

The horrible history of Big Pharma

Why we can't leave pharmaceutical corporations in the driving seat of the Covid-19 response



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Executive summary

Any long-term solution to the deadly Covid-19 pandemic involves the discovery and equitable distribution of an effective vaccine and treatment options. Yet, across the world, governments are handing responsibility for Covid-19 solutions over to big pharmaceutical firms, who have a long track record of prioritising corporate profit over people's health.

The pharmaceutical industry is one of the biggest and most profitable in the world. Many of the individual corporations that constitute 'Big Pharma' enjoy annual revenues well in excess of the majority of countries on the planet. Judged by revenue, Johnson & Johnson is wealthier than even rich countries like New Zealand and Hungary. Pfizer's revenues are bigger than oil-rich Kuwait or Malaysia.

Leaving Moderna aside, which currently has no products on the market, the six other giant corporations covered in this report made combined revenues of \$266 billion last year, with profits of \$46 billion. Consider these figures in comparison with the US's unprecedented programme of public spending on vaccine development, which could reach \$18 billion, but is currently at around £11 billion, most of which has been handed over to the same rich corporations detailed in this report.²

Many commentators look at the work of some of these corporations in 2020 – developing vaccines at breakneck speed – and conclude that, whatever the problems with 'Big Pharma', they have nearly delivered the goods.

But this is to miss many important elements of the story which, when taken together, show that the current pharmaceutical model is actually deeply flawed, with its drive to make sky-high returns to shareholders, not a healthier population. The pursuit for very high returns incentivises the most appalling behaviour.

The cases we examine include:

GlaxoSmithKlein (GSK) which, less than ten years ago, was handed a \$3 billion fine after it admitted to giving kickbacks to doctors in the US and encouraging the prescription of unsuitable antidepressants to children.³ Doctors and their spouses were flown to five-star resorts, given \$750, and access to snorkelling, golf and deep-sea fishing.⁴ The corporation also published an article in a medical journal which misled about the safety of a drug in children, and then used the piece to try to drum up business.⁵

GSK has also been fined in Britain for paying producers of generic drugs to delay entry of generics onto the market.⁶ And it hiked the price of an asthma inhaler by nearly 18% on the US market, raising the price to often over \$300 per month,⁷ helping this blockbuster drug make the corporation over \$100 billion.⁸

Pfizer was in the top 30 most profitable corporations in the world last year, with \$52 billion in revenue and a whopping \$16 billion in profits. Back in 2013, a case study revealed one small example of how it reached that position. Pfizer and its UK distributor Flynn hiked the price of on anti-epilepsy drug which 48,000 UK patients relied upon. As a result, NHS expenditure on the capsules rose from about £2 million a year in 2012 to about £50 million in 2013 with the price of 100mg packs of the drug rising from £2.83 to £67.50, before reducing to £54 from May 2014. Overall, UK wholesalers and pharmacies faced price hikes of 2,300% – 2,600%.

Meanwhile, Pfizer's testing of experimental new drugs during a meningitis outbreak in Kano, Nigeria, dogged the corporation for 20 years, and was reportedly the inspiration for John le Carré's novel The Constant Gardener.¹² Pfizer tested a new drug during a serious meningitis outbreak.¹³ But an employee claimed Pfizer's trial violated ethical rules,¹⁴ and in the years that followed, several lawsuits were initiated, in Nigeria and the US, with

claims that the parents hadn't given meaningful consent because they hadn't realised their children were part of an experimental trial.¹⁵ Ultimately, Pfizer agreed to out of court settlements of \$75 million with the state of Kano¹⁶ as well as payments of \$175,000 to four sets of affected parents¹⁷ and denied any wrongdoing.

In 2013, Gilead faced extensive criticism for the pricing of its new hepatitis C drug (and possible Covid-19 treatment) Sovaldi, introduced to the US market at \$84,000 for a 12-week course. A US Senate committee investigation concluded: "it was always Gilead's plan to max out revenue, and ... accessibility and affordability were pretty much an afterthought."18 Gilead's next hepatitis C drug, Harvoni, was priced at \$94,500. Following release of these drugs, Gilead's corporate profits increased fivefold to \$21.7 billion¹⁹ with Hep-C drugs generating nearly \$62 billion in sales since 2013.²⁰

While drug companies typically claim that high prices are necessary to recoup the high costs of manufacturing, this kind of defence looks ridiculous in the case of Sovaldi. According to Professor Jeffrey Sachs, Gilead may have spent around \$300 million on research and development (R&D) for the drug,²¹ a figure that would be recouped in just a few weeks of US sales of the drug. To add insult to injury, the advocacy group Americans for Tax Fairness, accuse Gilead of reducing its tax bill by moving some of its intellectual property to Ireland, cutting \$10 billion between 2013 and 2015, the period in which its profits were booming from its hepatitis C medications.²²

Johnson & Johnson (J&J), currently the biggest pharmaceutical corporation in the world, made \$82 billion in revenue over the last year, and \$15 billion in profit.²³ It was the seventh most profitable corporation in the US in 2020,²⁴ and in the top 30 most profitable corporations in the world.²⁵ Perhaps this is unsurprising given its record of hiking prices. Between 2016 and 2018, for example, the company increased the US price of bestselling leukaemia and prostate cancer drugs by 19% and a HIV medication by 16%.26

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J&J owns the patent for bedaquiline – one of only three new tuberculosis drugs to be developed in over 50 years.²⁷ But despite public investment and subsidies for the drug constituting five times the investment put in by J&J,²⁸ the corporation has sole rights to determine the countries in which the drug is sold.²⁹ Médecins Sans Frontières (MSF), which contributed to the development of the drug, has criticised J&J for the prohibitive costs it has placed on access, arguing that the drug could be produced at a profit for just \$0.25 per day and, therefore, should be sold at no more than \$1 per day – \$600 for a 20-month treatment. The lowest price J&J charges is double this, with the price much higher in countries ineligible to purchase through the Global Drug Facility – including Indonesia, the Philippines and Angola.³⁰

Pfizer and GSK produced a vitally important pneumonia vaccine,31 which MSF claims is far too expensive for many of those who need it.32 While MSF has won price reductions for lower income countries,³³ it says the reductions are not close to sufficient, as the costs are still "roughly US\$9 for each child to be vaccinated in the poorest countries, and as much as \$80 per child for middle-income countries that don't qualify".34 Campaigners claim: "Pfizer and GSK have earned over \$50 billion in sales of the pneumococcal vaccine in the past ten years, with Pfizer winning the lion's share of these revenues. Today, 55 million children around the world still do not have access to the pneumonia vaccine, largely due to high prices."35

Sanofi is the sixth biggest corporation in France, making \$42 billion in revenue and \$3 billion in profit last year. It has been accused of hiking up prices for their insulin Lantus³⁶ by 18% each year from 2012 to 2016 in the US, during which time \$22 billion of US public money was paid out via Medicare and Medicaid to purchase the drug.³⁷ Sanofi repeatedly blocked the emergence of competition for Lantus in the US by filing 74 patents applications, with the potential to delay the emergence of competition for 37 years.38

In May 2020, **AstraZeneca** (AZ) usurped Shell to become the UK's most valuable company by market capitalisation (the total value of a company's outstanding shares), with a 15% gain in equity so far this year to £115 billion.³⁹ The company has a relatively clean image compared to some of its competitors, but not an unblemished one. It has been accused, among other things, of preventing generic competition. The European Court of Justice upheld a decision made by the European Commission that found AZ guilty of abusing its market position to delay the introduction of generic versions of its stomach ulcer treatment Losec. When AZ introduced a second-generation version of Losec to the market, the company deregistered its market authorisation for Losec in several EU member states. AZ's move prevented generic drug manufacturers from relying upon the clinical trials conducted for the treatment, undermining the introduction of cheaper generic products, and AZ was ordered to pay €53 million.⁴⁰

These case studies are examples inherent in the current Big Pharma model. In short, the pharmaceutical sector is driven by the need for very high returns by a handful of mega corporations. In recent years, pharmaceutical corporations have often spent more on share buybacks to keep stock price high, and on dividend payments to wealthy shareholders, than they have on research and development of new drugs. All Many essential medicines, like new wave antibiotics, are currently not being developed precisely because Big Pharma believes there is insufficient profit involved.

Where useful research into essential medicines does actually take place, it is usually driven by public funding. And yet few conditions are placed on this funding, and big pharmaceutical corporations are allowed to sit on patents for a minimum of 20 years, monopolising supply and dictating prices. This artificially limits access to medicines at affordable prices - all to benefit from high profit margins.⁴³

Sadly, we can see these problems already at play in the development of coronavirus vaccines and treatments.

In early November 2020, **Pfizer** made headline news around the world when it announced its vaccine candidate was more than 90% effective in preventing

Covid-19.44 The announcement drew attention to the fact that Pfizer has so far made no promise to limit profits and has presold over one billion doses to rich governments, representing just 14% of the world's population. This represents 82% of the 1.35 billion doses Pfizer says it has the capacity to produce by the end of next year.⁴⁵ Pfizer has been outspoken in its desire to maintain patents and has derided attempts by the World Health Organisation (WHO) to create a patent-free mechanism to pool coronavirus research and development, commenting: "At this point in time, I think it's nonsense, and... it's also dangerous."46 Pfizer's drug is predicted to make \$13 billion in 2021.47 While the company claims not to have received any direct public support, its partner in the vaccine production process has received significant funding,48 and the massive advance bulk purchases of a drug of unknown efficacy (at the time of purchase) represents significant public resources.49

Moderna has also issued positive results for its vaccine but has already sold 780 million doses to rich governments - representing 78% of the one billion doses the corporation says it has the capacity to produce by the end of next year.⁵⁰ Public money totalling \$2.5 billion directly contributed to this vaccine.⁵¹ Campaign group Public Citizen claims that in effect this means "Taxpayers are paying for 100% of Moderna's COVID-19 vaccine development. All of it".52 Yet the USA has subsequently bought up to 600 million doses, an amount thought likely to make the company \$8 billion.53 What's more, Moderna is proposing a vaccine cost well above the average. Moderna's two-dose vaccine regimen is estimated to cost between \$64 and \$74 per person under its cheaper 'pandemic pricing'.54

Moderna has also been criticised for the huge amount of stock its corporate executives sold after the company announced early positive results in May 2020, when its stock price rose rapidly,⁵⁵ even though the results weren't released in any detail.⁵⁶ Hours after releasing, two Moderna executives sold off nearly \$30 million in automated sale shares. Days later, Moderna's leading shareholder sold 1 million shares, earning \$69.5 million.⁵⁷ Former Securities and Exchange Commission officials said the events were "highly problematic" and worthy of investigation.⁵⁸

Gilead made an extraordinary application in the US for 'orphan status' on its drug remdesivir which it was believed could be used in the treatment of coronavirus.⁵⁹ This status gives special protection for drugs that could help a tiny number of patients – the very opposite of a pandemic. A public outcry led Gilead to withdraw their request and reverse the status.⁶⁰ Nonetheless, amid the spike in interest in remdesivir, Gilead's expenditure on lobbying US Congress reached a record high of \$2.45 million in the first quarter of 2020.⁶¹ Perhaps even more alarming, Gilead's treatment has not been judged very effective,⁶² and the WHO recommends against using it.⁶³

GlaxoSmithKline and Sanofi are working on a vaccine which has received over \$2 billion for drug development and expansion of manufacturing capacity. Up to a billion doses have been presold to rich countries, with 200 million made available for global distribution through COVAX. But according to Sanofi CEO Paul Hudson, the US would likely get access to the vaccine before the rest of the world.64

The promising vaccine being developed by Oxford University was to be produced on a nonexclusive, royalty-free basis. The director of Oxford's Jenner Institute told the media "I personally don't believe that in a time of pandemic there should be exclusive licenses." However, on entering a deal with AstraZeneca, the situation changed. The deal is exclusive and while the company maintains it will not profit during the pandemic, it has failed to release details of its contract and how it calculates research costs. It has been reported that AZ has the right to declare an end to the pandemic as soon as July 2021 with respect to its non-profit promise.65 This would leave AZ free to charge monopoly prices on this public-funded vaccine beyond that point, even if the WHO has not officially declared an end to the pandemic.

