PEOPLE BEFORE PROFIT

FIGHTING FOR WORKERS & ECO-SOCIALISM

Access To Medicines And Vaccines

Jan 2022 Revision

PEOPLE BEFORE PROFIT
SOCIALISM FOR THE 21ST CENTURY

Access To Medicines And Vaccines

Introduction

The rollout of Covid-19 vaccines has been front-page news since the start of the year when vaccinations started. Significant progress has been made but the global rollout remains behind schedule, plagued by issues of supply and almost constant controversy.

As the more transmissible Omicron variant of the SARS-CoV2 virus becomes dominant across the island and cases rise once more, rapid vaccination, particularly focused on completion of immunisation in older cohorts, will be essential if we are to avoid another serious wave of infections.

While we are entering another phase of uncertainty in Ireland, with much of the population still to be vaccinated, the situation globally is much worse – labelled by Oxfam as “vaccine apartheid”.

As it stands, 9 in 10 people in 70 of the world’s poorest countries will have no access to Covid-19 vaccines in 2021[1]– people living in the countries with the least developed public health systems and the least capacity to deal with the pandemic are being locked out of access to vaccines that could save their lives. The deadly cost of this vaccine inequality was hammered home in real-time on the Indian subcontinent recently, where over 400,000 people died from an infection despite the existence of an effective vaccine.

Meanwhile, wealthy countries, representing just 14% of the world’s population have bought up enough vaccine to cover their populations several times over – together, the EU, US, UK and a handful of other countries have purchased almost the entire supply of the Moderna vaccine for 2021 and over 96% of the supply of the Pfizer/BionNTech vaccine[2].

This is a moral outrage, in a global public health emergency, vaccines and medicines should be distributed based on need, not the ability to pay or monopolise production. Vaccine inequality will prolong the pandemic for us all, costing more lives, and causing more misery. A recent report from the International Chamber of Commerce projected that vaccine inequality could cost up to $9.2 trillion in economic losses if it continues at the level it is at today – with a disproportionate burden falling on the poorest and least developed countries of the Global South[3]. Continuing vaccine inequality threatens us all. As the virus is allowed to continue circulating in unvaccinated populations, the risk of novel strains emerging is greater and more prolonged.

We have already seen the emergence of more transmissible and deadly strains, and some that reduce the efficacy of certain vaccines – the P1 variant that first emerged in Brazil, and the Delta strain that is becoming dominant across Europe, after wreaking havoc on the Indian subcontinent. The longer people in the Global South are denied vaccines, the longer this pandemic will persist and the greater the risk will be of strains emerging that render vaccines ineffective, and our progress to date, lost. We will not be safe until everyone is safe.

1 https://www.oxfam.org/en/press-releases/campaigners-warn-9-out-10-people-poor-countries-are-set-miss-out-covid-19-vaccine

2Dyer O. Covid-19: Many poor countries will see almost no vaccine next year, aid groups warn BMJ 2020; 371 :m4809 doi:10.1136/bmj.m4809

3 https://iccwbo.org/publication/the-economic-case-for-global-vaccinations/

To tackle these grave threats and crises, we must understand and address their root causes. Patent protection, corporate secrecy, and the prioritisation of private profits over public health in the pharmaceutical industry. These issues have recently come to the fore, but they are not unique to the pandemic. Rather, they are key features of the capitalist system in the pharmaceutical industry, which have become entrenched over the course of decades through a deliberate process of commodification of healthcare. The present moment offers an opportunity to break from the broken capitalist model of pharmaceutical development in favour of a more democratic, socialist model that would put people's health and wellbeing before profit.

Medicines and Capitalism

Science has immense liberatory potential, to save, improve and enrich life. Under capitalism, however, this is a potential that is too often untapped. Under capitalism, science is instrumentalised and applied to generate profit; other benefits to humanity are disregarded as incidental to the process of accumulation.

Nowhere is this more apparent than in the pharmaceutical industry, where the medicines that are developed and sold are the medicines that offer the best financial returns to their manufacturers, not necessarily the medicines for which there is a most clinical need. A glaring example of this is the opioid epidemic in the United States, which cost close to 500,000 lives between 1999 and 2019[4]. The disaster of the opioid abuse epidemic was fuelled by Big Pharma's relentless drive for-profit – companies misled the public on the dangers of addiction and used their tremendous wealth and power to improperly influence doctors, public health agencies and policymakers[5]. In October 2020, Purdue Pharmaceuticals, the manufacturers of Oxycontin, paid an $8Bn settlement, after a US Federal court found the company guilty on multiple charges related to marketing and encouraging the prescription of Oxycontin "without legitimate medical purpose". Four other large pharmaceutical companies, including Johnson & Johnson, paid out a combined $26Bn following other court actions related to the opioid crisis in the US.[6]

Another example of Big Pharma's self-serving application of science is the practice of "evergreening" – where researchers make small chemical modifications to their drugs, yielding little or no therapeutic benefit over their original formulae, all to allow for the extension of patent protection, to lock generic competitor drugs out of the market. Vast amounts of money are spent on R&D related to the practice of evergreening, and this comes at the expense of genuine innovation – 78% of new drug patents awarded in the past decade were for drugs similar to existing drugs[7], and around 50% of all newly approved drugs offer no benefit over existing treatments. This cynical abuse of the patent regime gives the lie to the idea that profit drives innovation; in the case of evergreening, the promise of extending profitable patent monopolies on existing drugs pulls money away from riskier or less lucrative R&D[8]. This has meant chronic

4 Understanding the Epidemic | Drug Overdose | CDC Injury Center. Available at: https://www.dc.gov/drugoverdose/epidemic/index.html (Accessed: 14th April 2021)

5 Marks, J. H. Lessons from Corporate Influence in the Opioid Epidemic: Toward a Norm of Separation. J. Bioeth. Inq. 17, 173–189 (2020).

