DI III CALL III COVID 19, VACCINES, BG PHARMA AND PUBLIC MODELL

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# Paying the Piper to Call the Tune—COVID 19, Vaccines, Big Pharma, and Public Money

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At the time of writing, Ireland has just passed another significant anniversary in the ongoing global COVID 19 pandemic, the one-year anniversary of our first lockdown. We have spent that anniversary not—as most of us would have believed a year ago—by looking back on a difficult year, remembering the dead, and fighting to change all the existing inequalities newly highlighted by the sharp glare of the pandemic, but in the midst of a third lockdown following from the government's 'Living with COVID' plan and the catastrophic failure of three weeks of 'meaningful Christmas'. Indeed, the current epidemiological situation, while not quite at the absolute low point of the post-Christmas surge, is exceedingly grim. Case numbers remain stubbornly high, and while the picture around the country is mixed, after repeated warnings that numbers are 'plateauing' or 'on a knife edge', there are worrying signs that the situation is deteriorating, with the most recent weekly case numbers showing a 9 percent increase on the previous week.1

The situation across Europe doesn't look much better,<sup>2</sup> and globally—with the notable exception of those countries which have adopted a zero-COVID approach or at least taken seriously and fully resourced comprehensive public health programmes to test, trace, and isolate all cases to prevent onward transmission—countries are struggling to contain the virus, with the Africa CDC and WHO warning of increasing fatality rates across the continent,<sup>3</sup> or struggling to prevent the collapse of their health

systems as the virus spirals out of control. Brazil faces 'a historic collapse of its health service', with the country recently recording its highest ever daily death toll as a new strain, which emerged in the already badly hit north-eastern region of Manaus, sweeps the country. Papua New Guinea, a country with only some five hundred doctors and a population of nine million, and which was already struggling with outbreaks of measles, tuberculosis, and polio, has seen a tripling of case numbers in a month despite their limited testing capabilities, with over 120 staff in the capital of Port Moresby's hospital among the number of infected.

From what we have learned—through bitter experience—of exponential growth and with the numbers of deaths, cases, and hospitalisations as precarious as they are, lockdowns and their attendant heavy restrictions on much of our personal and social lives look set to continue for quite some time to come. 6 The government is reluctant to be drawn on the question of reopening,<sup>7</sup> and even the usual suspects (the Michael O'Learvs of this world notwithstanding) who cheered on our previous reopening, like IBEC, the Restaurants Association, or the Vintners, are, if not quite chastened by experience, relatively mute on the subject this time round. The exception to this is of course the prospect of a 'return to normality' as vaccination of the population continues

# A light at the end of the tunnel?

Vaccination has emerged as a glimmer of light at the end of the tunnel. With case numbers where they are, and the government set against taking any further measures to suppress the virus, it is hard to see numbers coming down in even the medium term without widespread vaccination of the population. The government's vaccination rollout has been beset with delays in the supply of vaccines and atbest questionable decisions about who receives the available doses. But it is worth remembering that the fact we have multiple highly effective vaccines available, even if they are in limited supply, is something that few would have confidently predicted a year ago.

The rapid development and production of multiple vaccines on unprecedented timescales should stand

as a testament to our ability to harness the power of scientific knowledge for the public good, but instead it increasingly highlights how public money ends up as profits for Big Pharma shareholders and the stark global inequalities when it comes to access to healthcare.

If the promise of vaccination is the silver lining to the dark cloud of our ongoing lockdowns, it is one we share with only a small portion of the world's population, in only the wealthiest countries. For most of the global population, particularly those in the poorest parts of the developing world, the prospect of vaccination is still a long way off, measured on the scale of years rather than months, and accusations of vaccine nationalism abound.

## Vaccine hoarding

As early as last November, wealthy countries had already done deals to purchase most of the world's vaccine supply for this year. Between them, Canada, the USA, the UK, Australia, the EU, and Japan countries which account for around 13 percent of the world's population—have already purchased over 50 percent of all expected production. Some have purchased quantities far in excess of their needs, with Canada ordering nearly eight doses per person. <sup>9</sup> Even with allowance for supply delays, the countries on this list can be fairly confident of fully vaccinating their adult populations this year, while Oxfam estimate that 61 percent of the world's population will not receive a vaccine until at least 2022. 10 The hoarding only gets worse when you consider that the US has at least 30 million doses of the AstraZeneca vaccine ready to use and enough vaccine for 'tens of millions more doses once it is filled into vials and packaged'11 despite the vaccine not yet being approved for use in the US.