Everyone wants to end this pandemic as quickly as possible. Most of us are excited by the positive vaccine trial results and amazed by the ingenuity of the scientists who have got us to this stage so quickly. And yet, we could do better and help end the pandemic in a fair and equitable way.

Imagine if the drive of the pharmaceutical corporations for ever greater profit was removed from the equation. Imagine if we could replace

cutthroat competition and secrecy with collaboration and openness. Imagine if our research was driven solely by the desire to rid the world of disease and suffering, starting with the most serious and deadly conditions. When combined with our technological knowhow, the dedication of our brilliant researchers and the trust which such a model could inspire in the population at large, imagine what we could achieve.

Coronavirus gives us the opportunity to reset the way we produce medicines. If we seize the opportunity, the health of people across the world could look very different. If we achieve that, this awful pandemic could give way to a better, fairer world.

To achieve this, we need to put in place a better system. We are calling on the UK government to take following steps to ensure fair and affordable access to Covid-19 related health products:

- Impose conditions on all UK funding committed to developing Covid-19 vaccines and treatments to ensure there are no monopolies on publicly funded health products.
- Join and support the WHO's Covid-19
 Technology Access Pool that will facilitate the open licensing and technology transfer of Covid-19 related health products.
- 3. Support the proposal submitted by the governments of India and South Africa to waiver the relevant chapters of the WTO global agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the prevention, containment and treatment of Covid-19.
- 4. Where patient access or research is restricted by intellectual property rights, issue Crown Use Licences for any patented technologies that are potentially useful for tackling Covid-19 and actively support other countries to do likewise.
- Leverage the UK's position on the Gavi Board to ensure urgent changes are made to the COVAX Facility to push for at-cost prices, fair allocation between self-financing and funded countries, transparency and support for the COVID-19 Technology Access Pool.
- 6. Cease the UK's advanced purchasing of potential vaccines and contribute vaccine doses secured through bilateral deals to the COVAX mechanism above the minimum level required by the WHO's Fair Allocation Framework.

Introduction

The pharmaceutical industry is one of the biggest and most profitable in the world. Many of the individual corporations that constitute 'Big Pharma' enjoy annual revenues well in excess of the majority of countries on the planet. Judged by revenue, Johnson & Johnson is wealthier than even rich countries like New Zealand and Hungary. Pfizer's revenues are bigger than oil-rich Kuwait or Malaysia.

Leaving Moderna aside, which currently has no products on the market, the six other giant corporations covered in this report made combined revenues of \$266 billion last year, with profits of \$46 billion. Consider these figures in comparison with the US's unprecedented programme of public spending on vaccine development, which could reach \$18 billion,66 but is currently at around £11 billion, most of which has been handed over to the same rich corporations detailed in this report.67

Many commentators look at the work of some of these corporations in 2020 – developing vaccines at breakneck speed – and conclude that, whatever the problems with 'Big Pharma', they have nearly delivered the goods.

But this is to miss many important elements of the story which, when taken together, show that the current pharmaceutical model is actually deeply flawed, delivering outcomes which are poor value for money for the public sector, which exacerbate global inequality and which are driven by the objective to make sky-high returns to shareholders, not a healthier population.

We find that this central drive in the industry for very high returns incentivises the most appalling behaviour including aggressive marketing of inappropriate drugs, kickbacks to doctors, claims of testing drugs on children without proper consent, massive price hikes on essential medicines, profiteering, blocking competition, and secrecy.

Some of this behaviour has given rise to serious legal challenges and even some of the largest fines in history. Despite all of this, governments like our own regularly claim, despite all evidence to the contrary, that these incentives are vital for the production of medicines.

Before documenting this behaviour and examining the companies themselves, it's worth summarising the fundamental problems of our current pharmaceutical model:

The pharmaceutical sector is driven by the need for very high returns among a handful of mega corporations. In recent years, pharmaceutical corporations have often spent more on share buybacks to keep stock prices high, and dividend payments to wealthy shareholders, than they have on research and development of new drugs.⁶⁸ In fact, many essential medicines, like new antibiotics, are currently not being developed precisely because Big Pharma believes there is insufficient profit involved.⁶⁹ It is entirely possible that a vaccine, or at least an effective treatment regime, could have quickly been developed if we'd had a sector that was focused on making people healthy, rather than one structured around the imperative of accruing as much wealth from illness as possible.7071

Where useful research into essential medicines does actually take place, it is usually driven by public funding. This report looks at how this is the case in the coronavirus pandemic, where a mix of basic research funding, support for clinical trials, expansion of manufacturing capability and, not to forget, mass bulk purchase of untested medicines has allowed for the rapid development of the treatments we so desperately need. But this situation is not unusual. Most essential medicines depend upon public funding.⁷²



Sadly, few conditions are placed on this funding, and big pharmaceutical corporations are allowed to sit on patents for a minimum of 20 years, monopolising supply and dictating prices. This artificially limits access to medicines at affordable prices – all to benefit from high profit margins.⁷³ Private companies might well have a role to play in the development and distribution of medicines, but payment should not come in the form of monopoly power.

Coronavirus gives one of the most distrusted industries in the world⁷⁴ an opportunity to resuscitate its image, if it can convince the public that it has 'delivered the goods' – vaccines and treatments for coronavirus. Its public relations machine has gone into overdrive, with some corporations even promising not to profit⁷⁵ from any such drugs 'during the pandemic'.

But look closer and the dangers of leaving the world's healthcare in the hands of these corporations is already obvious: a lack of transparency and collaboration, artificial shortages of desperately needed medicines; a focus on selling most medicines to very rich countries, which is not only unfair but will actually make it much harder to control the virus;⁷⁶ and the transfer of vast amounts of public money into private hands for profiteering. Indeed, the fact that the outline of these problems is widely understood could be one driver of the worrying growth of 'anti-vax' sentiment in society.⁷⁷

Everyone wants to end this pandemic as quickly as possible. Most of us are excited by the positive vaccine trial results and amazed by the ingenuity of the scientists who have got us to this stage so quickly. And yet, we could do better and help end the pandemic in a fair and equitable way.

Imagine if the drive of the pharmaceutical corporations for ever greater profit was removed from the equation. Imagine if we could replace cutthroat competition and secrecy with collaboration and openness. Imagine if our

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research was driven solely by the desire to rid the world of disease and suffering, starting with the most serious and deadly conditions. When combined with our technological knowhow, the dedication of our brilliant researchers and the trust which such a model could inspire in the population at large, imagine what we could achieve.

Coronavirus gives us the opportunity to reset the way we produce medicines. If we seize the opportunity, the health of people across the world could look very different. If we achieve that, this awful pandemic could give way to a better, fairer world.

About this report

This report sets out the track record of the companies touted as leading players in the race to develop a Covid-19 vaccine. Each chapter summarises the history of these firms, bringing to light a series of controversies and malpractices that show we cannot trust them to provide safe and fair solutions to the global pandemic.

Some of these companies have already demonstrated they are conducting business as usual and while some claim to be developing Covid-19 vaccines and treatments without a profit, in many instances these firms are financially benefiting from bumper share price increases.

We also document the deals companies have secured with high income countries which are accelerating the damaging race to hoard vaccines at the expense of a coordinated global response with a serious risk that low and middle incomes countries will be left without.

The report concludes with a series of recommendations directed at the government to ensure that Big Pharma behaviour does not impede equitable global access to vital Covid-19 vaccines and treatment.

1. Johnson & Johnson

Summary*

Johnson & Johnson (J&J) is the world's largest pharmaceutical drug company in the world, making \$82 billion in revenue and \$15 billion in profit over the last year.

- J&J claims it will have a Covid-19 vaccine ready for early 2021, with the backing of \$456 million of US public money.
- In the first year of the Trump administration alone,
 J&J raised the prices of two of its bestselling drugs
 blood thinner Xarelto and Stelara, a treatment for cancer and rheumatoid arthritis by over 16%.
- J&J has been criticised for refusing to grant access to three HIV drugs – rilpivirine, darunavir and etravirine.
- J&J has a track record of profiteering from the public purse: public investment in TB drug bedaquiline was up to five times the investment committed by J&J. However, J&J alone owns the patent on bedaquiline in many countries and has

- sole rights to determine the countries in which the drug is sold. Médecins Sans Frontières (MSF) argues the drug could be produced and sold at a profit for \$0.25 per day, but the lowest price J&J charges is \$2 per day (and in most countries far more than this).
- J&J's handling of vaccines has recently proved controversial in the case of Ebola. In July 2019
 Democratic Republic of the Congo health minister
 Dr Oly Ilunga Kalenga insisted that a clinical trial of J&J's Ebola vaccine would not go ahead in his country after J&J allegedly failed to listen to the concerns of DRC officials regarding its deployment.
- J&J also has a track record of safety concerns, which have led to a number of product recalls and legal challenges over the years. For example, in 2018, a jury in Missouri ordered the company to pay \$4.7 billion in damages to 22 women sufferers of ovarian cancer who alleged that their illness was caused by J&J talc-based baby powder.

*References in this summary can be found in this chapter

Johnson & Johnson is currently the biggest pharmaceutical corporation in the world, making \$82 billion in revenue over the last year, and \$15 billion in profit. It was the seventh most profitable corporation in the US last year, and in the top 30 most profitable corporations in the world, earning investors 16%. To put this in context, judged by revenue, Johnson and Johnson is vastly more wealthy than most countries in the world – richer even than rich countries like New Zealand and Hungary.

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Covid-19

Johnson & Johnson (J&J) has been working on a vaccine since January 2020, announcing its selection of a leading candidate in March. J&J began its human clinical studies on its lead vaccine in September 2021⁸² and has said that first batches of the vaccine could be available from early 2021.⁸³ The company claims the vaccine would be available on a not-for-profit basis for emergency pandemic use.⁸⁴ However, if the virus becomes endemic in our society, J&J would be able to profit and charge whatever price it wishes for doses after the official pandemic is declared over.

