Democratic public ownership in the UK pharmaceutical sector

Working paper

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Dana Brown,
Heidi Chow,
Thomas M. Hanna,
Diarmaid McDonald

Global Justice Now

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1. Introduction

The pharmaceutical industry is of vital strategic importance to public health and to the economy. The UK life sciences sector, made up of businesses that develop, manufacture and market therapeutic products and medical devices—as well as specialist services and supply chains that support them—employs more than 240,000 people and generates more than £70bn in turnover. Biopharmaceuticals represent half of the employment and generate two-thirds of the life sciences turnover (68%).[1] Made up of 673 business, the pharmaceutical sector employs 64,100 people and generated a total turnover of £33.3bn in 2017.[2]

Moreover, the pharmaceutical industry receives substantial public investment and subsidies. For example, the government funds a network of institutions which support the medical innovation of researchers and companies, spending £2.4bn on health-focused research and development in 2015.[3] This sits alongside annual medical research funding from medical charities of £1.3bn and private sector spending on pharmaceutical R&D totaling £4.3bn.[4]

The biopharma sector also interacts with a wider ecosystem that includes academic institutions and publicly funded research laboratories and institutes. However, this ecosystem is highly fragmented, with each actor working in isolation on a specific part of the process, with strong upstream intellectual property rights, leading to insufficient collaboration.

The Medical Research Council (MRC) spent £814m funding research in 2017-18,[5] investing in a vast range of clinical research across our universities and research institutes. Researchers reported that almost 6,000 MRC grants have led to the development of 1,254 medical products or interventions. Almost a third were new medicines, underscoring the critical role of public funding in pharmaceutical innovation.[6]

The products from our health innovation model are essential to achieving the right to health. But the industry has demonstrated major failings that include lack of patient access to new advanced drugs, extortionate pricing that is unsustainable for the National Health Service (NHS), and a lack of innovative medicines that address key public health priorities. The cystic fibrosis drug Orkambi, which has gained substantial media attention recently, illustrates these failings. In spite of years of negotiations, the drug is not available on the NHS because the manufacturer, Vertex, is refusing to lower its £104,000 price tag.[7] Rejecting and rationing drugs is increasingly commonplace in the NHS.

In general, we have a public healthcare system that relies on privatised medicines (developed with public

support) that are developed for the areas of greatest financial return rather than the areas of greatest public health need. They are then priced at extortionate levels and protected by patents that prevent affordable pricing. And instead of ploughing profits back into research and development, many drug firms spend more in marketing[8] or share buybacks[9] than on R&D. This is not a sustainable system—socially or financially—as patients are being denied access to essential treatment and the NHS cannot sustain paying extortionate drug prices. It is an economically inefficient system that is not delivering the drugs we need at prices we can afford.

Greater democratic, public control over the research, development, production, and sale of medicines would help the government fulfil its obligations to ensure the right to health for all. It would also be consistent with, and reinforce, the principles of the NHS. Delivering universality and equity in accessing medicines is crucial to ensuring that our public healthcare system is accessible for all. And it could increase the number of secure, high-quality jobs in our economy.

There is scope for greater public, democratic control in the R&D of new medicines. Public funding is often directed at the earlier (and riskier) stages of research, with later-stage clinical trials funded by the pharmaceutical industry. This enables pharmaceutical companies to patent medicines developed with public funds, creating monopolies that enable them to charge high prices. It also makes it harder for public institutions to impose conditions around access, pricing, or transparency on publicly funded innovation, as there is a reliance on industry to carry out late-stage clinical trials.

Public involvement in the later stages of clinical trials is a good place to start as it could drive up standards—addressing inherent bias in industry-funded trials as well as forcing pharmaceutical companies to accept conditions around pricing and patient access if they want to secure licenses to promising research.

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There is also scope for democratic, public control over drug production. Across the world, countries including Brazil, Thailand, Cuba and China have invested in the public production of medicines to ensure consistent supply. By investing in similar public production capacities, public funds would be directed toward the most critical public health needs and prioritised medicines. Public manufacturers could also be designed to ensure any profits are used to offset the cost of drugs that are more expensive to produce, or invested in public health interventions that can improve health outcomes. These public companies could be linked to the existing network of publicly funded R&D facilities and processes of democratic participation and accountability could create greater transparency in the industry as a whole.