6 https://www.washingtonpost.com/health/opioid-settlement-drug-distributors/2020/11/05/6a8da214-1fc7-11eb-b532-05c751cd5dc2_story.html

7 John Braithwaite & Peter Drahos. Global Business Regulation. (Cambridge University Press, 2000).

8 Feldman, R. (2018) May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, Pages 590–647, https://doi.org/10.1093/jlb/lsy022

underinvestment in developing new medicines for a whole host of diseases and conditions. Here we'll examine two key areas that have been deprived of adequate investment by the pharmaceutical industry; (i) antibiotic-resistant bacterial infections, and (ii)neglected tropical diseases.

How The Drive for Profit Deprives us of New Drugs – Two Cases:

(i) New Antibiotics:

Antibiotic-resistant bacterial infections are a growing problem worldwide, a 2019 UN report indicated that at least 700,000 deaths per year are caused by drug-resistant pathogens[9,10] The same report, from the UN Interagency Coordination Group on Antimicrobial Resistance, predicted that the number of deaths caused by drug-resistant infections could reach ten million per year by 2050 if current trends continue.

Although not as widely feared, antibiotic resistance represents a major threat to humanity in the next century, just like climate breakdown. The escalation of this crisis will mean routine surgical procedures come with an inflated risk; a risk that the WHO has warned could lead to further deaths as procedures are deferred on a balance of risk of infection versus likely benefit.

The driving force behind this crisis has been the overuse of existing antibiotics, in animals and to a lesser extent in humans. Antibiotics are deployed in enormous quantities in industrial agriculture to encourage disease-free growth of livestock in high-density factory farms, with this practice encouraged for years by veterinary drug manufacturers[11]. This over-deployment of antibiotics has selected for the widespread emergence of drug-resistant mutant bacteria, impervious to many of the frontline drugs used to treat common infections. Pharmaceutical innovation has so far failed to keep up with the pace of bacterial evolution. While small improvements have been made to existing antibiotics, no new class of antibiotics has been discovered and successfully brought to market since 1987.

This is not primarily a technical problem, it is a problem of investment. A 2017 study put the cost of developing a novel antibiotic at $1.5Bn[12], meanwhile, the average revenue generated for an antibiotic's sale is $46m per year[13] – not nearly enough for private pharmaceutical companies to justify their investment. As drugs administered for short durations, compared to drugs for chronic illnesses, this further tips the balance away from investment in risky research on new antibiotics. This lack of private interest in

9 UN Interagency Cooperating Group on Antimicrobial Resistance (2020). No Time To Wait – Securing the Future from Drug Resistant Infections – accessible: https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf

10 Strathdee, S. A., Davies, S. C., & Marcelin, J. R. (2020). Confronting antimicrobial resistance beyond the COVID-19 pandemic and the 2020 US election. The Lancet, 396(10257), 1050-1053.

11 Angus, I. (2019). Superbugs in the Anthropocene. Mon Rev, 71, 1-28.

12 Towse, A., Hoyle, C. K., Goodall, J., Hirsch, M., Mestre-Ferrandiz, J., & Rex, J. H. (2017). Time for a change in how new antibiotics are reimbursed: Development of an insurance framework for funding new antibiotics based on a policy of risk mitigation. Health policy (Amsterdam, Netherlands), 121(10), 1025–1030. https://doi.org/10.1016/j.healthpol.2017.07.011

13 Placket, B. (2020) Why big pharma has abandoned antibiotics Nature 586, S50-S52 doi: https://doi.org/10.1038/d41586-020-02884-3

antibiotics is reflected in publicly funded research too, where priorities are often influenced by the interests of pharmaceutical giants – from 2008 to 2013, 0.7% of all public research funding in the UK went to antibiotic research, while just 1.9% of available funding went to bacteriology projects.[14]

(ii) Treatments for Tropical Diseases

Tropical diseases such as malaria also cause a huge burden of illness and mortality worldwide. Malaria, for example, is estimated to cause around 400,000 deaths annually. It is estimated that 1.7 billion people worldwide are infected with Tuberculosis (23% of the world population) and the disease kills 1.5 million people a year on average14, while the BCG vaccine is effective against paediatric tuberculosis, no effective vaccine exists for adults. A vaccine for this disease is achievable in theory, but no financial incentive exists to attract Big Pharma. Shockingly, from 2000-2011 only 4% of newly approved drugs were for neglected tropical diseases[15]. As these are seen as diseases of the poor, they are also seen as unappealing targets for profit-driven Big Pharma.

Even for diseases that do receive attention, pharmaceutical companies often prefer to direct research towards developing treatments, rather than cures or preventive measures like vaccines. Famously, in a 2018 report on the pharmaceutical industry, Goldman Sachs analysts asked, “Is curing patients a sustainable business model?[16] Under the privately-run, for-profit model in the pharmaceutical industry, the answer to this question is too often “No”.

Vaccines:

In particular, as they are high-volume, low unit-price products, developing vaccines is a particularly unattractive prospect for private pharmaceutical companies. Before 2020, many of the world’s largest pharmaceutical companies had moved away from vaccines altogether, with just 5 companies accounting for 80% of the global vaccine market.[17] This has led to chronic underinvestment in vaccine research and productive capacity, meaning global shortages of important vaccines like BCG, and an inability to respond to unforeseen demand for vaccines brought on by epidemics, or pandemic diseases like Covid-19. Scientists have said for example that we would have been better prepared for this pandemic if more research had been done to develop a vaccine for the coronaviruses that caused the SARS outbreak of 2002-2004 and the MERS outbreak of 2012 (both coronaviruses closely related to SARS-CoV2, the virus that causes Covid-19). Before the pandemic, Baylor University scientist Peter Hotez and his team had developed promising vaccine candidates for SARS and MERS but could not progress their research further due to a lack of funding and interest from the pharmaceutical industry.[18]

14 Bragginton, E. C., & Piddock, L. J. (2014). UK and European Union public and charitable funding from 2008 to 2013 for bacteriology and antibiotic research in the UK: an observation al study. The Lancet. Infectious diseases, 14(9), 857–868. https://www.nature.com/articles/d41586-020-02884-3

15 Pedrique, B., Strub-Wourgaft, N., Some, C., Olliaro, P., Trouiller, P., Ford, N., Pécoul, B. & Bradol, J. H. The drug and vaccine landscape for neglected diseases (2000-11): A systematic assessment. Lancet Glob. Heal. 1, e371–e379 (2013).

