms to "break the shackles of intellectual property on vaccines and COVID-19 knowledge" calling on governments to "support the WTO [World Trade Organization's] proposal by India and South Africa to temporarily waive intellectual property on COVID-19 vaccines, treatments and related technologies" and called on pharmaceutical companies to openly share their knowledge in the World Health Organization COVID-19 Technology Access Pool (The People's Vaccine 2020).

A few episodes epitomized the conflict. One involved Oxford University, which did the laboratory work on one of the most promising vaccine candidates. Originally, they offered to make their license freely available to manufacturers but then had second thoughts about their ability to conduct clinical trials. On advice by the Gates Foundation, they reversed course and partnered with the British-Swedish company AstraZeneca. This company then provided the license to the Serum Institute of India, which, supported by Gates's funding, scaled up its production capacity and became the largest supplier of vaccine to COVAX. This development has alternatively been described as either an example of successful philanthropy and public-private partnership in the interest of getting vaccines to low-income countries quickly or of a forward-looking humanitarian initiative quashed by ruthless capitalism (Zaitchik 2021). In October 2020, the governments of India and South Africa, both countries with a formidable pharmaceutical industry and high infection rates, called on the World Trade Organization (WTO) to suspend intellectual property rights related to COVID-19 with regard to vaccines, medicines, and other new technologies needed to control the pandemic. The call was supported by nearly 100 low- and middle-income countries, but immediately rejected by the United States, the European Union, and several high-income countries. The arguments of both sides are well known: the former argue that waiving patent rights would enable many manufacturers to produce life-saving generic versions, while the latter insist that keeping IP rights is essential to incentivize innovations.

The debate has such acrimonious undertones because it ties into a well-established pro- or anti-capitalist narratives and because of its history, going back at least to the bitter conflict about patent rights regarding HIV/AIDS medicine during the 1990s. At that time, intensive lobbying by NGOs had resulted in the mitigation of patent protection of ARV drugs making them available to many patients in low-income countries who needed them. Furthermore, research into payment required for cocktail therapy in developing countries differed significantly, whereby prices would be correlated both with the inclusion of patented drugs and with per capita income both in patented and non-patented regimes (Borrell 2007). Such information lent support to the idea that drug pricing had more to do with considerations of profit maximization than cost recovery. Other research has confirmed how intellectual property regulations provides a barrier to the production and distribution of affordable drugs in the Global South (Bhaduri 2018). The experience with drugs is not necessarily applicable to that of vaccines, where safety and efficacy requirements are higher. However, the Indian-South African proposal also cited past cases in which Pfizer enforced its patent on pneumococcal vaccine, effectively forcing companies in India and South Korea to close the production of alternative versions of the vaccine (Usher 2020). The controversy goes to the heart of the existing dilemma in which on the "one hand,

the profit opportunities motivate companies to extensively research and develop critical new pharmaceuticals. On the other hand, the public needs access to affordable medication in times of crisis" (Eppich 2002, 290). The dilemma involves several inter-related questions: (How) Is technology transfer possible, desired, and relevant to distributing vaccines more effectively around the world?

In an article entitled "Doctors Without Borders to Pfizer: Share Vaccine Recipe With the World," an unnamed spokesperson of *Médecins sans Frontières* has been quoted as declaring that "at least seven manufacturers in African countries currently meet the prerequisites to produce mRNA vaccines, if all necessary technology and training were openly shared" (Johnson 2021). Similar positions have been taken by others, including by representatives of the health administrations of India, Kenya, and Bolivia, who complained that efforts by local manufactures had been rebuffed by large pharmaceutical companies **(**Mayta, Shailaja, and Nyong'o 2021). But elsewhere, Alain Alsalhani, also working for the Doctors without Borders, has acknowledged that sharing a "recipe" is barely the beginning. For a new and little-known technique, the process would inevitably involve a far-reaching technology, tantamount to giving away the basis for years or possibly decades of company work as this knowledge could be potentially applied to the development of vaccines for cancer, HIV, and malaria. Views differ. Many commentators have accused pharmaceutical companies of putting profits over lives in a market which is expected to present them with an incredible $53 billion in revenue in 2021. Other observers have argued that forcing manufacturers to divert attention and manpower from production to building up laboratory capacity for complicated processes elsewhere would end up slowing rather than accelerating production. Meanwhile, WHO's Initiative for Vaccine Research threatened to copy this technique with or without input by these companies (Nolen and Stolberg 2021).