This working paper identifies how the key principles of public ownership can apply in pharmaceutical sector (part 2). It then provides more details that show the need for public ownership in two aspects of the drug development continuum: R&D (part 3) and drugs production (part 4), and sets out a vision of what democratic participation, engagement, and transparency would look like as well as the implications for governance and operations.

2. Principles of democratic public ownership in pharmaceutical research, development, and production

Several responses to a recent Labour Party consultation on democratic public ownership provide useful starting points on what components might inform the governance structure and operation of any democratic public enterprise.[10] The following shows how some of these components can apply to public ownership of pharmaceuticals and the development of a public-health-centric innovation model.

2.1 Direction-setting

In our current pharmaceutical sector, innovation is driven by the areas of greatest financial return which does not always correspond with the area of greatest public health need. Disease areas that are not potential 'growth markets' are largely ignored. For example, between 2000 and 2011, only 37 of 850 (4%) of newly approved products were for neglected diseases that affect middle and low-income countries.[11] Disease prevention and vaccines are often neglected in favour of high-incidence chronic or life-long treatments (such as diabetes), as the latter offer better prospects for medicines sales. The same applies to antibiotics, where the lack of market incentives has led to few investments to develop new compounds, despite an impending global public health crisis.

Market incentives are not always sufficient to ensure that health innovation addresses public health priorities. Instead intentional direction-setting is required. Indeed, periods of high innovation have often been times when innovation was not an inevitable outcome left to markets, but a result of strategic decision-making by the state.[12]

Setting directions for health innovation through purpose-led missions involves decisions about what disease areas to prioritise and identifying unmet health needs that require new treatment options.[13] This can be done collaboratively with a wide range of stakeholders that includes health practitioners and patients. Health innovation can learn from how missions have been set in other policy areas (e.g. some aspects of defence and energy policy) where the identification of national or social problems drive the agenda. In these cases, a direction is set by public institutions with clear targets; collaboration is required across multiple sectors; and government levers (e.g. prizes, procurement etc.) are used to nurture bottom-up experimentation and learning—all of which are critical to a healthy innovation system. There is also space within this direction-setting process to accommodate input from regional and local constituents and stakeholders.

As is evident in other sectors, when direction setting is left to the private sector, profits and returns to shareholders often take priority over public needs. Public ownership in the pharmaceutical sector would give

the public the highest level of control to determine the public health priorities of pharmaceutical innovation as well as set and enforce conditions on patient access. Taking more of the pharmaceutical sector into public control and ensuring democratic participation in the new public bodies created would help deliver patient access to medicines which is crucial for attaining the right to health for all.

2.2 Collaboration and transparency

Collaboration and transparency are important principles for both democratic public ownership as well as for a health innovation model that delivers public health goods and services. First and foremost, collaboration and transparency maximise the rate of innovation. Moreover, tackling public health problems requires a collaborative environment where different actors interact across the whole innovation chain. Like with overall direction setting, publicly owned pharmaceutical institutions could play an important part in facilitating collaboration and transparency.

A key feature of collective endeavours is continuous exchange within and across sectors, which allows the creation, diffusion, and sharing of knowledge, allowing innovation to thrive. However, the current health innovation model is characterised by the private ownership of knowledge, where the strong intellectual property regime restricts the flow of information and locks away know-how that the next generation of inventions needs to build on. Not only does this create waste and duplication, it also has implications for developing innovative solutions and wider economic growth. Knowledge is not a finite resource, it can grow as more people use it. Given the low marginal costs of sharing knowledge, access to it should be maximised rather than restricted in order to drive innovation and build the 'knowledge commons.'

Promoting the knowledge commons ensures that information is shared and flows through the system to create socially-equitable outcomes. Democratic public ownership in pharmaceuticals could (and should) ensure the building of the knowledge commons as well as full transparency around R&D, production costs, and clinical trial data. By ensuring open access to the data associated with the intellectual property on their inventions and/or clinical trial data, a public R&D institute can contribute to, and further promote, an open science approach which contributes to the knowledge commons. This would enable the sharing of knowledge and resources for the wider scientific community which will multiply innovation across the sector rather than enclosing knowledge for individual profit and competitive market advantage.