16 https://www.cnbc.com/2018/04/11/goldman-asks-is-curing-patients-a-sustainable-business-model.html

17 https://www.who.int/immunization/programmes_systems/procurement/market/global_supply/en/

18 https://www.nbcnews.com/health/health-care/scientists-were-close-coronavirus-vaccine years-ago-then-money-dried-n1150091

Now that Big Pharma is returning to vaccine development during the pandemic, their main goal is to maximise profits by achieving regulatory approval in rich countries as soon as possible. Therefore, clinical trials have been designed in such a way as to clear this bar in the shortest possible time. Questions about whether or not the vaccines asymptomatic infection and transmission as well as symptomatic infection, or what the best dosing regimen is, or how storage requirements can be optimised to facilitate rollout in developing countries with little infrastructure, are secondary to the concerns of Big Pharma, but vital to public health. Even developing the best possible vaccine is secondary to the drive for profit, as companies refuse to cooperate with each other or share data and technology.

Building Trust in Science and Vaccines

The development and production of not one, but several highly effective vaccines against SARS-CoV2 in less than a year is a landmark achievement for modern science and a testament to its life-saving potential. The speed of the process was truly unprecedented – vaccines that would usually take several years to develop were delivered in several months, with millions of doses administered worldwide.

While the vast majority of us found great relief in the advent of new vaccines, others have found aspects of their development concerning. Many have asked whether the speed of development has come at the cost of safety, whether the clinical trial process was as robust as it usually would be, and whether the vaccines can be trusted. Here, it is important not to dismiss concerns out of hand, as some commentators have. Instead, concerns should be heard, understood, and met with clear responses that communicate what is known, and crucially, what remains uncertain.

Trust in science must not be treated as a virtue, nor should it be expected on faith. To truly tackle the problem of vaccine hesitancy and mistrust, we must be clear about the benefits of vaccination, and crucially, about where the mistrust comes from. Addressing the former is relatively simple – from 2010 to 2015, the WHO estimate that vaccines have prevented at least 10 million deaths[19]. Between 1990 and 2016, global cases of measles fell by 93%. Diphtheria by 89%. Tetanus also by 89% [20]. Polio has been virtually eradicated. Smallpox, once a nightmare disease and major killer, has been totally eradicated. These are just some of the indisputable triumphs of vaccines.

The source of mistrust is more complex. An obvious contributory factor has been the behaviour of the pharmaceutical industry itself, which has shrouded itself in secrecy and committed serious crimes. The British Science writer Ben Goldacre has written several books detailing the anti-scientific practices of Big Pharma [21 22 23]– ranging from the non-publication of negative trial data, to the selective use of evidence for regulatory purposes and the aggressive marketing of drugs for unproven purposes. These routine

19 Kaufmann S. (2019). Highly affordable vaccines are critical for our continued efforts to re duce global childhood mortality. Human vaccines & immunotherapeutics, 15(11), 2660–2665. https://doi.org/10.1080/21645515.2019.1605817

20 https://www.who.int/publications/10-year-review/vaccines/en/

21 Goldacre, B. (2014). Bad pharma: how drug companies mislead doctors and harm patients. Macmillan

22 Goldacre, B. (2010). Bad science: Quacks, hacks, and big pharma flacks. McClelland & Stewart.

23 Goldacre, B. (2014). Preventing bad reporting on health research.

practices undermine trust in science and the process of science itself, but they pale in comparison to some of Big Pharma's more spectacular crimes:

- **Opioid Crisis:** Purdue Pharmaceuticals and several other US Pharma Giants, including Johnson & Johnson aggressively promoted and marketed highly addictive pain medication, encouraging doctors to prescribe them to patients, while concealing and misleading the public about their potential for harm. An estimated 500,000 people have died as a result of the crisis between 1999 and 2019. Purdue was found guilty on multiple criminal and civil charges in an October 2020 US Court Case, they were ordered to pay $8Bn – the largest settlement ordered in US history.
- **Trovan Trials:** In 1996, during a Meningitis outbreak in Kano, Nige ria, Pfizer administered the experimental, unapproved drug *Trovan* to hundreds of children suffering from meningitis, in place of the gold standard treatment, Ceftriaxone. The medication was administered without parental consent. 11 children died and many more suffered serious side effects including brain damage and paralysis. In 2011, after a 15-year legal battle, Pfizer settled with some of the families involved.[24]
- **Mother and Baby Homes:** The 2020 Mother and Baby Home Commission Report found evidence of at least 13 separate unethical clinical trials of vaccines carried out on "illegitimate children" in Mother and Baby Homes. Although there is no evidence that any children were harmed in the trials, over 40,000 children were enrolled without consent of their mothers, or proper regulatory approval. Involved in the trials were the Pharmaceutical company Glaxo (now part of GSK) and the funding agency, Wellcome.[25]
- **Study 329:** A 2001 study into the efficacy of the anti-depressant Paxel (Paroxetine) in adolescents, caused major controversy when it emerged that the study had been ghost-written by SmithKline Beecham, the manufacturer of the drug[26]. A 2003 analysis of the study by the UK MHRA, found that there was no evidence for the efficacy of Paxel in treating a major depressive disorder in children or adolescents, as the study had claimed. The MHRA further stated that there was "robust evidence" of a causal link between the drug and suicidal behaviour – something the initial authors had downplayed, concluding that Paxel was "generally well tolerated and effective for major depression in adolescents". In 2012, the US Department of Justice fined GSK $3Bn dollars, finding evidence that results had been concealed (particularly around suicidal tendencies)[27] [28].

These examples are far from an exhaustive list. The problem of mistrust in science cannot be divorced from people's understanding and perceptions of the pharmaceutical industry. Given the real scandals and

24 https://www.theguardian.com/world/2011/aug/11/pfizer-nigeria-meningitis-drug-compensation

25 https://www.irishexaminer.com/news/arid-40206482.html

26 https://www.newscientist.com/article/mg22730394-500-new-look-at-antidepressant-suicide-risks-from-infamous-trial/

27 Letter from Kent Woods, MHRA, to Jean-Pierre Garnier, GSK, Medicines and Healthcare products Regulatory Agency, 6 March 2008- https://webarchive.nationalarchives.gov.uk/ukgwa/20141206221415/http://www.mhra.gov.uk/home/groups/es-policy/documents/websiteresources/con014157.pdf

28 https://www.justice.gov/opa/pr/glaxosmithkline-plead-guilty-and-pay-3-billion-resolve-fraud-allegations-and-failure-report

crimes committed by the industry, it is not surprising that there is mistrust and even belief in outlandish conspiracy theories.