However, the issue may not only be about profits but also about safety, as recent experience with generic drugs suggests. Even when the active ingredients are apparently the same, differences in the production process matter, sometimes with serious consequences for patients, especially when quality control structures are stretched thin as they inevitably are during a period of health crisis (Stockman 2021). For vaccines, which are designed to be given to many thousands of healthy people, forcing the spread of production may come with real health risks. At the same time, the profit motive is also real. The pharmaceutical industry invested heavily in vaccine development and they would scarcely have done so without the prospect of substantial profits. This is true not only for those companies whose gamble paid off but also for the – far more numerous – companies, who invested time, money, and energy in research, which then failed to produce a vaccine. Their efforts will not

result in profitable business, but they also contributed to the entire spectrum of trials and errors that produced the vaccines in record time.

On the other hand, the fact that this process was successful in providing vaccines quickly does not mean that it was the most cost-effective or even the most efficient method. Given how much time and funding could be saved by avoiding wasteful duplications, there is legitimate reason to consider alternative methods. This question of how to improve medical research is not new, and some scientists have experimented with open-source drug discovery, insisting that, given clear rules, the process can be scientifically exciting, fast, and productive (Todd 2019). However, these efforts appear to work best with academic laboratories, which are not required to earn money from the products of their work. If the entire pharmaceutical sector became public, eliminating the commercial dimension, the repercussions would be far-reaching: taxpayers would have to be prepared to finance R&D, including the many unsuccessful attempts that inevitably come with pharmaceutical research. This would put governments into the position of deciding which forms of drug research to pursue or give up while they would simultaneously act as funders and regulators of medical drugs, having safety regulations compete against cost-cutting efforts on a national level (Marden 2010, 255).

Whatever benefit there may be in transforming the pharmaceutical sector in ways that promote open cooperation and de-emphasize commercial interests, changes are likely to be incremental and gradual. Considering fundamental transformations seems to make more sense in the context of overall drug management than with regard to vaccine preparedness, and if any such changes prove to be an advantage at the time of a future pandemic, this may be viewed as a lucky fringe benefit rather than the central policy aim.

Overall, vaccine business has performed well for vaccine development, extremely well for vaccine production, and marginally or negatively for distribution.

3. Conclusions

Much of the debate about global provisions with COVID vaccines has focused on the uneven distribution, often with a moralizing approach, which gives precedence to globalism and condemns nationalism and business. Considering that vaccine inequity costs lives, this indignation is understandable. However, given the degree to which vaccine nationalism and commercialism provide powerful drivers of vaccine development and production, which are preconditions of any distribution, it would seem neither desirable nor prudent (nor probably possible) to seek to eliminate them without having strong alternatives.

Besides, in reality, the various dimensions are not neatly separated. In a globalized world with highly specialized manufacturing, all production entails elements of globalism, and vaccines are no exception. Their production inevitably relies on many ingredients and equipment coming from many different manufacturers and countries (Nkgadima 2021). Besides, it has proved difficult to criticize vaccine nationalism and commercialism without making use of just those rationalizations that are being criticized. For instance, proponents of suspending IP rights have pointed out the absurdity of a system in which the development of vaccines was partially or entirely financed by taxpayer money yet manufacturing companies retain the profits by selling the products to governments, using tax money a second time, while the public paying those taxes is forced to wait longer than necessary because IP rights prevent an expansion of production facilities (Prabhala, Jayadev, and Baker 2020). In that vein, critics of recent development have argued that companies should not be considered the owners of their vaccines but that they should be considered the public property of those societies that financed them. For instance, in an open letter signed by hundreds of scientists, academics, and artists to then president-elect Biden, The People's Vaccine argued that "US taxpayers have already committed more than $10 billion in public money towards a COVID19 vaccine. *A vaccine paid for by the people should work for the people and remain of the people*" (emphasis in the original; The People's Vaccine 2021a). The problem about this reasoning is that billions of people around the world have not paid or committed tax money towards a vaccine. Arguing that people should be entitled to a vaccine because they paid for it suggests that people who have not paid should not be entitled. It is basically a capitalist and nationalist argument that avoids the central dilemma of the global discrepancy of access. In any vaccine for a new pandemic disease, initially there will not be enough for all people around the world, so some will have to come first and others later. Distributing COVID-19 vaccines according to people's needs rather than wealth requires that people receive the vaccine without having paid for it while other people, who have paid for it through their tax money, would need to wait. By implication this means that a global distribution of COVID-19 vaccines according to people's needs requires that stake holders, including companies, governments, scientists, and citizens, act altruistically, potentially putting the interests and the wellbeing of themselves and those near them behind those of unknown people far away. But pure altruism is not the human condition. Neither is pure selfishness. In the real world, people make decisions on the basis of different, sometimes contradictory incentives. If the aim is to find a system that provides sufficient vaccines to all those who need it as fast as possible, one might want to look for an intelligent combination that taps into all motivations while, overall, strengthening distribution as the weakest component of vaccine provisions to date. Specifically, stakeholders might seek to strengthen incentives towards a fairer and more efficient