Significant amounts of public funding have been committed to Covid-19 vaccine development. The US Department of Health and Human Services, has invested almost half a billion dollars (\$456 million) of public money in J&J subsidiary Janssen

Pharmaceuticals for research, development and testing of the vaccine as well as \$1 billion to support a manufacturing demonstration.85

Table 1:

Advanced sales of Covid-19 vaccine doses

Buyer	Details	Value (if reported)
UK	30 million doses with option of additional 22 million doses ⁸⁶	
Canada	38 million doses ⁸⁷	
USA	100 million doses with option to buy a further 200 million ⁸⁸	"Over \$1bn" ⁸⁹
EU	200 million doses with option for further 200 million later ⁹⁰	
Lower income countries	500 million doses ⁹¹	

Corporate share value92

On 30 March 2020, J&J announced that a phase I human clinical study of its vaccine would begin in September.93 Its share price jumped 8% on the day of the announcement.94 By 23 April, less than one month later, its share price had increased by 16.9%.95 Share price increased 19.6% in the year between 30 August 2019 and 31 August 2020.96

Price-gouging

J&J is notorious for its high prices for essential medicines. According to the US-based Institute for Clinical and Economic Review, between 2016 and 2018, J&J increased the US price of a number of its bestselling drugs as follows:97

- Leukaemia drug Imbruvica (ibrutinib) by 19.0%
- Prostate cancer drug Zytiga (abiraterone acetate) by 18.6%
- HIV drug Prezista/Prezcobix (darunavir, darunavir/ cobicistat) by 16.4%
- Psoriasis drug Stelara (ustekinumab) by 15.8%
- Anti-psychotic drug Invega Sustenna/Invega Trinza (paliperidone palmitate) by 14.7%
- Cancer drug Darzalex (daratumumab) by 10.2%
- Autoimmune disease drug Remicade (infliximab) by 4.9%

Indeed, in the first year of the Trump administration alone, J&J raised the prices of two of its bestselling drugs – blood thinner Xarelto and Stelara, a treatment for cancer and rheumatoid arthritis – by over 16%.98

J&J revealed its logic around its pricing in its handling of controversy around marketing Levamisole, a drug used to treat colon cancer, in the 1990s. This drug was a reformulated version of a pill sold to treat sheep for worms. Yet as a cancer treatment, a year's medicine cost \$1,495 – 100 times the price of the equivalent pill sold for animal-usage.99 Questioned about this pricing decision on live television, J&J vice president at the time Robert Gosson explained: "A sheep farmer probably would not pay \$6 a pill."100

Blocking access

J&J has also been criticised for refusing to grant access to three HIV drugs - rilpivirine, darunavir and etravirine – for which the company holds key patents. Although J&J agreed to grant rights to produce and distribute lower-priced versions of rilpivirine to three generic drug makers within sub-Saharan Africa, MSF argued that this was not good enough as the agreement did not cover all of Africa and did not provide a sufficient cost reduction.¹⁰¹ Indeed, J&J refused to participate in the Medicines Patents Pool at the time, which seeks to increase access to vital medicines across the global south.¹⁰²

Profiting from the public purse

J&J's pricing of its tuberculosis (TB) medication bedaquiline has recently proved controversial. Bedaquiline is just one of three new TB drugs to be developed in over 50 years and was hailed as a game changer in the TB treatment landscape.¹⁰³ It was developed by J&J alongside public and philanthropic partners. Indeed, public investment in bedaquiline was up to five times the investment committed by J&J.¹⁰⁴ This includes being awarded a priority review voucher by the US Food and Drug Administration (FDA),¹⁰⁵ a significant financial bonus for the company which can be used to accelerate marketing approval for other of its products in the future.

However, J&J alone owns the patent on bedaquiline in many countries and has sole rights to determine the countries in which the drug is sold. 106 Civil society organisations such as MSF which contributed to the development of the drug have subsequently criticised J&J for the prohibitive costs it has placed on access to the drug. MSF argued that the drug could be produced and sold at a profit for just \$0.25 per day and, therefore, should be sold at no more than \$1 per day. However, the lowest price J&J charges is double this, with the price much higher in countries ineligible to purchase through the Global Drug Facility – ineligible buyers include many poorer countries of the global south and many that are among those worst affected by TB, including Indonesia, the Philippines and Angola.¹⁰⁷

Safety concerns

J&J also has a track record of safety concerns, which have led to a number of product recalls and legal challenges over the years. In 2010 J&J subsidiary McNeil Consumer Healthcare recalled seven over-the-counter children's medicines after concerns around manufacturing specifications came to light in an inspection of a Pennsylvania manufacturing facility.¹⁰⁸

In 2018, a jury in Missouri ordered the company to pay \$4.7 billion in damages to 22 women sufferers of ovarian cancer who alleged that their illness was caused by J&J talc-based baby powder contaminated with carcinogen asbestos. 109 Although the size of the fine was reduced on appeal, the ruling stands, with J&J saying it will take the case to the US supreme court.¹¹⁰ This was just one of 21,800 lawsuits brought against the company around links between its talcum powder and cancer.¹¹¹ Although J&J denies these links and has won some of these cases, in May 2020 it decided to stop selling talcbased baby powder in the US and Canada.¹¹²

In 2019, J&J agreed to a \$120 million settlement following concerns around subsidiary DePuy Orthopaedics' misrepresentation of the effectiveness, durability and safety of hip replacement products, which were found to have violated consumer protection laws. 113 DePuy announced a worldwide recall of its hip implant systems in 2010, saying that 12% of them failed within five years.¹¹⁴ J&J was reported by 2019 to have paid out about \$1 billion settling thousands of hip replacement lawsuits.¹¹⁵

Safety concerns are especially significant in the context of Covid-19 vaccine development where it has been reported that the industry is pressuring authorities for exemptions from product liability. Vaccine Europe – which represents a number of companies including Janssen (which belongs to Johnson & Johnson) – has been advocating a "comprehensive no-fault and non-adversarial compensation system, and an exemption from civil liability".116

2. AstraZeneca

Summary*

- In May 2020, AstraZeneca (AZ) became the UK's most valuable company by market capitalisation, with a 15% gain in equity so far this year to £115 billion.
- AZ is developing the much-touted University of Oxford vaccine on the back of over \$1 billion investment from the US government alongside £20 million from the UK government.
- The company has pledged to make no profit on from this publicly funded vaccine during the pandemic, however it has been revealed that the company will define when that will be and at the earliest will be July 2021.
- In 2018, many of AZ's US drug prices were raised by between 5% and 10% – price hikes described as 'modest' by CEO Pascal Soriot.
- In 2014, AZ withdrew all early-stage research and development for tuberculosis, malaria and neglected tropical diseases. It was subsequently criticised for prioritising products with commercial markets in the global north instead of less profitable treatments for health conditions more typical in countries of the global south.

- AZ has a track record of product hopping (making minor changes in a drug as its patent is about to expire and rebranding to block new competitors) particularly with regards to indigestion and stomach ulcer medication.
- In 2010, AZ agreed to a \$520 million settlement over allegations that the company defrauded US government-funded care programs such as Medicare and Medicaid in relation to its marketing of antipsychotic drug Seroquel.
- AZ has paid out almost \$350 million to resolve thousands of lawsuits alleging links between antipsychotic medication Seroquel and diabetes.
- In 2010, AZ agreed to a £505 million settlement to HMRC after a 15-year dispute relating to "transfer pricing", whereby profits from a subsidiary in a higher tax jurisdiction are registered to another subsidiary in a lower tax jurisdiction.

*References in this summary can be found in this chapter

AstraZeneca made £25 billion in revenues last year, and £1 billion in profits, 117 putting it in the top 20 British corporations. 118 In May 2020, AstraZeneca (AZ) usurped Shell to become the UK's most valuable company by market capitalisation (the total value of a company's outstanding shares), with a 15% gain in equity so far this year to £115 billion. 119

Covid-19

AZ owns the licence to one of the most promising potential Covid-19 vaccines, AZD1222, developed at the University of Oxford. AZ has received over \$1 billion investment from the US Biomedical Advanced Research and Development Authority (BARDA) to support the development and production of the vaccine. 120 The UK government has also invested £67.7 million in the Oxford University research and trials. 121 AZ has pledged that it will not profit from the vaccine 'during the pandemic'. 122 In spite of numerous demands 123 for transparency to scrutinise these claims, it has failed to release details of its contract and how it calculates research costs. 124

It has subsequently been reported that AZ has the right to declare an end to the pandemic as early as July 2021 with respect to its non-profit promise.¹²⁵ This would leave AZ free to charge monopoly prices on this publicly funded vaccine beyond that point, even if the WHO has not officially declared an end to the pandemic.

The director of Oxford's Jenner Institute told the media "I personally don't believe that in a time of pandemic there should be exclusive licenses."126 However, on entering a deal with AZ, the situation changed. It has also been reported that intervention from Bill Gates was a factor in preventing the Oxford University vaccine from being available on a non-exclusive, open licence basis. 127

AZ has dismissed moves towards patent-free collaborative coronavirus research via the World Health Organisation. AZ chief executive Pascal Soriot argued that intellectual property is "a fundamental part of our industry and if you don't protect IP, then essentially, there is no incentive for anybody to innovate.¹²⁸ However, in this instance, the Covid-19 vaccine innovation has been largely researched and developed by Oxford University using public funds. 129

Corporate share value

Taking on the manufacture and distribution of the Oxford University vaccine has not been without financial benefits. After months of decline, AZ's share prices began to rise sharply on Monday 16 March 2020,130 at a time when the extent of the pandemic was beginning to become clear, as widespread speculation about a UK lockdown mounted. By 20 June, just over three months later, its share price had increased by 49.8%.¹³¹ During this period, on 30 April, AZ announced its vaccine collaboration with Oxford University.¹³² By 13 May, less than two weeks later, its share price had increased by 8.2%.¹³³

Price gouging

In 2018 the prices of many of AZ's drugs were raised by between 5% and 10% in the US – price hikes described as "modest" by CEO Pascal Soriot. 154

In another instance, when AZ learned that a generic version of its Crestor treatment for high cholesterol was coming to market, AZ rapidly hiked prices for Crestor several times, including a 15% increase just before the generic drug was released.¹⁵⁵

Withdrawn R&D

In 2014, AZ withdrew all early-stage research and development for tuberculosis, malaria and neglected tropical diseases.¹⁵⁶ Commenting on the decision, head of innovative medicines and early development at AZ Mene Pangalos said: "We have limited R&D budgets ... You can spread yourself so thin you end up not doing anything well." AZ's decision to withdraw from this R&D seems to have been driven by a desire to streamline its business operations around its core priorities of cancer and cardiovascular, respiratory and autoimmune diseases. It was subsequently criticised for prioritising products with commercial markets in the global north instead of less profitable treatments for health conditions more typical in countries of the global south. Neil Schluger, Chief Scientific Officer of the World Lung Foundation said: "Drug companies want to make drugs for chronic diseases that people in western countries are going to take for the rest of their lives."157

MSF commented that "AstraZeneca would never withdraw its R&D into these diseases if they affected rich countries or if there was more of an incentive to produce them – instead, they're going where they see the biggest profits, and it's not in these drugs."158

AstraZenca has secured numerous deals with governments as well as other suppliers.