This mistrust is compounded by the dominance of “Scientism” and the increasing fetishisation of “expertise”, exemplified by calls to “follow the science” from governments around the world throughout the pandemic, even as their actions contradicted the majority opinion of working scientists and medics. Scientism traffics in absolutes and certainties – real science is never so clear. It involves the elevation of selected experts to an almost priestly status and removes all space for criticism or disagreement, trafficking in soundbites rather than carefully qualified statements or observations. In most cases, the kind of scientism espoused by governments, establishment pundits and lobbyists only involves listening to actual science when it is politically convenient. As a crude impression of science, scientism is grossly unappealing and damages popular engagement. To rebuild trust, we need a science that engages experts and non-experts alike – a democratised, open Science where information is shared and explained rather than hidden or selectively interpreted. This will not be realised in a system dominated by private interests, where public research is anaemically funded and mainly disseminated by private publishers. We need a Science for the People to rebuild trust and foster curiosity throughout society.

Medical Extortion: The Crisis of Drug Pricing & Access

The crisis of access to vaccines around the world is not primarily a problem of pricing but into the future price will become a significant concern. The CFO of Pfizer has already stated that the price of vaccines needed for future annual booster shots will be significantly higher, suggesting the cost of one dose could increase from €19.50 in the US to as much as $175 [29]. This is alarming as it would make cost a significant barrier to vaccination for many people. However, this is part of a long-standing pattern of treating healthcare as a commodity rather than a basic right and treating medicines as financial assets for Big Pharma rather than public goods that belong to everyone. In the US, where there is little regulation of drug prices, citizens are fleeced when paying for life-saving drugs. In 2018, for example, it is estimated that Americans spent $535 billion on medicines. When diabetes patients are short of money, they often have to make do with using insulin less frequently and in lower amounts; this practice leading to a number of well-publicised deaths.

In Ireland, the situation is less extreme, but the cost of medicines is still a cause for concern. At present, spending on drugs is the largest single-item expenditure in primary care and national health budgets, accounting for 65% of all spending under the Primary Care Reimbursement Service (PCRS) [30]. On the level of drug procurement, the pharmaceutical industry in Ireland, through their lobby, the Irish Pharmaceutical Healthcare Association (IPHA) essentially dictate prices to the HSE in negotiations that happen once every four or five years. Ostensibly, these negotiations have delivered savings to the HSE through markdowns on branded medications but they have also cemented the control of the pharmaceutical industry; the HSE as price-taker and the biggest players in Pharma as preferred vendors for drugs that could be produced and provided more cheaply by generics manufacturers – Biologicals are a case in point. Biosimilars are in effect generic versions of biological medicines. The HSE spends on average €280million per year on branded biologicals when Biosimilars would work just as well at a fraction of the cost (as of 2019 6% of all biologicals prescribed in Ireland are Biosimilars) [31]. The most commonly prescribed biological in Ireland, Enbrel (Pfizer), used primarily to treat Rheumatoid Arthritis, was dispensed in 98.7% of all cases, an equally effective biosimilar was prescribed in just 1.3% of cases despite both drugs being manufactured in Ireland. In Norway, Enbrel biosimilars were prescribed in 82% of cases, in Britain, 58% of prescriptions were for Enbrel biosimilars.[32]

Biologicals are among the most profitable drugs of all. As one example, Humira (Adalimumab), which was developed using public money in a lab in Cambridge was sold to Abbvie Pharmaceuticals who made an estimated $20Bn in 2018 on Humira alone. Biologicals are an especially lucrative aspect of the pharma industry in Ireland and this may explain why Ireland proscribes so few biosimilar medications compared to other European countries. Biologicals and Biosimilars are provided under the High Tech Drug Scheme

29 https://www.fiercepharma.com/pharma/pfizer-eyes-higher-covid-19-vaccine-prices-after-pandemic-exec-analyst

30 Connors, J. (2017) Primary Care Reimbursement Service Trend Analysis – IGEES, DEPR – Accessed at: https://igees.gov.ie/wp-content/uploads/2018/04/8.Primary-Care-Reimbursement-Service-%E2%80%93-Trend-Analysis.pdf

31 https://www.irishtimes.com/business/health-pharma/state-fails-to-save-millions-on-hse medicines-bill-1.3786080

32 https://labour.org.uk/wp-content/uploads/2019/09/Medicines-For-The-Many.pdf

(HTDS), which is another aspect of the PCRS, in addition to the GMS, Drug Payment Scheme (DPS) and Long Term Illness (LTI) scheme. The HTDS accounts for 30% of total drug spending (€578 million in 2016) and in recent years, there have been battles to add medicines like Orkambi (Cystic Fibrosis) and Spinraza (Spinal Muscular Atrophy) to the HTDS, sometimes successfully.

In the case of Orkambi, Vertex Pharmaceuticals demanded €158,000 per patient per year, which the HSE was unable to cover. After campaigners in the UK and Ireland drew attention to a biosimilar, produced in Argentina, threatening to import the drug as part of a buyer's club, Vertex agreed to drop their prices and the NHS and HSE began to dispense the drug. This was a striking lesson in how Big Pharma operate, how corporations exercise patent monopolies to restrict supply and keep prices high, disregarding patients' needs.

To ensure that the liberatory potential of Science and Medicine are realised, there will have to be a fundamental change in the way medicines are developed and produced. The profit motive must be removed as the major organising principle in pharmaceutical R&D, and a new system that treats medicines as a global public good must take its place. People Before Profit believe that the first steps towards creating such a system could be taken in this country, by the creation of a not-for-profit National Pharmaceutical Company – this company could initially produce generic drugs for use in the HSE and for export, taking up genuine R&D, in collaboration with public research institutions as capital and technical capacity are built up over the medium term. With the possibility of global tax policy reform looming, the foundation of the private pharmaceutical industry in Ireland could soon be undone; establishing a National Pharmaceutical Agency could pick up the pieces, redeploying skilled workers and resources from the private system, buffeting the disastrous effects of major industry withdrawing from the country.