This hoarding will have real-world consequences: while wealthy countries can vaccinate their entire adult population, many countries cannot even vaccinate front-line health workers and those sections of their populations most at risk. A modelling study from the Laboratory for the Modelling of Biological and Socio-technical Systems at Northeastern University in Boston highlights the global impact of this 'uncooperative' approach over a 'cooperative' distribution based on population size.

They find that for a 80% vaccine efficacy the uncooperative vaccine allocation strategy would avert 33% deaths, while the cooperative allocation strategy is estimated to avert 61% deaths.<sup>12</sup>

The study further found that the effects of a more equitable distribution of vaccines would not be felt uniformly around the world and a reduction in averted deaths in wealthy countries would be relatively modest compared to the gains in poorer regions.

In Western Europe, the uncooperative strategy indicates a proportion of averted deaths of 74%, while the cooperative strategy achieves a 55% averted deaths; in Northern America the uncooperative strategy averted 67% deaths compared to the 53% of the cooperative strategy. This however has to be contrasted with other regions such as Western Africa where the uncooperative and cooperative strategies achieve 13% and 93% averted deaths, respectively, while in South-Eastern Asia they achieve 5% and 62% averted deaths, respectively.<sup>13</sup>

While, of course, any additional deaths would be a hard pill to swallow for any country it is worth re-emphasising that, given the levels of virus circulating globally, mass vaccination is now an absolute necessity in bringing the COVID 19 pandemic to an end, but it is not the only option available. Even as vaccine programmes are rolled out, non-pharmaceutical interventions (masking, social distancing, test, trace, isolate, and quarantine measures, etc) remain vital, and wealthier nations are (or at the very least *could be* with appropriate investment) much better placed to provide the necessary interventions to prevent the virus circulating while their citizens are awaiting vaccination

## An artificial scarcity

A global vaccination programme was always going to take significant time to implement, but right now we are working at a severe disadvantage as vaccines are manufactured by large pharmaceutical companies who continue to operate on a model which jealously guards its intellectual property rights and seeks to

maximise profits by preventing others from using their patents and refusing to share the technical knowledge required to produce vaccines. We have created an artificial scarcity of vaccines that benefits only a select few wealthy pharma shareholders and executives via the same 'business as usual' approach that is indifferent to suffering and death as long as profit margins are maintained.

The pharmaceutical industry has a long and ignominious history in this regard, possibly best exemplified by a court case initiated by 38 companies against South Africa in 1998 over a law that aimed to increase access to AIDS medications. The fact that the law in question relied on established practices agreed upon by the World Trade Organisation (WTO): compulsory licensing and parallel importing. Respectively these allow countries to manufacture generic versions of drugs while in a state of emergency by paying the patent owners a royalty and to import drugs produced more cheaply in another country, thus avoiding price differentials imposed by patent holders in different markets. 14 The case was eventually dropped in 2001 after substantial public pressure forced drug companies, and their political backers, to concede that the South African Law could be enforced.15

The position of supporters of the pharma model (rigorously defending patent rights to maximise profit), that without profits there would be no incentive to innovate and bring new drugs to market, already rang hollow long before this pandemic. The worst hypocrisies of this position are neatly summarised in the case of Valeant Pharmaceuticals. Under CEO Mike Pearson's motto of 'Don't bet on science—bet on management', R&D expenditure was slashed and the company went on a cheap credit and hedge fund–backed acquisition spree, acquiring over a hundred companies with proven products on the market before hiking their prices to generate spectacular returns for investors.<sup>16</sup>

# The people's money for a people's vaccine?

As the reality of a global pandemic dawned, governments scrambled to fund potential vaccine candidates and accelerate their development.

According to data from analytics company Airfinity, governments have provided £6.5 billion to vaccine

manufacturers while not-for-profit organisations have provided another £1.5 billion.<sup>17</sup> In light of the much-publicised public funding and widespread acknowledgment of the severe deficiencies of existing models of production, there were very promising signs of a change to business-as-usual, best exemplified in the University of Oxford's pledge that their default position would be to 'offer nonexclusive, royalty-free licences to support free of charge, at-cost or cost + limited margin supply'18 for the duration of the pandemic. Adrian Hill, the head of the Oxford's Jenner Institute—named for the famed inventor of the polio vaccine who famously refused to patent it, asking 'Would you patent the sun?' declared that 'I personally don't believe that in a time of pandemic there should be exclusive licenses' and 'Nobody is going to make a lot of money off this'.19