Advanced sales of Covid-19 vaccine doses Table 2:

Buyer	Details	Value (if reported)
UK	100 million doses including 30 million by September ¹³⁴	
USA	"At least 300 million doses" 135	\$1.2bn ¹³⁶
EU	400 million doses ¹³⁷	
Brazil	100 million doses ¹³⁸	
Australia	25 million doses, which Australia claims will be given to all citizens free of charge ¹³⁹	
Japan	120 million doses ¹⁴⁰	
Panama	1.09 million doses ¹⁴¹	
Morocco	17 million doses with option for an extra 3 million doses ¹⁴²	
Switzerland	5.3 million doses ¹⁴³	
Bangladesh	30 million doses ¹⁴⁴	
Egypt	30 million doses ¹⁴⁵	
Canada	20 million doses ¹⁴⁶	
China	Exclusive clinical development, production and commercialisation rights to manufacture the AZ vaccine in China given to BioKangtai, which will be able to make at least 100 million doses by the end of 2020 and 200 million doses per year by the end of 2021. ¹⁴⁷	
Indonesia	100 million doses ¹⁴⁸	
India	See Serum Institute in table below	
CEPI/Gavi	300 million doses ¹⁴⁹	\$750m ¹⁵⁰
Serum Institute of India (Indian drug firm)	1 billion doses earmarked for low and middle income countries, beginning with 400 million doses in 2020 ¹⁵¹	
RPharm (Russian drug firm)	RPharm will produce and distribute the AZ drug to Russia, Armenia, Azerbaijan, Belarus, Kazakhstan, Kyrgyzstan, Moldova, Tajikistan, Uzbekistan. Number of doses yet to be determined. ¹⁵²	
mAbxience (biotec company of the Spanish Insud Pharma group)	200 million doses to be produced in Argentina and Mexico and supplied to all Latin American countries except Brazil ¹⁵³	

Blocking cheaper competitors

Product hopping is a common strategy deployed by pharmaceutical firms when a patent for one of its drugs is about to expire. To block new competitors, companies "product hop" by making a minor change to the patented drug and introducing this new revised drug to the market as a rebranded product with a new patent. Companies will then devote considerable resources to persuading pharmacists, doctors and patients to move to the new version of the drug before any cheaper generic drug enters the market.

AZ executed a product hop in 2001 with its heartburn drug Prilosec. With the patent for this drug due to expire, AZ made a slight molecular modification and rebranded the drug as Nexium with a new patent. It then persuaded doctors to begin prescribing the new brand, despite protestations from some doctors and experts that Nexium is no different from its predecessor.¹⁵⁹

The European Court of Justice upheld a decision made by the European Commission that found AZ guilty of abusing its market position to delay the introduction of generic versions of its stomach ulcer treatment Losec. When AZ introduced a second-generation version of Losec to the market, the company deregistered its market authorisation for Losec in several EU member states. AZ's move prevented generic drug manufacturers from relying upon the clinical trials conducted for the treatment, undermining the introduction of cheaper generic products, and AZ was ordered to pay €53 million.¹⁶⁰

Fraud

In 2010, AZ agreed to a \$520 million settlement over allegations that the company defrauded US government-funded care programs such as Medicare and Medicaid in relation to its marketing of antipsychotic drug Seroquel. AZ was found to have illegally marketed the drug for uses not approved as safe and effective by the Food and Drug Administration (FDA).¹⁶¹ In 2009 alone, AZ made nearly \$5 billion from sales of the drug.¹⁶²

Safety concerns

In a 2004 University of Minnesota trial of AZ's antipsychotic medication Seroquel – a trial designed and funded by AZ, with delivery

outsourced to a research organisation – a participant in the trial named Dan Markingson committed suicide. According to Minnesota bioethics Professor Carl Elliott, Markingson was enrolled in the trial against the wishes of his mother, made to choose between participating in the trial or else being involuntarily sectioned.¹⁶³ Indeed, Markingson's mother made several attempts to remove her son from the trial – but to no avail.¹⁶⁴

Several questions have since been raised about the AZ trial: the trial prohibited subjects from being taken off the drug and restricted the usage of further medication to limit side-effects such as depression and anxiety. While most antipsychotic trials ban subjects at risk of violence to others or at rick of suicide attempts from participating, the AZ study only barred those deemed at risk of suicide. Had the conventional protocol been followed, Markingson would not have been able to join the trial.¹⁶⁵ Of particular concern was the fact that under AZ's agreement with the university, the company paid \$15,000 for every successful trial patient enrolled providing a financial incentive to push ahead with trials.166 Indeed, various academics have criticised the study in which Markingson died for its failure to compare Seroquel to older antipsychotic drugs. Commenting on the study, Cardiff University senior psychiatrist Dr David Healy said: "This is a non-study of the worst kind ... It is designed not to pick up a difference between the three drugs. It looks like an entirely marketing-driven exercise."167

AZ's Seroquel has proved controversial on other grounds as well. AZ reportedly paid out almost \$350 million to resolve thousands of lawsuits alleging links between Seroquel and diabetes.¹⁶⁸ Safety concerns are especially significant in the context of Covid-19 vaccine development. A senior executive at AstraZeneca told Reuters that the company has been granted protection from future product liability claims related to its Covid-19 vaccine by most of the countries with which it has struck supply agreements. 169

Tax avoidance

In 2010, AZ agreed to a £505 million settlement to HMRC after a 15-year dispute relating to "transfer pricing", whereby profits from a subsidiary in a higher tax jurisdiction are registered to another subsidiary in a lower tax jurisdiction.¹⁷⁰

3. GlaxoSmithKline

Summary*

- GlaxoSmithKline (GSK) is one of the biggest British corporations, with \$43 billion in global revenues last year. It is collaborating with Sanofi on a Covid-19 vaccine that has received \$30 million in US government funding. According to Sanofi CEO Paul Hudson, the US would likely get access to the vaccine before the rest of the world.
- GSK was sharply criticised by MSF for five years between 2009 and 2014 for the unaffordable pricing of its pneumonia vaccine. High costs meant that in 2016, one third of the world's countries had been unable to introduce the vaccine. Gavi, the Vaccine Alliance, has paid GSK and Pfizer around \$9 per child for the vaccine (on top of the subsidy), a price that is unaffordable for many countries in the global south and has subsequently led to vaccine shortages at several points across the course of the initiative.
- GSK has routinely exploited legal loopholes to block the market entrance of cheaper, generic versions of its drugs. For example, in 2016, the UK Competition and Markets Authority fined GSK £37.6 million after finding that GSK paid companies to delay the entrance of generic versions of its Paxil drug. When generics did finally enter the market, prices fell by 70%.
- In 2012, GSK agreed to the highest value health fraud settlement in US history, pleading guilty to: false advertisement pertaining to medication safety and efficacy; misbranding drugs; bribing doctors to promote and prescribe their medications; omitting safety data in Food and Drug Administration (FDA) reports; and inflating price reports to underpay government healthcare programs.
- In 2007, it came to light that GSK had given HK\$3.8 billion in kickbacks to doctors, hospitals and others who prescribed the drugs. GSK were found guilty of bribery for the case in 2014 and fined \$490 million.

*References in this summary can be found in this chapter

GSK is one of the biggest British corporations¹⁷¹ with \$43 billion in global revenues and \$6 billion profits last year. It's in the top 10 British corporations by market capitalisation.¹⁷² This is despite the fact GSK was handed one of biggest corporate fines in history less than a decade ago.¹⁷³

Covid-19

GlaxoSmithKline (GSK) has announced a collaboration with Sanofi to develop an adjuvanted vaccine for Covid-19. Phase I clinical trials are planned for the second half of 2020, aiming for the vaccine to be available by the second half of 2021.¹⁷⁴ The collaborative project has received \$30 million funding from the US Biomedical Advanced Research and Development Authority (BARDA). Therefore, according to Sanofi CEO Paul Hudson, the US would likely get access to the vaccine before the rest of the world.¹⁷⁵

Further to the Sanofi collaboration, GSK is also working with a number of other companies and research groups across the world to explore potential vaccines.¹⁷⁶ The company states, "(We) do not expect to profit from our portfolio of collaborations for Covid-19 adjuvanted vaccines. Any short-term profit that may be generated will be invested in support of coronavirus related research and long-term pandemic preparedness."177 These claims around not profiting in the short-term need to be substantiated by making the company's research and development costs transparent which it has not done to date.

GSK also claims that it will make its adjuvant "available to the world's poorest countries, through donations and by working with global institutions that prioritise access." 178 In spite of these claims, the company has not made any commitments to remove intellectual property barriers and to engage in open technology sharing - without which, supply will be restricted and therefore insufficient to meet global demand.

Table 3:

Advanced sales of Covid-19 vaccine doses

Buyer	Details	Value (if reported)
UK	60 million doses ¹⁷⁹	
USA	100 million doses with option to buy further 500 million ¹⁸⁰	\$2.1bn ¹⁸¹
EU	300 million doses ¹⁸²	
Canada	72 million doses ¹⁸³	
COVAX Facility (for global distribution)	200 million doses ¹⁸⁴	

Price gouging

In 2019, GSK increased its US prices for more than 30 of its drugs by between 1% and 5%, including blockbuster treatments for cancer and HIV.¹⁸⁵ This recent price hike comes as no surprise, given GSK's track record.