Making Academic Research Work in the Public Interest

Much publicly funded scientific research takes place in an academic set ting. People Before Profit recognises the importance of the independence of universities in a democratic society. However, there are some structural issues regarding the conduct of publicly funded research in academia which should be addressed by the State.

There is a lack of appropriate avenues through which scientists in academia can ensure that their research is used in the public interest and not harnessed for private profit. A significant issue is the current scientific and academic publishing system. Most scientific journals are privately owned by just a handful of large publishing companies (e.g. Elsevier, Springer Nature, Wiley). When scientists write original research articles or reviews, they are often charged large publication fees to have their work processed and published by journals – often covered by publicly funded research grants. Once published, journals take ownership of the material they publish, often making it inaccessible, behind a paywall. To gain access, public research institutions pay large subscription fees to scientific journals, even though these may contain research carried out in their own institution.

Essentially, taxpayers pay for scientific research in academia three times over; first by covering the research costs, then by paying for publication fees, and then by paying subscription fees. Publishing

companies add little value, as authors who publish in a journal are asked to peer-review other scientists' work on a voluntary basis. An article in The Guardian described this system as if "the New Yorker or the Economist demanded that journalists write and edit each other's work for free, and asked the government to foot the bill [33]." Using this model, scientific publishing has become one of the most profitable industries in the world, with some publishers reporting profit margins higher than tech giants like Google and Apple – in 2019, Elsevier posted net profits of $1.2Bn, for a 37% profit margin. This is higher than average margins in banking (31%), pharmaceuticals (18%), Tobacco (17%) and oil (9%)[34]. Scientists in academia are locked into this system and forced to "publish or perish", with future funding contingent on "high impact" publications as a key metric of research output. Attempts to address this issue have included measures such as making publication of results in an open-access manner a condition of research grants. However, this mantra of individual responsibility is inadequate as it does not provide a viable alternative to for-profit publishing companies.

Furthermore, there is also a lack of any feasible pathways for researchers in academia to develop their innovations into products that can be distributed widely on a not-for-profit basis. Instead, they are faced with two options. They can patent their invention and sell or license the patent to a private company, as Oxford University did when they gave exclusive rights to their publicly funded Covid-19 vaccine to AstraZeneca, a private company. Alternatively, researchers could go it alone with a start-up, or spin-off, autonomous or semi-autonomous from their university. However, this second option is fraught with difficulty, has a high failure rate and entails an amount of work that not many academics could handle. Often, "successful" private ventures are bought up by anti-competitive pharmaceutical companies, who choose to sit on new technologies, rather than further developing them. Neither option is conducive to ensuring scientific innovations are used for the public interest.

An increase in funding for academic research is needed, however, this must come hand in hand with conditions regarding public ownership of innovations arising from the research. Publicly funded research should be published in an open, freely accessible way, not behind paywalls in academic journals owned by private companies. The onus is on the government to create the conditions that will make these changes possible, as reorienting the distribution of the benefits of academic research away from a neoliberal model is beyond the scope of individual responsibility of researchers. This change is badly needed, however, as currently, pharmaceutical companies can reap the benefits of academic research by building on it (for example mRNA vaccines were made possible by years of research in academia) and commercialising the resulting innovations, while the public is ripped off.

Proposals:

- Ireland to increase public spending on research from 0.78% GDP to at least the EU average of 2.19% – in the coming period, faced with economic uncertainty, ecological breakdown and the threat of future pandemics, there is a strong case for further investment beyond this, as part of a

33 https://www.theguardian.com/science/2017/jun/30/lab-notes-staggeringly-profitable-scientific-publishing-a-skull-cult-and-asteroid-day

34 Damorandan, A. (2021) – Profit Margins By Sector (US) – NYU Press – accessible: https://pages.stern.nyu.edu/~adamodar/New_Home_Page/datafile/margin.html

new developmental model for Ireland. Increasing funding to 4% of GDP over time would make bring Ireland to the top of the table in terms of public funding.

- Explore alternative models of disseminating research, such as publicly owned not-for-profit academic publishing companies.
- End precarious employment conditions in academia, employ researchers on a permanent, pensionable basis, with defined responsibilities in research, teaching and other areas (e.g. public policy, replication of experiments/trials, advisory roles).
- Introduce new rules around Intellectual Property originating from publicly-funded research to ensure public benefit and protect against predatory purchase by pharmaceutical companies.
- Explore ways to encourage the dissemination of research outside the traditional paradigm of scientific publishing, for example through online platforms like arXiv.org.

Tax Dodging in the Pharmaceutical Industry

During the pandemic, as Covid-19 has taken millions of lives, many now look to the producers of vaccines as their main hope of escape from this deadly virus. Pfizer, Moderna, AstraZeneca and Johnson and Johnson have become household names. Governments and the EU itself seem to be at their mercy, hoping there will be no more supply problems. Prior to Covid-19, however, Big Pharma was among the most loathed of all industries. When the polling company, Gallup, asked US respondents to rank the industries that they favoured, Big Pharma came in last. There is a good reason for this dislike. The big pharmaceutical corporations, including the vaccine producers who are now trying to refurbish their image, are among the greediest and most rapacious in the capitalist world. Their primary interest is not in helping to end the pandemic, but rather in maximizing their own profits. They pursue this goal through monopolistic practices, unfair pricing, and crucially, paying as little tax as possible.

One of the main tactics of Big Pharma is to get close to political power to ensure they get full cover for their activities. In 2019, the pharmaceutical industry in the US spent $295 million on lobbying, far more than any other sector. During Joe Biden's election campaign for US President, the largest financial contributors were the pharmaceutical and health insurance industries, who contributed nearly $100 million. In Ireland, Big Pharma has cosied up to the government and ensured that it promotes its interests. In the EU, Big Pharma spent €16 million on its lobbying activities in 2019.