distribution within a comprehensive nationalism-globalism-commercialism model.

One approach could be to strengthen global cooperation between pharmaceutical companies with the aim of multiplying and decentralizing production. As explained, inter-company cooperation along license schemes and with full training for all technological steps of production is likely to be more realistic and also more effective than patent suspension. This will increasingly be true the more future vaccines will be based on complex methods of genetic engineering. Governments and international organizations could incentivize such inter-company cooperation, for instance, by promising to add bonuses to prices paid for vaccines whose production involves such cooperative schemes, notably if they take place between companies in the Global North and the South.

Similar strategies might be sought to mitigate the gap between nationalism and globalism with regard to distribution as foreign policy soft power. A global scheme that distributes vaccines according to its plan will not deliver foreign policy alliances donor countries seek, but they might do more to provide prestige and international standing. The ACT already visualizes donations on its website. This principle could be applied to vaccine donations, adding videos and other features, which governments could use to promote their policies.

Using crisis as opportunity, stake holders may also turn mechanisms that appear helpful in the short term into long-term structures. This may not only enhance preparedness for future pandemics, it might improve global vaccine and drug provision during normal, non-crisis times. For instance, at the moment, companies have strong financial incentives to keep knowledge relevant to new vaccines and therapeutic drugs to themselves. They have almost no incentive to share it or to engage in complicated open-source schemes. Given that governments and international organizations are major buyers, they could give powerful market signals that schemes that help relevant knowledge to different parts of the world would be financially rewarded. Pharmaceutical production would still be a business, and the system would hardly eliminate the contradictions such a mixture of profit and medical need entails, but it might shift the balance towards medical needs.

Another strategy might be to encourage or institutionalize existing initiative of open scientific knowledge sharing. This might include C-Tap. Just because it was not a roaring success the first time around does not mean that it could not grow into a meaningful mechanism over time. The same is true for COVAX as an institution of vaccine distribution. Though, so far, it has fallen far short of expectations, one might also say that the outcome has been impressive for a new mechanism that was hastily put into place and had no precedent to rely on. If COVAX becomes a permanent institution in charge of all types of vaccines, it could draw up plans for a global vaccine distribution

scheme, based on scientifically grounded and intuitively plausible criteria that take into account vulnerability, essential frontline work, high risk infectious hubs, and possibly also some national quota according to population. While the details would differ for every disease and its infection specificities, the criteria might be the same, and having an internationally agreed template in place would help establish a tangible plan when a new pandemic emerges. While in an ideal world, such a plan could be implemented completely, in the real world it would serve as a goal post and guideline to give orientation to actual policies. In addition, it might also de-emotionalize the debate. At present, the frequently cited data about vaccine distribution inequalities between rich and poor countries provoke indignation, but actually say little about how far off reality has been from an ideal distribution. As Bill Gates has rightly pointed out, some of the worst outcomes of COVID-19 have been in industrialized countries in the Global North, where demographics and possibly other, not fully understood factors have increased population vulnerability (Gates 2021). Having a clearer discussion about how much vaccine populations in different parts of the world SHOULD get when in a generally accepted fair distribution scheme might both reduce tensions and put pressure on governments and companies to move closer to that ideal.

Generally, the pandemic has highlighted the degree to which the threats of the present and the future cannot be localized but affect everybody, requiring innovative thinking and a global strategy. Comparisons with climate change have repeatedly been made. But in reality, this is true for many of the developmental challenges, be they environmental, economic, or social, which are all subject to increasingly dense webs of interactions and contacts. In this sense, distributing vaccines to the global population may seem like an early example of what will be the new normal of challenges, and the COVID-19 pandemic could be viewed as a valuable learning experience. It might be wise to seize this opportunity to draw lessons for ongoing and future challenges, both related to vaccine provision and otherwise.

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