Take, for instance, the case of GSK's breakthrough Benlysta medication for lupus. Lupus is an autoimmune disease that disproportionately affects women of African, Asian and Latina heritage. Yet when Benlysta was released in the US, it was priced at approximately \$3,000 per month, rendering it unaffordable to many of those who need it.186

Or consider GSK's blockbuster asthma inhaler. Advair. Since its release in 2001, sales of Advair have exceeded \$100 billion, 187 yet in 2017 GSK hiked Advair's US price by 17.7%,188 meaning costs are often over \$300 per month.¹⁸⁹

Previous vaccine controversy

GSK (alongside Pfizer) was sharply criticised by MSF for seven years between 2009 and 2016 for their unaffordable pricing of its pneumococcal conjugate vaccine (PCV) to humanitarian organisations.¹⁹⁰ Pneumonia is the foremost cause of child mortality globally, killing around one million children each year, with children affected by conflict or humanitarian emergencies particularly at risk.¹⁹¹ Yet this is a disease that is preventable by the PCV vaccine, for which only Pfizer and GSK own the rights. Between 2009 and 2014, MSF lobbied these firms to offer a fair and sustainable price for PCV. High costs meant that, in 2016, one third of the world's countries had been unable to introduce the vaccine.¹⁹² Finally, in 2016, GSK agreed to lower prices for the vaccine for children caught up in humanitarian emergencies.193

In 2009, Gavi, the Gates foundation, the World Bank and several governments from around the world including the UK established a funding mechanism called the Advanced Market Commitment (AMC) to help stimulate more production of this lifesaving vaccine and accelerate its global rollout. AMC donors pledged \$1.5 billion to subsidise vaccine

providers to accelerate the global rollout of the pneumonia vaccine. Given that for a number of years only GSK and Pfizer produced the vaccine, the lion's share of this subsidy (\$1.2bn of the total \$1.5bn) has been enjoyed by GSK and Pfizer, who in addition to this have earned a combined sum of over \$2.6 billion in revenues from selling the vaccine to Gavi. 194

Gavi paid GSK and Pfizer around \$9 per child¹⁹⁵ for the vaccine (on top of the subsidy) in the poorest countries, a price that is unaffordable for many countries in the global south and has subsequently led to vaccine shortages at several points across the course of the initiative, particularly during 2012 and 2013.¹⁹⁶ Indeed, when donors decided to reserve some of the subsidy for a potential third vaccine manufacturer, GSK and Pfizer responded by diminishing their efforts to scale up vaccine production.¹⁹⁷ Drawing on this experience, MSF argues that similar global mechanisms devised around a Covid-19 vaccine must force pharmaceutical firms to provide vaccines at cost price.¹⁹⁸

Blocking cheaper competitors

GSK has routinely exploited legal loopholes to block the market entrance of cheaper, generic versions of their drugs. For example, in 2002 a US Federal Trade Commission study showed that GSK delayed the entry of a generic version of its antidepressant medication Paxil by 65 months through filing a series of patent infringement lawsuits that forced the FDA to pause approval on generic entries. ¹⁹⁹ GSK was subsequently sued in 49 states and Washington DC, ending in GSK settling for \$14 million. ²⁰⁰

In 2016, the UK Competition and Markets Authority fined GSK £37.6 million after finding that the firm paid companies to delay the entrance of generic versions of its Paxil drug.²⁰¹ When generics did finally enter the market, prices fell by 70% over the following two years.²⁰²

In 2013, GSK settled claims for a total of \$185 million²⁰³ in two legal actions where it was alleged that GSK had abused the US FDA citizen petition programme that allows citizens to submit concerns about products being assessed for approval by the agency.

It was alleged that GSK submitted several sham petitions before its patents for anti-allergen medication Flonase was due to expire, and through doing so were able to delay the release of a generic competitor for 23 months, earning the company an estimated \$2.5 billion.²⁰⁴

In 2019, a leaked memo showed that GSK was paying rebates to a pharmacy manager in return for their promotion of GSK's asthma inhaler Advair (see above for price gouging on this drug) instead of a new generic drug that was 70% cheaper.²⁰⁵

Safety concerns

In 2012, GSK agreed to plead guilty and to pay \$3 billion to resolve its criminal and civil liability arising from the company's unlawful promotion of certain prescription drugs, its failure to report certain safety data, and its civil liability for alleged false price reporting practices.²⁰⁶ The corporation admitted to giving kickbacks to doctors in the US and encouraging the prescription of unsuitable antidepressants to children.²⁰⁷ Doctors and their spouses were flown to five-star resorts, given \$750, and access to snorkelling, golf and deep-sea fishing.²⁰⁸ The corporation also published an article in a medical journal which misled about the safety of a drug in children, and then used the piece to try to drum up business.²⁰⁹ The resolution is the largest health care fraud settlement in US history and the largest payment ever by a drug company.²¹⁰

Previously, in 2010, the US Department of Justice fined GSK subsidiary, SB Pharmco Puerto Rico \$150 million for producing improperly made and adulterated drugs – including antiemetic Kytril; Bactroban, used to treat skin infections; Paxil, the anti-depressant; and Avandamet, a diabetes drug.²¹¹

Corruption

In 2013, GSK allegedly gave at least three billion yuan (HK\$3.8 billion)²¹² in bribes to doctors, hospitals and others to boost sales in China.²¹³ GSK was fined \$500 million for bribery in 2014.²¹⁴

4. Gilead

Summary*

- US pharmaceutical giant Gilead is the developer behind remdesivir, a potential Covid-19 treatment. A recent June 2020 phase III trial boosted hopes for the treatment. Responding to this news, one influential analyst has estimated that sales of the drug could total \$7.7 billion for Gilead by 2022.
- The development of remdesivir has benefited from significant US government support and investment, with the specific figure debated (\$70.5m according to Public Citizen).
- Gilead has come under fire for its pricing of Hep C drug Sovaldi and HIV drug Truvada. While Truvada costs less than \$67 per person per year to manufacture, in 2019 it was being sold at \$20,000 per person per year in the US.

- In 2019 the Trump administration announced that it would be suing Gilead for infringing upon patents for HIV drug Truvada, given that hundreds of millions of dollars in taxpayer money went into research that led to the patents.
- Gilead has also become notorious for its tax practices, accused of dodging tens of billions of dollars in tax via Irish tax loopholes.
- In 2018, Gilead announced an "access initiative", pledging lower prices for liposomal amphatericin B (L-AmB, a treatment for cryptococcal meningitis, the second biggest killer of people living with HIV) in 116 countries in the global south. Yet by June 2019, the drug had been registered in only six of the 116 countries and, where registered, was unaffordable.

*References in this summary can be found in this chapter

Gilead made \$22 billion in revenues last year and £5 billion in profits. Although smaller than some of its competitors' revenues, these profits still leave Gilead richer than most countries on earth judged by revenue.²¹⁵

Covid-19

US pharmaceutical giant Gilead is the developer behind remdesivir (brand name Veklury), a potential Covid-19 treatment.²¹⁶

Conventionally used as a broad-spectrum antiviral medication, remdesivir has been authorized for emergency use as a Covid-19 treatment in the US²¹⁷ and approved for use in Japan for people with severe Covid-19 symptoms.²¹⁸ It also received approval in the UK in May 2020 but will be rationed due to limited supply.²¹⁹ A recent, June 2020 phase III trial boosted hopes for the treatment: trial participants that took a five day course of remdesivir were 65% more likely to show clinical improvement at day 11 than those who did not.²²⁰ Responding to this news, one influential analyst has estimated that sales of the drug could total \$7.7 billion for Gilead by 2022.221

The development of remdesivir has benefited from significant US government support and investment. The amount committed by the US public purse to the development of the drug is unclear. Berkeley Professor Robert Reich recently claimed that remdesivir was developed with a \$37.5 million grant from the US government.²²² US advocacy organisation Public Citizen estimates that total government support for the development of the drug comes to at least \$70.5 million.²²³ Two eminent US lawmakers recently wrote to the US Department of Health and Human Services asking for information on how the agency might have funded the development of the drug.²²⁴ A 2015 research paper on the potential of remdesivir to tackle coronaviruses was co-authored by Gilead employees and government scientists.²²⁵

In March 2020, the US Food and Drug Administration (FDA) granted Gilead seven years of exclusive marketing rights for remdesivir using the Orphan Drug Act. Yet because this Act was intended for treatments pertaining to rare diseases that affect fewer than 200,000 people, this FDA decision attracted substantive criticism,²²⁶ which ultimately led to Gilead requesting that the FDA rescind their decision.²²⁷

Coinciding with the spike in interest in remdesivir, Gilead's expenditure on lobbying the US Congress reached a record high of \$2.45 million in the first quarter of 2020, a 32% increase on lobbying expenditure for the first quarter of 2019.²²⁸ Perhaps even more alarming, Gilead's treatment has not been judged very effective,²²⁹ and the WHO recommends against using it.²³⁰

Besides remdesivir, Gilead's hepatitis C treatment sofosbuvir (branded as Sovaldi) is also touted as a potential Covid-19 treatment. A Chinese research foundation – the Jack Ma Foundation – has given \$2.1 million to Columbia University researchers to investigate a series of potential Covid-19 treatments including Sovaldi.²³¹

Corporate share value

Gilead's share price increased 38.9% in just under four months between 21 January and 23 April.²³² On 26 February, Gilead announced two phase III clinical studies to investigate the potential of remdesivir as a Covid-19 treatment.²³³ By 6 March, just nine days after the remdesivir announcement, Gilead share prices had increased by 7.4%.²³⁴ By 23 April, just under two months following the remdesivir announcement, share prices had increased by 12.4%.²³⁵

Price gouging

In 2013, Gilead faced extensive criticism for the pricing of its new hepatitis C drug (and now possible Covid-19 treatment) Sovaldi. Sovaldi was introduced to the US market at \$84,000 for a 12-week course of the treatment (\$1,000 per pill). A public backlash against this exorbitant price resulted in an 18-month US Senate committee investigation into the pricing of the drug, involving over 20,000 pages of company documents. The leaders of the investigation concluded: "The documents show it was always Gilead's plan to max out revenue, and that accessibility and affordability were pretty much an afterthought." 236

The investigation showed that Gilead's price was set so high, in part, to raise prices for future hepatitis C drugs.²³⁷ Indeed, Gilead's next hepatitis C drug, Harvoni, was priced at \$94,500. Further, the investigation revealed that the high costs of Sovaldi saw Medicaid programs in many US states limiting the availability of the drug to thousands of patients deemed good candidates for it because they could not afford to offer it to all who needed it.²³⁸

To give some estimate of just how much money Gilead was making from Sovaldi and follow up Hep-C drug Harvoni, between 2013 and 2015 global revenues for Gilead tripled, rising to \$32.6 billion;²³⁹ total corporate profits increased fivefold to \$21.7 billion; and total post-tax income increased sixfold to \$18.1 billion.²⁴⁰ Combined sales for Solvadi and Harvoni representing 56% of the company's total revenue between 2014 and 2015. In 2014 alone, Sovaldi made \$10 billion in sales,²⁴¹ while Hep-C drugs have generated nearly \$62 billion in sales since 2013.²⁴² By 2015, Gilead's post-tax profit margin was 55%.²⁴³

Gilead has also come under pressure, particularly in the US, for its pricing of HIV drug Truvada. In 2019 it was being sold at \$20,000 per person per year in the US.²⁴⁴ According to the Centers for Disease Control and Prevention, while 1.1 million Americans were in need of Truvada in 2018, only 90,000 prescriptions were filed for the drug by commercial pharmacies (which account for between 85% and 90% of all Truvada prescriptions).²⁴⁵ Going by this data, then, less than 10% of those Americans who need the drug are accessing it. Access to the drug plays out in ways that reflect and consolidate racial inequalities. In 2018 the Centers for Disease Control and Prevention estimated that approximately 500,000 African American people in the US could potentially benefit from taking the drug, yet only 1% of these potential beneficiaries (7,000 African American people) were doing so. Similarly, of the 300,000 Latino people who could potentially benefit from the drug, only 3% of these people (7,600) were taking it.246

Tax avoidance

As well as its price gouging controversies, Gilead has also become notorious for its tax practices. According to the advocacy group Americans for Tax Fairness, by moving some of its intellectual property to Ireland, Gilead reduced its US tax bill by \$10 billion between 2013 and 2015, the period in which its profits were booming from its hepatitis C medications as documented above.²⁴⁷