Through its friendship with the highest echelons of government, Big Pharma protects its obscene profits. From 2000 to 2018, 35 large pharmaceutical companies made a gross profit of $8.6 trillion. The rate of profit compared to the level of investment was in the region of 15% to 20% – one of the highest rates of any sector. These vast profits are reflected in the income paid to the CEOs of these corporations. Thus, Alex Gorsky of Johnson and Johnson received a yearly income of $30 million dollars while the former CEO of Pfizer, Ian Reid, got marginally less at $28 million. These salaries are a reward for ripping people off across the world and creating huge suffering by restricting access to life-saving medicines.

Access To Medicines And Vaccines

Ireland plays a central role in the operations of Big Pharma. Nine of the world's largest pharmaceutical companies are located in Ireland and seven of the world's top-selling drugs are manufactured in this country. This raises an important question: why do these giants decide to locate in Ireland and claim that their drugs are made here?

The answer lies in Ireland's role as a global tax haven. Almost everybody knows that its official rate of tax on corporate profits is 12.5%. Politicians constantly warn us that if we ever raise that figure, the multinationals would flee and the country would be reduced to a jobless desert.

However, hardly any corporation pays even the minimal tax of 12.5%. Rather they avail of a host of 'loopholes' to reduce their tax bill to between 2% and 6% a year. According to the official narrative, these 'loopholes' were discovered by clever accountants who discovered them in laws passed by the Dáil. But this is a myth. The loopholes are deliberately written into legislation by government Ministers who have been shown the way by the clever accountants.

The evidence of how Ireland facilitates Big Pharma in tax avoidance is overwhelming. A study by Oxfam, for example, found that Johnson & Johnson recorded profits of €4.31 billion in Ireland in 2015 but only paid an effective tax rate of six per cent, €250 million less than they should have paid at Ireland's corporate tax rate of 12.5%. Abbott declared a profit of €1.2 billion in Ireland in 2015 but paid absolutely no tax on these profits, based on the data that was accessible.

Johnson & Johnson's subsidiaries in Thailand posted an 8% profit while its Irish subsidiaries posted 38% profit for the years 2013-15. Yet the costs of labour are far cheaper in Thailand, which begs the question – how could the Irish rate of profit be nearly five times higher?

The answer to this conundrum lies in the fact that Big Pharma pretends that more is produced in Ireland and at a cheaper rate than elsewhere. This tactic is known as "transfer pricing" and is a sophisticated form of tax dodging. Components used in the production of the drugs are sourced from a parent company. The prices of these components are artificially lowered. This is relatively easy as the transfers are all occurring within the same corporation. The result is that a higher level of profit appears to be made in Ireland.

Another ploy used by Big Pharma in Ireland is buying intellectual property from their parent company and then using that expense to write down their taxable profits. In this case, the price of the intellectual property is artificially inflated to allow for more tax write-downs. This tactic helps to explain the extraordinary figures on royalties on intellectual property sent out of Ireland. In 2015, royalties sent out of the country were equivalent to 26% of Ireland's GDP – more royalties than were sent out of the rest of the EU combined, making Ireland the world's number one royalties provider.

Finally, Big Pharma, in particular, can net a special tax rate of 6.25% which is reserved for companies who conduct research and develop intellectual property in Ireland. This special rate was introduced by the Fine Gael Finance Minister Michael Noonan after Ireland was shamed through the use of its 'Double Irish' tax avoidance scheme. This set up a link between Ire land and Bermuda to enable big corporations to pay no tax. Once its workings were exposed, the Irish authorities felt there was a need for a more 'legitimate' device to enable companies to do some tax dodging. The new measure was the 6.25% Knowledge

Development Box rate. The prime beneficiaries of this very low tax rate, which allows for the use of further loopholes, are Big Pharma.

Patent Protections and Corporate Secrecy

Internationally, the principle mechanism Big Pharma uses to preserve its profits is intellectual property law. They file for twenty-year patent protection to stop others from producing cheaper generic versions of their medicines. The power of the American state enforces compliance with patent rules through the agency of the WTO. One result is that the poorest people on the planet cannot afford the drugs they need.

The history of intellectual property laws is rooted in colonialism and extractivism. The first major international treaty dealing with patent protections, known as the Paris Convention, was agreed in 1883 between colonial powers, with the goal of maintaining control of production in their

colonies, including after these had achieved independence. Newly independent countries in the Global South were later pressured to join the Paris Convention.[35] This treaty is still in force today but has also been further built upon, particularly from the 1970s onwards. In the 1990s, a major process of reform in global IP law was initiated – the World Intellectual Property Organisation, previously a standalone organisation with little enforcement power, was tied to the World Trade Organisation so that trade sanctions could be meted out to nations where IP infringement was perceived to be endemic. In 1995, this process culminated in the publication of TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement, by the WTO, which is now the main international treaty on patent protections.

While the Paris Convention came about during the heyday of colonialism, the TRIPS agreement can be viewed as arising from the neo-colonial attitudes of large corporations who wanted the ability to locate their production facilities anywhere in the world, taking advantage of workers in low-wage economies, safe in the knowledge that their monopolies would be enforced through patent protections, allowing them to continue to keep supplies of medicines artificially low in order to keep prices high. The American pharmaceutical giant Pfizer was a key player in lobbying for intellectual property rights to be more strongly linked to trade, and lead a group of large companies, which also included Johnson and Johnson, in successfully lobbying governments in the US and other developed countries to push forward negotiations on TRIPS, and in particular for the inclusion of a strong enforcement mechanism.[36] Furthermore, Big Pharma companies have even lobbied the US government to include intellectual property provisions stronger even than TRIPS in bilateral trade deals with developing countries.

Today the TRIPS agreement requires every WTO member state, as a condition of membership, to grant and enforce patents, including for pharmaceutical innovations. This has resulted in a process of enclosure and appropriation of scientific and medical knowledge and created a system under which lifesaving information, such as the recipe for producing a drug or vaccine, can be privately owned, and traded like a

35 Alexander Peukert. The Colonial Legacy of the International Copyright System. SSRN (2012).

36 John Braithwaite & Peter Drahos. Global Business Regulation. (Cambridge University Press, 2000).

commodity.