This early optimism proved short lived. With prompting from Bill Gates<sup>20</sup> in his role as founder of the Coalition for Epidemic Preparedness Innovations (CEPI), the university quickly partnered with pharma company AstraZeneca. As public money flowed into the company and share prices rose, the ideals of a royalty-free, open-access vaccine were quickly abandoned as details of the deal began to emerge. AstraZeneca are reportedly allowed to earn up to 20 percent on top of manufacturing costs<sup>21</sup> and have a contractual right to declare the pandemic over as early as July of this year, thus paving the way for price increases.<sup>22</sup> The deal also paves the way for Vaccitech, the privately owned Oxford spin-out which owns the publicly funded IP licensed to AstraZeneca, to begin collecting royalty payments and profiting once the pandemic is declared over. The two main scientists involved in the vaccine programme each own 5 percent stakes in the company, including the previously mentioned Adrian 'Nobody is going to make a lot of money off this' Hill.

Vaccitech is just one of a host of companies in the portfolio of Oxford Sciences Innovation (OSI), a university-affiliated, private company which takes stakes in companies started in the university. OSI has a 46 percent stake in Vaccitech, but its share of the future profits will mainly go to private investors as the University of Oxford only owns 5 percent of OSI.<sup>23</sup>

Promises from other major manufacturers have also failed to materialise. Moderna, whose mRNA vaccine relies on several fundamental discoveries from publicly funded research at the US National Institutes of Health (NIH),<sup>24</sup> promised not to enforce their patents related to COVID 19 during the pandemic,<sup>25</sup> yet in late October CEO Stephane Bancel told investors that 'Moderna retains worldwide rights to develop and commercialize [the vaccine]'. adding that 'Moderna will realize all the profits from our COVID-19 vaccine' and 'We should have a unique cash position at the end of 2021'.26 Moderna also stands out among the major COVID vaccine manufacturers for failing to reach a deal with the COVAX programme and instead agreeing to sell their entire production run for the year exclusively to the wealthiest countries, where of course profit margins are highest.

Moderna are not alone in relying on public research. Pfizer's vaccine partner, the German company BioNTech, also relies on the same patents for RNA modification and has received the equivalent of \$445 million from the German government.<sup>27</sup> In addition to these patents relating to the mRNA vaccines, Moderna and Pfizer-BioNTech, along with Novavax, Sanofi, and Johnson & Johnson, rely on additional patents from the NIH relating to the production of the spike protein of the SARS-Cov2 virus.<sup>28</sup>

## A capitalist pick 'n' mix

While this much public money directed at drug development for a specific disease is almost certainly unique, it is not entirely out of step with the usual course of events. Virtually all drugs that make it to market are supported by public research along the way. A study in the Proceedings of the American Academy of Sciences from 2018 looked at all 210 drugs which were approved by the FDA in the US in the period 2010–2016 and found that every single one had been supported by publicly funded research from the NIH.<sup>29</sup>

It should be stressed that it is not the case that pharmaceutical companies carry out no research of their own and simply take ready-made public discoveries and package them up for market; not every pharma company goes to the extremes of Valeant. Most pharma companies do in fact carry out

significant amounts of R&D and employ many fine and dedicated researchers (although they too have generally benefited significantly from public funding during their training). What is extremely unlikely, however, is that a pharma company will engage in basic science research, the type of research that can lead to entirely new classes of drugs such as the mRNA, recombinant DNA, and Adenovirus vector technologies used in most of the new COVID 19 vaccines <sup>30</sup>

It is with this fact in mind, that the fundamental problems of the pharmaceutical industry become clear. Having benefited from publicly funded basic research and publicly funded training of their staff, pharma companies are then free to choose what research they carry out, what conditions they look to treat, and what price they put on the results—all with the goal of maximising profits for their shareholders.

The industry has, for decades, been allowed, with hardly any regulation from governments, to take from public research and choose what diseases and conditions to investigate for potential treatments. often with little to no return for the taxpayers who originally funded the work—as with Oxford's deal with AstraZeneca or the NIH deal with Moderna. The profit motive is the ultimate driving force behind the trend for pharma companies to invest in developing treatments for relatively rare diseases to be sold predominantly in wealthier countries. Due to the low prevalence, these drugs can often be approved with smaller and thus cheaper trials, and the low number of patients allows the company to charge high unit prices which governments and health insurers will often pay.<sup>31</sup> It is also the reason why there exists what Médecins Sans Frontières (MSF) calls neglected tropical diseases (NTDs). These are illnesses that almost exclusively affect people living in extreme poverty; they are often deadly and debilitating, yet there are no vaccines, diagnostic tools are limited. and treatments are often either unavailable or unaffordable or both. As MSF put it in their most recent report on NTDs:

The private for-profit sector continues to have limited interest in developing new tools for NTDs as they overwhelmingly affect people with extremely limited financial resources. The global

R&D system is skewed towards the development of highly priced drugs for diseases most prevalent in high-income countries.<sup>32</sup>

### A return to business as usual?

Even with all the broken promises around access and sharing of patents and knowledge we have seen from the pharma industry, pandemic conditions and public scrutiny have kept them somewhat in check. Even the most expensive of the new COVID vaccines are still cheaper than might be expected under normal conditions; for example, Pfizer is charging almost \$64 a dose for its COVID vaccine in the EU, while their pneumococcal vaccine, Prevnar 13, costs \$200 a dose.<sup>33</sup> There are worrying signs that pharma companies are getting ready to 'rectify' the situation and return to charging 'what the market will bear'.

We have already seen how AstraZeneca's contract allows them to essentially declare the pandemic over at a time of their choosing, but they are not alone amongst the vaccine manufacturers in this regard. Journalist Lee Fang, in a piece for *The Intercept*,<sup>34</sup> recently revealed how vaccine manufacturers are letting their investors know that they will be reevaluating their pricing once the pandemic is over.

For Pfizer CFO Frank D'Amelio, the current pricing is 'clearly not being driven by...normal market conditions, normal market forces', but by the 'pandemic state that we've been in and the needs of governments to really secure doses from the various vaccine suppliers'. He also noted that there would be 'significant opportunity' for Pfizer once the pandemic ends. Moderna president Stephen Hoge expects 'more normal pricing based on value', and the executive vice president of Johnson & Johnson, Joseph Wolk, envisages 'pricing that's much more in line with a commercial opportunity'. Wolk went further, describing the end of the pandemic as a 'fluid' question, but making clear that it was a question which it would be up to Johnson & Johnson to answer.35

# Taking back control

While there have been many criticisms levelled at the pharma industry over equitable access to COVID 19 vaccines, for the time being they still have strong government support—at least among the wealthy governments who have managed to secure vaccine supplies for their own populations, the Irish government among them. They have backed the European Commission in their stance at the WTO, opposing demands by developing nations to wave certain IP rights to allow them to produce their own vaccines. Responding to a question on the subject in the Dáil from People Before Profit TD Gino Kenny, health minister Stephen Donnelly stated that, while he shared his 'desired end goal', he was 'concerned that, were we to do this once, we could unintentionally undermine the companies' ability or willingness to do what we need them to do in future'.<sup>36</sup>

Governments have the power to force pharma companies to make vaccine availability more equitable, through both rights on publicly funded IP and international trade agreements dealing with emergency situations. However, for the time being they seem reluctant to use these measures. This may change when governments in wealthier countries feel under less pressure as their vaccination programmes near completion and the early public goodwill towards the manufacturers of vaccines begins to fade. both from repeated delays in the delivery of promised doses and the increasing attention given to global vaccine inequality, with all the associated deaths in the developing world and dangers posed by new mutations which could potentially render existing vaccines less effective, or worse, ineffective.

As with the case of drug companies taking the South African government to court over two decades ago, the deciding factor in what actions governments take will be down to how much pressure the public can bring to bear on them. In the South African case, the companies initially had strong support from wealthy governments, but this evaporated in the face of public pressure, leaving the companies no choice but to concede.

Big Pharma has been forced to make drugs available at an affordable cost before, when the public and public health demanded it; they can be forced to do so again.

We have been paying the piper long enough—it's long past time we called the tune.

#### **NOTES**

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- <sup>15</sup> Swans, R.L. (2001) 'Drug makers drop South Africa suit over AIDS medicine', *The New York Times*, 20 April, available from: nytimes.com/2001/04/20/world/drug-makers-drop-south-africa-suit-over-aids-medicine.html
- <sup>16</sup> As distasteful as these actions were, they were only one aspect of Valeant's profit-maximizing strategies. They also engaged in tax-inversion deals using offshore entities to avoid tax as well as secretly running a network of pharmacies to sell their price-inflated drugs to consumers and get medical insurers to pay for them. For a full account see: Mclean, B.(2016) 'The Valeant Meltdown and Wall Street's Major Drug Problem', *Vanity Fair*, 5 June, available from: vanityfair.com/news/2016/06/the-valeant-meltdown-and-wall-streets-major-drug-problem
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<sup>&</sup>lt;sup>30</sup> For a somewhat pro-pharmaceutical industry view which discusses some of these issues, but which sees issues such as drug pricing and choice of