Profiting from the public purse

While drug companies typically claim that high prices are necessary to recoup the high costs of manufacturing, this kind of defence looks ridiculous in the case of Gilead's hepatitis C drug Sovaldi (see above). According to Professor Jeffrey Sachs of Colombia University, Gilead may have spent around \$300 million on R&D for the drug,²⁴⁸ a figure that would be recouped in just a few weeks of US sales of the drug. The drug, in fact, was initially discovered by Professor Raymond Schinazi of Emory University, whose initial research on the drug was funded by the US government.²⁴⁹ US advocacy organisation Americans for Tax Fairness estimates that public funding for R&D on the drug totals at least \$4.2 million dollars.250

In 2019 the Trump administration announced that it would be suing Gilead for infringing upon patents for HIV drug Truvada (see above) held by the Department of Health and Human Services, given that hundreds of millions of dollars in taxpayer money went into research that led to the patents.²⁵¹

Flawed access initiatives

In 2018, Gilead announced an "access initiative", pledging lower prices for liposomal amphatericin B (L-AmB, a treatment for cryptococcal meningitis, the second biggest killer of people living with HIV) in 116 countries in the global south. Yet in 2019, MSF criticised Gilead's progress on the scheme. By June 2019, the drug had been registered in only six of the 116 countries and, where registered, was unaffordable. At this point in time, a full treatment course of the drug costs \$4,200 in South Africa and \$1,000 in India. MSF argued that Gilead prioritised registering L-AmB in high-income countries, where higher prices could be charged.²⁵²

Withholding development

Gilead is currently facing several lawsuits over allegations that it withheld HIV drugs based on newer technologies in order to maximise profits from previous medications. This meant people taking old drugs - with serious side-effects - for longer. The lawsuits allege that Gilead withheld TAF-based drugs for ten years before they were finally released in 2015, despite evidence that TAF was safer than TDF, particularly with regards to kidney and bone risks.²⁵³

5. Pfizer

Summary*

- Pfizer was in the top 30 most profitable corporations in the world last year, with \$52 billion in revenue and a whopping \$16 billion in profits

 exceeding spending on the unprecedented US
 'operation warp speed'. Its revenues are bigger than oil-rich Kuwait or Malaysia.
- Pfizer is working with German biotech company BioNTech to develop a potential Covid-19 vaccine. Announcing positive results in November 2020, Pfizer came under criticism for failing to limit prices. The company is expected to make \$13 billion in 2021 and has already sold 82% of the doses it expects to make, to rich countries. When asked if it would join efforts to produce patent-free medicines for coronavirus, Pfizer's CEO responded: "At this point in time, I think it's nonsense, and... it's also dangerous."
- Pfizer and its British distributor hugely hiked the prices of anti-epilepsy drug phenytoin which 48,000 NHS patients relied upon. NHS expenditure on the drug rose from £2 million a year to £50 million in a single year, with the cost of 100mg packs rising from £2.83 to £67.50. Overall, UK wholesalers and pharmacies faced price hikes of between 2,300% and 2,600%.
- MSF ran a campaign against the price of Pfizer's pneumonia vaccines, which it claimed were 68 times more expensive in 2015 than in 2001.

- While Pfizer did reduce prices for the lowest income countries, MSF said the cost to vaccinate remained "roughly US\$9 for each child to be vaccinated in the poorest countries, and as much as \$80 per child for middle-income countries". It claimed Pfizer and GSK have earned over \$50 billion for the drug, but "Today, 55 million children around the world still do not have access to the pneumonia vaccine, largely due to high prices."
- In 1996, Pfizer dispatched doctors to Nigeria to assist in the most serious meningitis outbreak the country had ever seen and to test a potential new blockbuster drug. Ultimately eleven children died – Pfizer claims of meningitis rather than the treatment. But in the years that followed, lawsuits claimed that the parents hadn't given consent to the experimental trials. Ultimately, Pfizer agreed to out of court settlements of over \$75 million and did not admit to any wrongdoing.
- In 2009, Pfizer was forced to pay \$2.3 billion in a set of complex suits which included the company's illegal marketing of arthritis drug Bextra, as well as kickbacks to doctors. A whistleblower claimed that sales staff were incentivised to sell Bextra to doctors for conditions for which the drug wasn't approved and at doses up to eight times those recommended. "At Pfizer I was expected to increase profits at all costs, even when sales meant endangering lives. I couldn't do that," he stated.

*References in this summary can be found in this chapter

Pfizer was in the top 30 most profitable corporations in the world last year, with \$52 billion in revenue and a whopping \$16 billion in profits.²⁵⁴ Those revenues are bigger than oil-rich Kuwait or Malaysia.255 It's the ninth most profitable corporation in the US.²⁵⁶ The corporation's annual profit last year exceeded the spending to date on the unprecedented US 'operation warp speed' to find a vaccine for Covid-19.257 This is despite the company being handed a huge \$2.3 billion fine just over ten years ago.²⁵⁸

Covid-19

Pfizer is working alongside German biotech company BioNTech to co-develop a potential Covid-19 vaccine, seeking to develop the latter's BNT162 vaccine programme, which includes four vaccine candidates. ²⁵⁹ Clinical trials of the vaccine were approved in Germany in April. ²⁶⁰ The first clinical trials in the US began in May. A Pfizer press release explains the terms of the collaboration:

Under the terms of the agreement, Pfizer will pay BioNTech \$185 million in upfront payments, including a cash payment of \$72 million and an equity investment of \$113 million. BioNTech is also eligible to receive future milestone payments of up to \$563 million for a potential total consideration of \$748 million. Pfizer and BioNTech will share development costs equally. Initially, Pfizer will fund 100 percent of the development costs, and BioNTech will repay Pfizer its 50 percent share of these costs during the commercialization of the vaccine. 261

In early November 2020, Pfizer made headline news around the world when it announced its vaccine candidate was more than 90% effective in preventing Covid-19 in its tests. ²⁶² While good news for many, others questioned why the news was released to the press without detailed data, sparking concerns that the decision was more to do with boosting stock price than communicating complex results. "The lack of data is very concerning" one scientist told National Geographic. ²⁶³ Pfizer's own CEO did well out of the announcement, selling company shares worth \$5.56 million on the day the company announced its vaccine results, though he broke no rules as the sale was pre-planned. ²⁶⁴

The announcement also drew attention to the fact that Pfizer has made no promise to limit its profits from its vaccine and has presold over one billion doses to rich governments, representing just 14% of the world's population. This represents 82% of the 1.35 billion doses Pfizer says it has the capacity to produce by the end of next year. ²⁶⁵ It is unclear how this can be squared with any notion of fair international distribution.

Pfizer is also trialling a new antiviral drug as a potential Covid-19 treatment,²⁶⁶ and is involved in a study assessing the potential of its arthritis drug Xeljanz as a potential treatment.²⁶⁷

Pfizer has promised to share data from its
Covid-19 research with other companies, and to
use manufacturing capacity to develop other
companies' products²⁶⁸ but it hasn't made clear
how this will happen, and it hasn't made any
guarantees about profit levels. In fact, Pfizer's
drug is predicted make \$13 billion in 2021.²⁶⁹ While
the company claims not to have received any
direct public support, its partner in the vaccine
production process has received significant funding

from the EU and German governments,²⁷⁰ while the massive advance bulk purchases of a drug of unknown efficacy, detailed in the table below, does represent a very significant indirect mobilisation of public resources. It also ignores the state support for the technology underlying the vaccine.²⁷¹

Pfizer has been outspoken in its desire to maintain patents and has derided attempts by the WHO to create a patent-free mechanism to pool coronavirus research and development and allow for universal access to vaccines. Pfizer's CEO Albert Bourla commented: "At this point in time, I think it's nonsense, and... it's also dangerous."

Table 4: Advanced sales of Pfizer / BioNTech's Covid-19 vaccine doses

Buyer	Details	Value (if reported)
UK	40 million doses ²⁷³	
USA	100 million vaccine doses with option to buy further 500 million doses ²⁷⁴ Pfizer says Americans will receive vaccine free of charge ²⁷⁵	\$1.95bn for the first 100 million doses ²⁷⁶
EU	300 million doses ²⁷⁷ (though apparently up to another 405 million direct from CureVac for an estimated \$4.7bn) ²⁷⁸	\$5.5bn ²⁷⁹
Canada	20 million doses ²⁸⁰	
Japan	120 million doses ²⁸¹	
Australia	10 million doses ²⁸²	
Switzerland	3 million doses ²⁸³	
Israel	8 million doses ²⁸⁴	
Ecuador	2 million doses ²⁸⁵	
Chile	10 million doses ²⁸⁶	
Egypt	20 million doses ²⁸⁷	
Peru	9.9 million doses ²⁸⁸	
Argentina	750,000 doses ²⁸⁹	
New Zealand	1.5 million doses ²⁹⁰	
Hong Kong / Macau	Deal with BioNTech (Pfizer's partner) 10 million doses ²⁹¹	
Costa Rica	3 million doses ²⁹²	

Corporate share price

After the UK lockdown was announced on 23 March, Pfizer share prices increased 32.6% to August.²⁹³ It was during this period that clinical trials were approved in Germany and the US.²⁹⁴

Price gouging

Pfizer was investigated by the UK's Competition and Markets Authority (CMA) for price gouging in a case that was recently heard in the Court of Appeal.²⁹⁵ The CMA was responding to very high price rises made by Pfizer and its UK distributor Flynn on anti-epilepsy drug phenytoin which 48,000 UK patients relied upon. As a result, NHS expenditure on phenytoin capsules rose from about £2 million a year in 2012 to about £50 million in 2013 with the price of 100mg packs of the drug rising from £2.83 to £67.50, before reducing to £54 from May 2014.²⁹⁶ Overall, UK wholesalers and pharmacies faced price hikes of between 2,300% and 2,600%.²⁹⁷

Initially, the CMA concluded that prices in the UK were far higher than in any other European country and, in December 2016, Pfizer was given the highest fine ever levied by the CMA: £84.2m (alongside £5.2m for Flynn).²⁹⁸ However, Pfizer and Flynn appealed and in June 2018 the Competition Appeal Tribunal upheld the CMA's decision that the firms held dominant market positions, but concluded these positions were not abused, therefore quashing the CMA fines. The CMA then appealed and in March 2020, the Court of Appeal upheld the CAT's decision to quash the fines yet reopened the question over whether the CMA's ruling as to the firms' pricing was excessive. The CMA is now considering the next steps in the case.²⁹⁹ Despite this, the judge in the case stated:

It was quite easy to lose sight of a stark reality, which was that, literally overnight, Pfizer and Flynn increased their prices for phenytoin sodium capsules by factors of between approximately 7 and 27, when they were in a dominant position in each of their markets.³⁰⁰

Back in 2017, Pfizer hiked the US price of 91 of its drugs by an average of 20%. ³⁰¹ In July 2018, responding to criticism from President Trump, Pfizer reneged on a set of planned US price increases –

before announcing a raft of price hikes for January 2019, which included increases on 41 of its products (around 10% of the company's total portfolio). One price rise was of 9%, with most being at around 5%. 302 A study of pharmaceutical industry price hikes for US products in early 2020 showed that Pfizer's price increases were the highest in the sector. 303

Vaccine pricing

MSF has spent many years criticising Pfizer (alongside GSK) for their unaffordable pricing of their vitally important pneumonia vaccine (pneumococcal conjugate vaccine or PCV). 304 Pneumonia is the foremost cause of child mortality globally, killing around one million children each year with children affected by conflict or humanitarian emergencies particularly at risk. 305 This is a disease that is preventable by the PCV vaccine, for which only Pfizer and GSK owned the rights.