The common justification for this system is that patent protections stimulate innovation, as companies are incentivised to compete for profits by investing in research and development. This is a false narrative. In reality, patent protections and the drive for profit hinder open sharing of knowledge, data and technological innovations, motivating companies to maintain strict corporate secrecy around their research.[37] This leads to a fragmented process, where companies compete to bring similar products to market, cooperation is limited and only possible after lengthy contractual negotiations.

Proposals:

- The Irish government should lobby the EU to support the TRIPS waiver for IP rights on Covid-19 vaccines, therapeutics and diagnostics.
- Government should outline what qualifies as genuine innovation, and restrict R&D tax credits and special tax rates to genuine innovation, with a tangible connection to Ireland.
- Advocate for reform of global IP law, to end the practice of “evergreening” and to allow for automatic waivers on IP in national and/or international health emergencies – e.g. epidemics, pandemics, highly prevalent genetic diseases in specific populations (e.g. hemoglobinopathies in African populations, cystic fibrosis in Ireland).
- Reform tax law, to compel pharmaceutical companies to share IP registered in Ireland with knowledge and technology sharing mechanisms like C-TAP (Covid Technology Access Pool).
- Require the publication of all private clinical trial data gathered in Ireland, including for unsuccessful trials. This should be seen as a moral obligation towards clinical trial participants who take the risk of undergoing unproven treatments on the understanding that it will help advance medical science. Ireland should advocate for similar rules across the EU.

Accelerating Vaccine Production

Current shortages of vaccines are a result of an artificial scarcity, imposed by pharmaceutical companies, who are zealously protecting their intellectual property and monopoly on vaccine supply. A recent figure from UNICEF suggests that less than 50% of available Covid-19 vaccine manufacturing capacity is being utilised. Corporate secrecy makes it difficult to know how much vaccine manufacturing capacity there could be globally, but it is likely that there are other facilities that could be repurposed to make vaccines or vaccine components, provided technologies were shared or transferred from current producers.

Sanofi and GSK for example are two of the three biggest vaccine producers in the world but are producing minimal amounts of Covid-19 vaccines. These companies have been trying to develop a Covid-19 vaccine in collaboration with each other, however, the rollout of this vaccine has been delayed following disappointing clinical trial results. Sanofi has since agreed to make 125 million doses of the

37 Els Torreele, Mariana Mazzucato & Henry Lishi Li. Delivering the People!s Vaccine: Challenges and Proposals for the Biopharmaceutical Innovation System.

Pfizer/BioNTech vaccine and to help fill vials of the Johnson and Johnson vaccine. GSK will help CureVac manufacture 100 million doses of their vaccine, which is yet to be approved. These commitments amount to a very small fraction of the over 1 billion doses of the Sanofi/GSK vaccine that the companies had planned to make by the end of 2021. However, rather than doing more to make use of their spare capacity, which may require the reconfiguration of manufacturing plants, these companies prefer to keep their capacity in reserve in anticipation of bringing their own vaccine to market at a later stage, as this is likely to be more profitable for them.

A number of other companies have the capability and willingness to produce Covid-19 vaccines, but this capacity is untapped. Danish pharmaceutical company Bavarian Nordic publicly offered up the capacity to produce 240 million doses of a Covid-19 vaccine in its factory, but none of the companies with the successful vaccines took up the offer[38]. Similarly, Incepta in Bangladesh and Biolyse in Canada have offered to produce one of the approved vaccines, but these offers have not been accepted either. While it is hard to say for certain how much capacity there could be in developing countries, there are at least eight vaccine manufacturers on the African continent alone. With mandatory technology transfer, it is likely that some of this capacity could be used to produce vaccines where they are needed most – in the longer term, scaling up production capacity for vaccines and other essential medicines in the Global South must be supported by wealthier countries as a matter of urgency.

Fundamentally, the inequitable global distribution of vaccines and other medicines must be seen as a consequence of the private ownership and organisation of the pharmaceutical industry. Capitalism subordinates human needs to the drive for profit, under capitalism, pharmaceutical companies are organised to make profits, not widely-accessible and life-saving medicines. To guarantee access to vaccines and other medicines wherever and whenever they are needed, we will need to move towards a new system that is democratically and rationally managed, with the provision of medicines as its main organising principle. This will require a move towards public ownership, which might be achieved through nationalisation, through the construction of new state-owned pharmaceutical companies, or through a combination of these two methods. In the meantime, there are a number of measures that could be deployed to alleviate production shortfalls and scarcity in the short to medium term – this could include:

- The use of Article 122 of the Treaty on the Functioning of the European Union to suspend patent rights and bring all privately owned facilities in the EU that can be used to manufacture vaccines under Emergency public control.
- The Irish government should follow other countries in strengthening the legal framework for compulsory licensing of patents, and issue compulsory licenses to pharmaceutical companies with manufacturing capacity in Ireland
- The use of sections 77 and 78 of the Patents Act, which allow for the use of a patented invention in the service of the State without the patent holder's consent. This can be done for purposes including: "the maintenance of supplies and services essential to the life of the community and

38 https://www.thelocal.dk/20210202/danish-company-offers-to-help-with-covid-19-vaccine-production/

securing a sufficiency of supplies/services essential to community well-being."

The immediate crisis wrought by the pandemic is part of a much larger crisis, namely that of ecological collapse, driven by Capitalism's boundless exploitation and destruction of nature. Since the turn of the century, we have witnessed the spread of H1N1 and H5N1 influenza viruses, SARs, MERs, Zika virus, and the Ebola crisis, to name but a few. For years, the World Health Organisation has warned of the imminent risk of major pandemics – in their 2019, A World at Risk report[39], they warned that "there is a very real threat of a rapidly moving, highly lethal pandemic of a respiratory pathogen, killing 50 to 80 million people and wiping out nearly 5% of the world's economy". These warnings were grounded in observations of an enhanced rate of spillover of zoonotic diseases from animals to humans observed around the world but particularly concentrated in tropical and subtropical regions, where the population has grown rapidly at the expense of natural habitats, driven by consumer demand from wealthier countries and corporations. These incursions of capital into nature have driven animal species out of old habitats and into new areas, into much closer proximity to humans, offering zoonotic diseases a greater range of potential hosts to adapt to and colonise.