Between 2009 and 2014, MSF lobbied these firms to offer a fair and sustainable price for PCV, claiming in 2015 that pneumococcal vaccines were 68 times more expensive than in 2001.³⁰⁶ Eventually it won price reductions for lower income countries³⁰⁷ – though MSF was clear these reductions were not close to being sufficient, and only the release of generic vaccines, currently in development, will make these desperately needed vaccines affordable.308 Price reductions apply to 73 lower income countries,³⁰⁹ but MSF said the cost to vaccinate remains "roughly US\$9 for each child to be vaccinated in the poorest countries, and as much as \$80 per child for middle-income countries that don't qualify for Gavi support".310 What's more, the deal to supply the drug through Gavi – the Gates-funded body which aims to increase vaccinations across lower income countries - effectively involves a bulk purchase of the drug which MSF say translates into a multimillion subsidy to Pfizer on top of the high prices.³¹¹ In short, campaigners claim:

Pfizer and GSK have earned over \$50 billion in sales of the pneumococcal vaccine in the past ten years, with Pfizer winning the lion's share of these revenues. Today, 55 million children around the world still do not have access to the pneumonia vaccine, largely due to high prices.³¹²

Nigerian testing and other scandals

Pfizer's testing of experimental new drugs during a meningitis outbreak in Kano, Nigeria, dogged the corporation for 20 years, and was reportedly even the inspiration for John le Carré's novel The Constant Gardener. The story began in 1996, when Pfizer dispatched doctors to Nigeria to assist in the most serious meningitis outbreak the country had ever seen. Pfizer wanted to test a potential new blockbuster drug called Trovan which had not yet been tested against the standard medicine Ceftriaxone. Prizer wanted to the standard medicine Ceftriaxone.

Ultimately eleven children died – five who had been given Trovan and six who had taken the approved drug. Further children were left with brain damage, paralysis or slurred speech.³¹⁶ Pfizer claims the children died of meningitis, not the treatment.³¹⁷ But an employee claimed Pfizer's trial had violated ethical rules.³¹⁸ In the years that followed, several lawsuits were initiated, in Nigeria and the US, with claims that the parents hadn't given meaningful consent because they hadn't realised their children were part of an experimental trial.³¹⁹ There were also claims that Pfizer had administered lower doses of Ceftriaxone than necessary, with the implication that it was attempting to boost the contrasting effects of its new drug.³²⁰

The company's problems weren't helped when US regulators poked so many holes in the trials that Pfizer withdrew the request for authorisation of Trovan for meningitis³²¹ while the EU recommended suspending marketing approval in member states.³²² Ultimately, Pfizer agreed to out of court settlements of \$75 million with the state of Kano³²³ as well as payments of \$175,000 to four sets of affected parents.³²⁴

A further twist in the case came when Wikileaks released a US diplomatic cable which appeared to show that Pfizer hired investigators to look for evidence of corruption against the Nigerian attorney general in an effort to persuade him to drop the legal action.³²⁵ Pfizer claims this is "preposterous", and indeed maintains it is innocent of all wrongdoing in the case.³²⁶

Illegal marketing and kickbacks

In September 2009, Pfizer was forced to pay \$2.3 billion in a set of complex suits which included Pfizer's illegal marketing of arthritis drug Bextra, and other medicines for uses unapproved by the US regulator, as well as kickbacks to doctors. This was the largest health care fraud settlement and the biggest criminal fine in US history at that time. The case heard substantial evidence from a whistleblower who claimed that sales staff were incentivised to sell Bextra to doctors for conditions for which the drug wasn't approved and at doses up to eight times those recommended. At Pfizer I was expected to increase profits at all costs, even when sales meant endangering lives. I couldn't do that," the whistleblower stated.

6. Moderna

Summary*

- US biotech firm Moderna is a relatively new company working to advance a potential Covid-19 vaccine known as mRNA-1273. Announcing positive results in November 2020, the company came under criticism for preselling 780 million doses of its potential vaccine to rich governments representing just 12% of the global population. This is 78% of the one billion doses it has the capacity to produce by the end of next year.
- \$2.5 billion of public money has gone into the drug's development, which according to Public Citizen means "Taxpayers are paying for 100% of Moderna's vaccine". Yet the vaccine would be one of the most expensive on the market, with costs estimated at \$64 and \$74 per person per course under a special cheaper 'pandemic pricing' regime.
- Moderna ran into controversy in May 2020 for releasing very early and incomplete results leading to a stock boost of 30%. At the same time, two corporate executives sold off nearly \$30 million in automated sale shares, while the company's leading shareholder sold one million shares, earning \$69.5 million in the process. This was described by former Securities and Exchange Commission officials as "highly problematic" and worthy of investigation for potential market manipulation.
- The company has seen its share value rocket since the pandemic. Its share price increased 420.3% in just under five months between 21 February and 17 July 2020. If the US government confirms all its pre-orders and options, the company expects to make \$8 billion from those sales alone.

*References in this summary can be found in this chapter

Covid-19

Unlike most other companies competing to produce Covid-19 treatments, Moderna is a relatively new company, founded in 2010. It is a US-based biotech firm and is working to advance a potential Covid-19 vaccine known as mRNA-1273.332 Moderna has issued two positive news stories, most recently in November 2020, when the company said trials had shown a 95% effectiveness.³³³ However, this positive news was tempered by the fact that 780 million doses had already been sold to rich governments, 78% of the one billion doses Moderna says it has the capacity to produce by the end of next year, representing just 12% of the global population, campaigners warn.334

This is particularly shocking given the huge amount of public money that has gone into the vaccine. Manufacturing for the first batch of the product to be used in a phase I study was funded by the Coalition for Epidemic Preparedness Innovations (CEPI).³³⁵ In April, the US Department of Health and Human Services committed up to \$483 million to cover R&D costs,³³⁶ with a further \$472 million in July.³³⁷ MSF calculates that the total amount of public money contributed to be \$2.5 billion.338 Public Citizen claims that in effect this means "Taxpayers are paying for 100% of Moderna's COVID-19 vaccine development. All of it. Yet taxpayers may wind up paying tens of billions more to Moderna to buy our vaccine back, if it proves safe and effective". 339 Indeed the USA has bought

100 million doses with options to buy another 500 million – an amount thought likely to make the company \$8 billion.³⁴⁰

What's more, Moderna is proposing a vaccine cost well above the average. Moderna's two-dose vaccine regimen is estimated to cost between \$64 and \$74 per person under its cheaper 'pandemic pricing' regime.³⁴¹ Unlike some other vaccine developers, Moderna has not said it will limit the prices of its vaccine.³⁴² The potential prices have provoked public outcry from campaigners.³⁴³

Moderna has been criticised for the way it releases its research. After the company announced it had seen positive results from its Phase I trial in May 2020, its stock price increased by 30%,³⁴⁴ with the company valued at £29 billion, despite the fact it has no approved products to sell.³⁴⁵ Scientists, however, raised questions about the company's claims, suggesting that no significant data had been released to evidence them.³⁴⁶ Moderna disclosed early results from just 8 of its 45 trial participants.³⁴⁷

"It's a bit of a concern that they haven't published the results of any of their ongoing trials that they mention in their press release. They have not published any of that," Johns Hopkins University vaccine researcher Anna Durbin said. 348 One former Moderna executive, speaking anonymously to CNN Business, commented: "Issuing a press release around Phase 1 data is very unusual ... Issuing a press release around partial data from less than half the patients is very, very unusual – practically unheard of." 349

Some commentators suggested that Moderna was trying to capitalise on their surging stock price in the wake of their phase I trial via a series of stock market transactions. The firm's moves have been labelled by former Securities and Exchange Commission officials as "highly problematic" and worthy of investigation for potential market manipulation. Hours after press releasing their claims about positive trial results, Moderna sold 17.6 million shares to the public, raising \$1.3 billion. Two Moderna executives sold off nearly \$30 million in automated

sale shares. Days later, Moderna's leading shareholder – a venture capital firm called Flagship Pioneering founded by Noubar Afeyan, co-founder and chairman of Moderna – sold one million shares, earning \$69.5 million in the process. Moderna's share value then sank as the week went on.³⁵¹

Overall, corporate executives at Moderna were reported to have sold more than \$180 million of stock in automated sales for the year to September. The An anti-corruption watchdog group is urging the US Securities and Exchange Commission to investigate top executives at Moderna, while the chairman of the Securities and Exchange Commission cautioned companies against selling stock during the pandemic, saying even if sales are legal, the optics are not good.

In a positive development, Moderna has agreed not to enforce patents during the pandemic, though Public Citizen believes this could be a way of avoiding difficult disputes. The Nonetheless, Moderna can itself decide when the pandemic is 'over', and the decision doesn't necessarily assist with the technology transfer that would be necessary to produce sufficient vaccines across the world – a problem which could have been solved by the WHO proposals for a patent pool.

Corporate share value

The company has seen its share value rocket since the pandemic. Its share price increased 420.3% in just under five months between 21 February³⁵⁶ and 17 July 2020.³⁵⁷

Table 5: Advanced sales of Covid-19 vaccine doses

Buyer	Details	Value (if reported)
USA	100 million vaccine doses, with option to buy a further 400 million. ³⁵⁸	\$1.53bn ³⁶¹
	Moderna shares jumped 5% on the day deal announced.359	
	Price will be around \$30.50 per person for a two-dose regimen ³⁶⁰	
EU	80 million doses with option of further 80 million ³⁶²	
Canada	20 million doses, with option of further 36 million doses ³⁶³	
Japan	50 million doses ³⁶⁴	
Switzerland	4.5 million doses ³⁶⁵	
Kuwait	1.7 million doses ³⁶⁶	

Secrecy

As mentioned above, Moderna has been criticised for failing to reveal the data behind their apparently promising Covid-19 trial results. It has been criticised on the same grounds in the past: the first two potential treatments it brought to trial were both vaccines, yet the company refused to disclose which diseases the vaccines targeted and did not list the trials publicly. In the words of one former Moderna executive, speaking anonymously to CNN Business: "(Moderna's) behavior is to issue very scant, non-scientific information. And somehow, that's their magic power — is that the markets eat it up." Unlike other firms, the company don't publish work in scientific journals, instead jumping straight to press releases.367

7. Sanofi

Summary*

- Sanofi, one of France's biggest corporations, is promoting numerous Covid-19 initiatives including a collaboration with GSK to develop a Covid-19 vaccine. They have received over \$2 billion for drug development and expansion of manufacturing capacity for this vaccine. Up to a billion doses have been presold to rich countries, with 200 million made available for global distribution through COVAX. But according to Sanofi CEO Paul Hudson, the US would likely get access to the vaccine before the rest of the world.
- Sanofi has been accused of hiking up prices for their insulin Lantus, which increased 18% each year from 2012 to 2016 in the US, while \$22 billion of US public money was paid out via Medicare and Medicaid for the drug. Sanofi have also been accused of blocking competition for Lantus in the US, filing 74 patent applications, which would have had the potential to delay the emergence of competition for 37 years.