Simultaneously, the commodification of wildlife, and alongside it, the intensification of factory farming have created conditions that are ripe for the evolution of deadly new diseases. High-density animal agriculture and the drive for genetically homogenous animals in capitalist agriculture mean contagion can spread quickly, meeting less resistance than would be experienced in a more genetically diverse, natural population. The evolutionary biologist Rob Wallace has written extensively on the emergence of novel influenza strains in farming, drawing attention to "virulence ratchets" like Guangdong Province in China, where a number of novel influenza strains have emerged in recent years, thanks to the confluence of rapid urbanisation (displacing nature) and the development of large scale industrial agriculture, side by side [40] [41]. The emergence of these new diseases is part of a deepening "metabolic rift" between complex ecological systems and a similarly complex productive system, subordinated to capitalist logic [42]. This rift between humans and nature is widening and spells disaster unless it is addressed soon – novel pathogens, climate breakdown, collapse of ecosystems are all the consequence of a system organised around the short term drive to accumulate profit. The only way to repair this rift and avoid catastrophe is to create a new system that puts people's needs and the health of the planet first.

39 https://reliefweb.int/report/world/world-risk-annual-report-global-preparedness-health-emergencies-global-preparedness

40 Wallace, R. (2016). Big farms make big flu: dispatches on influenza, agribusiness, and the nature of science. NYU Press.

41 Wallace, R. (2020). Dead epidemiologists: On the origins of COVID-19. Monthly Review Press.

42 Foster, J. B., Clark, B., & York, R. (2011). The ecological rift: Capitalism!s war on the earth. NYU Press.

Alternatives for the Future

Unequal access to medicines, the fruit of pharmaceutical research has long caused needless suffering, but the issue has not received much attention. This is for a variety of reasons. Up to now, the problems and struggles for access have been felt most sharply in poor and developing countries of the Global South. HIV and Hepatitis C exemplify this trend. In richer countries, the problem has been more confined, or else specific to particular circumstances – the lack of universal health coverage in the US, for example. In Ireland, the fight to access Orkambi, a Cystic Fibrosis drug, via the HSE highlighted that the issue isn't totally confined to poorer countries, but a relatively small number of patients were affected.

The devastating impact of the Covid-19 pandemic is significant – it has forced a discussion on how medicines are developed and distributed, here and around the world. The present moment offers a unique opportunity to push for radical change and undo the enclosure of scientific and medical knowledge. This must be part of "building back better".

The obscene profit-seeking behaviour of vaccine manufacturers and their opposition to sharing vaccine intellectual property and manufacturing technology has made people more receptive to alternatives. The very idea that profit is essential for innovation has been undermined by companies that have largely socialized their costs, taking huge sums of public money to fund R&D and the development of manufacturing technology, while privatizing profit. The early refusal of Big Pharma and some national governments to participate in the WHO Covid-19 Technology Access Pool (C TAP) was significant too – at a time where cooperation and collaboration should have flourished, the competition and secrecy fostered by capitalism stood in the way.

The profit motive has not played a role in the most successful vaccination campaigns either, those against polio and the flu. When asked who owned the patent for the Polio vaccine he had created, Jonas Salk famously quipped; "Well, the people, I would say. There is no patent. Could you patent the sun?". Since then, polio cases have dropped by over 99%, from an estimated 350,000 cases in 1988 to only 22 cases reported worldwide in 2017. Flu vaccines prevent millions of illnesses and save tens of thousands of lives every year. This is made possible by the WHO's Global Influenza Surveillance and Response (GISR) System, a network of laboratories in 123 countries, that continuously monitor influenza strains in circulation, making recommendations for the formulation of seasonal flu vaccines, which are publicly available and free for any manufacturer to use.

These successes demonstrate the effectiveness of a not-for-profit model in vaccine development and should be replicated, not just for Covid-19, but for other infectious diseases.

People Before Profit believe that the principle of public-led pharmaceutical R&D should be extended beyond vaccines too. Our collective health and wellbeing should not be commoditised, or subject to market anarchy. To guarantee access to medicines, we believe in the creation of a state-owned pharmaceutical agency – which could begin by manufacturing generic drugs and vaccines, generating capital to conduct more ambitious research and development. A National Pharmaceutical Agency would allow for greater transparency in pharmaceutical R&D and enable the democratisation of translational research. Greater

transparency would increase trust in science, helping to address vaccine hesitancy and other fears, often fueled by suspicion of the profit-driven motives of Big Pharma. Democratisation would mean funding R&D according to a metric other than return on investment; panels of scientists, clinicians and patient advocates could set the agenda for a state-owned pharmaceutical company – allowing for investment in neglected and rare diseases that Big Pharma have no interest in pursuing. It would mean the start of Science for The People, where our collective resources, knowledge and technologies were harnessed in the interest of the many, rather than the few.

In Britain, the new Vaccine Manufacturing and Innovation Centre has parallels with aspects of our National Pharmaceutical Agency proposal. The Centre, currently under construction, was founded as a collaboration between three academic institutions and is owned by a newly established not-for-profit company. There are even closer parallels with Connaught Medical Research Laboratories, a Canadian non-profit which helped make Jonas Salk's polio vaccine.

Establishing a National Pharmaceutical Agency would require significant capital investment but part of this could be drawn from a Solidarity Tax on the profits of Big Pharma – in our 2021 Alternative Budget Statement, we calculated that a 10% tax on the profits of pharmaceutical and MedTech companies would bring in €2 Billion[43].

Finally, a National Pharmaceutical Agency could act as a safeguard for jobs, in the event that multinational pharmaceutical companies pulled out of Ireland. With increasing talk of global tax reform, led by Joe Biden in the US, we could soon be in a situation where vast sections of industry pull out of the country, losing the benefits offered by Tax Haven Ireland. In such a scenario, it would pay to have an alternative to save jobs and buffer effects on the wider economy.

43 https://www.pbp.ie/budget-2021/