- Sanofi dropped promising research work on a Zika virus vaccine when the US refused further support, despite significant funding already put in. Senator Bernie Sanders argued that any public-private vaccine partnership should come with a commitment to a price limit. Sanofi refused to make such a commitment.
- After vaccinating hundreds of thousands of people for Dengue in 2017, it materialised that the vaccine could be unsafe unless people had previously been exposed to the virus. While Sanofi denies any wrongdoing, the case has had a major impact on trust in vaccines in the country.
- This year, charges were brought against Sanofi in France over an alleged failure to warn pregnant women about the risk of birth defects from epilepsy drug Depakine. France's social affairs inspection agency estimated that between 2006 and 2014, 425 to 450 babies suffered congenital birth defects or were stillborn following exposure. Sanofi denies wrongdoing and claims it has been "totally transparent".

*References in this summary can be found in this chapter

Sanofi is the sixth biggest corporation in France³⁶⁸ making \$42 billion in revenue and \$3 billion in profit last year.³⁶⁹

Covid-19

French pharmaceutical firm Sanofi is promoting numerous Covid-19 initiatives. They have announced a collaboration with GSK to develop a Covid-19 vaccine. Phase I clinical trials are planned for the second half of 2020, aiming for the vaccine to be available by the second half of 2021. The collaborative project has received \$30 million funding from the US Biomedical Advanced Research and Development Authority (BARDA). Therefore, according to Sanofi CEO Paul Hudson, the US would likely get access to the vaccine before the rest of the world. In July, Sanofi and GSK were pledged as much as \$2.1 billion for drug development and expansion of manufacturing capacity, with the bulk going to Sanofi. Sanofi.

Sanofi is also working with Californian start-up Luminostics to develop a smartphone-based home test.³⁷³ And they are one of several developers of controversial potential Covid-19 treatment hydroxychloroquine,³⁷⁴ which was touted by President Trump.³⁷⁵ In fact, Trump and several of his associates appear to have a small financial interest in Sanofi.³⁷⁶ In April, Sanofi announced plans to donate 100 million doses of hydroxychloroquine across 50 countries.377

Table 6:

Advanced sales of Covid-19 vaccine doses

Buyer	Details	Value (if reported)
UK	60 million doses ³⁷⁸	
USA	100 million doses with option to buy further 500 million ³⁷⁹	\$2.1bn ³⁸⁰
EU	300 million doses ³⁸¹	
Canada	72 million doses ³⁸²	
COVAX Facility (for global distribution)	200 million doses ³⁸³	

Price gouging and blocking competition

In the US, Sanofi has been accused by the Initiative for Medicines, Access and Knowledge (I-MAK) of hiking up prices for their insulin Lantus, one of the main insulin products on the market.³⁸⁴ The US price of Lantus increased 18% each year from 2012 to 2016. In this time, \$22 billion of US public money was paid out to Sanofi via Medicare and Medicaid to purchase Lantus.385

Sanofi also stands accused of 'over-patenting'. Patents are supposed to last a set period of time, after which generic competitors can be developed. Sanofi, however, has repeatedly blocked the emergence of competition for Lantus in the US by filing 74 patent applications, 69 of which came after the drug was first patented in 1994. Together, these patents have the potential to delay the emergence of competition for 37 years.³⁸⁶

Sanofi is currently one of three firms facing a lawsuit filed by 67 diabetic patients, pertaining to fraud allegations connected to insulin price rises. Plaintiffs in the case allege that Sanofi, Novo Nordisk and Eli Lilly increased insulin list prices by over 150% over the past five years.³⁸⁷ Sanofi denies the claims.³⁸⁸ High insulin prices have a devastating human cost. One recent 2019 Yale University study found that one-quarter of patients at the Yale diabetes clinic reported using less insulin to cut costs in the previous 12 months.389

Previous vaccine controversies

Sanofi attracted criticism around its partnership with the US Army for a Zika virus vaccine developed by US Army researchers. The partnership was agreed in July 2016, with Sanofi winning \$43 million of US government funding to advance the vaccine in September that year alongside the potential for an additional £130 million follow-up funding and a potential exclusive commercialisation licence.³⁹⁰ Critics such as Bernie Sanders and US NGO Knowledge Ecology International argued that because the US taxpayer had paid over \$1 billion already on R&D around Zika – alongside the \$43 million specifically committed to Sanofi – no deal between the US government and Sanofi should be reached on a vaccine partnership without a commitment to a price limit.³⁹¹ Sanofi, however, refused to make such a commitment.392

As the spread of Zika slowed in 2017, the US government Biomedical Advanced Research and Development Authority (BARDA) decided to pull funding for the Sanofi partnership. As a result, Sanofi shelved its work on the vaccine³⁹³ – despite data published in the Lancet showing its performance was extremely promising, eliciting strong responses in over 90% of trial participants.³⁹⁴ Sanofi spokeswoman Ashleigh Koss said developing vaccines for emerging infectious disease is "a high-risk endeavor." She said: "We have been clear about the importance of public-private partnerships in addressing emerging infectious diseases like Zika and believe it is essential for vaccine manufacturers to collaborate with governmental scientific organizations."395 In other words: despite the massive potential health benefits of continuing work on the vaccine, Sanofi refused to fund this work itself, without continued public finance.

Sanofi's dengue fever vaccine Dengvaxia proved controversial when used in immunisation in the Philippines. In 2016, the Philippine Department of Health started using Dengvaxia in the midst of a national epidemic, beginning a national immunisation program targeting one million children.³⁹⁶ But in 2017, Sanofi announced that the drug should only be used on those who had already been exposed to the virus, following a reanalysis of test results which Sanofi said presented evidence that people who had not been exposed to the virus could be rendered more vulnerable to severe infections post-vaccination.³⁹⁷ For some children who had been vaccinated, this meant they could now be at *greater* risk of the dangerous condition than before they'd been vaccinated.398

What's more, researchers claimed that they had warned about the potential problem before the vaccinations had even begun with one expert telling journalists: "All officials who spoke with me about the Dengvaxia campaign worried about the potential for future severe dengue cases in vaccinated persons who had never had a previous case of dengue." 399

By February 2018, safety concerns around the vaccine had become widespread in the Philippines, and allegations surfaced around the deaths of several children. 400 The Philippine government permanently withdrew the vaccine's licence, and even initiated legal action against health officials and Sanofi staff, citing an "inexcusable lack of precaution and foresight."401 Sanofi denies any wrongdoing and indeed there is no evidence that Dengvaxia is linked to the deaths in question.⁴⁰² But the case demonstrates the real problems with perceived shortcuts in vaccine development. Faith in vaccines plummeted in the Philippines as the controversy hit the media and aroused enormous fear in the population. As one expert told journalists, "That fear can impact negatively on the established immune programs that are actually safe and work very well."403

Safety concerns

This year, charges were brought against Sanofi in France over an alleged failure to warn pregnant women about the risk of birth defects from epilepsy drug Depakine. 404 France's social affairs inspection agency IGAS estimated that between 2006 and 2014, 425 to 450 babies suffered congenital birth defects or were stillborn following exposure to Depakine.⁴⁰⁵ One 2017 study by France's National Agency for the Safety of Medicines (ANSM) estimated that between 2,150 and 4,100 children suffered severe malformations linked to the drug. 406 In August 2020, an investigation was launched into Sanofi for possible manslaughter charges in France over the deaths of four babies whose mothers took the anti-epilepsy drug.⁴⁰⁷ Sanofi claims it has been "totally transparent with health authorities."408

In 2012, the US FDA found dozens of health and safety problems in a Sanofi factory in Toronto that produced the vaccine BCG, used against tuberculosis and bladder cancer. The FDA documented various issues with mould and contamination in the plant. 409 This included 58 different mould issues within the vaccine processing areas, problems with vial handling, issues with employees' movement between the live vaccine area to the washing and sterilising area, questions with disinfecting practices and nesting birds in the air handling units. 410 Sanofi withdrew four batches of BCG and suspended production from the Toronto plant for two years. 411

Recommendations

This report documents decades of controversy that has dogged an industry that has been characterised by high prices, profiteering and secrecy. And its products are not just consumer luxuries but are health products that are essential for public health and wellbeing. Even without a crisis, this industry is not fit for purpose. Maintaining business as usual is not going to be good enough in the face of a global pandemic.

At a time like this, we cannot afford to leave the industry in the driving seat to decide who gets access to essential vaccines and treatments. And we cannot rely on the good will of an industry that puts profits above public health. Instead, the UK government needs to take active steps to ensure equitable access to potential Covid-19 vaccines and treatments and commit to the following recommendations:

- 1. Impose conditions on all UK funding committed to developing Covid-19 vaccines and treatments. These should mandate:
 - Universal, non-exclusive licences on any vaccine or medical product.
 - Full transparency of all licensing agreements made between research institutes and pharmaceutical companies and other actors as well as information on R&D costs and prices.
 - The sharing of intellectual property, research and knowhow with the WHO's Covid-19 Technology Access Pool (see point 2 below).
- 2. Join and support the WHO's Covid-19 Technology Access Pool and use their position to ensure that the pool:
 - Serves all countries and includes all necessary technologies, knowledge and data.
 - Safeguards rights for all to use and produce by not allowing monopolies and exclusivities to hinder technology transfer, production or access to any Covid-19 health technologies.
 - Implements full transparency of stakeholder negotiations, production and prices to ensure accountability for all countries and organisations involved.

- 3. Support the proposal submitted by the governments of India and South Africa to waiver the relevant chapters of the WTO global agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS) for the prevention, containment and treatment of Covid-19.
- 4. Where patient access or research is restricted by intellectual property rights, the government should issue Crown Use Licences for any patented technologies that are potentially useful for tackling Covid-19 and actively support other countries to do likewise.
- 5. Leverage the UK's position on the Gavi Board to ensure urgent changes are made to the COVAX Facility, including:
 - In light of the significant taxpayer money already invested in Covid-19 vaccine R&D, the COVAX Facility must insist that it pay no more than the at-cost price for Covid-19.
 - Gavi should support measures and solutions, including the COVID-19 Technology Access Pool, which aim to overcome intellectual property barriers that limit manufacturing capacity.
 - The Fair Allocation Framework led by WHO must be followed and applied equally to all countries participating in the COVAX Facility, including both self-financing and funded countries.
 - All deals agreed with pharmaceutical companies for COVID-19 technologies should be published in full including information on research and development costs and final prices.
- 6. Cease the UK's advanced purchasing of potential vaccines and contribute vaccine doses secured through bilateral deals to the COVAX mechanism above that required by the Fair Allocation Framework.

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Global Justice Now campaigns for a world where resources are controlled by the many, not the few. We work in solidarity with social movements to fight injustice and inequality.