Collaboration between different countries is also an important aspect of public ownership in pharmaceuticals. Given the impact of high drug prices on high-income, middle-income, and low-income countries alike, and the fact that many health problems are global, a publicly owned company could facilitate global collaboration which would not only further stimulate innovation, but demonstrate a spirit of genuine internationalism. The development of a global R&D framework requires international collaboration and a commitment to a multilateral approach. The UN Social Development Goals (SDGs) related to health require global solutions, and the UN High-Level Panel on Access to Medicines recommends the UN Secretary-General initiate "a process for governments to negotiate global agreements on the coordination, financing, and development of health technologies. This includes negotiations for a binding R&D Convention ... to promote access to good health for all."

2.3 Affordability and access

Any assessment of what parts of the economy should be considered for democratic ownership must include the pharmaceutical sector as it plays such a significant role in the health and wellbeing of the population alongside our most treasured public service—the NHS. Moreover, access to essential medicines is fundamental to the realisation of the right to health. There is little public value in having medicines which are so expensive that only a limited number of people

can access them. It is imperative, therefore, that affordability and access are foundational principles of any public pharmaceutical enterprise.

Ensuring that patients and their families can have forms of democratic representation in the governance structures of public enterprises is also important. This not only ensures access and affordability remain core principles but also opens up democratic input as well as stakeholder representation into strategic decision-making and planning processes.

The next section examines two broad parts of the UK pharmaceutical sector that could generate increased public economic and societal value if a government were to facilitate and support the creation of new public interventions and organisations. These are (i) publicly funded research and development (section 3) and (ii) democratic public ownership of generics manufacturing (section 4). Beyond this, we could also envision that pharmacies and other parts of the pharmaceutical value chain could also benefit from such alternative ownership models, but this is beyond the scope of this paper to detail those here.

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3. Publicly funded research and development

3.1 Why we need increased public involvement throughout the pharmaceutical innovation process; what could democratic public ownership in pharmaceutical R&D look like?

The UK is a global leader in scientific research and medical innovation. We rank as the second highest government funder of medical R&D in the world, our universities and their research are among the best in the world, and we sit alongside a handful of countries in the level of pharmaceutical innovation we create.[14,15,16] These proposals aim to build from this base, recognising our strengths and addressing the weaknesses that arise from the current incentive model and ownership structures.

Too often, taxpayer-funded research leads to life-saving new medical technologies that are then patented by the private sector and priced at a level which drains NHS resources, or even prevents access for UK patients altogether.[17] University technology transfer and licencing offices were envisioned as a means of effectively commercialising the research conducted at our third sector institutions but instead they often fail to generate significant income and sign weak licencing agreements that cede control of the innovation too cheaply with negative outcomes for patients.[18,19]

Traditionally, the public sector ends or significantly reduces its involvement in the drug development process at quite an early stage, once the foundational research has been conducted. Whilst we recognise the significant expertise and importance of the work of the private pharmaceutical sector in translating basic research into medicines that are safe and efficacious for patients to take, there are good reasons to consider continued public involvement throughout the drug development pipeline.

Ultimately we believe that the government should prioritise exploration of a systemic shift to a more fully publicly-driven approach to medical innovation based on a 'delinked' model.[20] This would see innovation rewarded through upfront grants and prizes, tailored to public health needs, rather than through high drug prices protected with patent-based monopolies. But both before, and alongside, this shift there are a number of ways increased public involvement and democratic ownership could benefit pharmaceutical research in the UK. These include:

(i) Publicly funded and/or conducted clinical trials

At present, there is considerable public financial support for early stage research and initial clinical trials of medicines. These early stages are the riskiest part

of the scientific process, with large numbers of promising compounds being whittled down to a much smaller number which continue to later stage trials in humans. These later phase two and three clinical trials are more commonly funded by industry.

This can create a number of problems. As there is limited funding for later-stage trials, other than from the private sector, it is more difficult for the licensor—often a university, charity, or public research body—to impose access, pricing, or transparency conditions on the licensee as there are few alternatives if the licensor wants to see the continued development of the drug. This monopsonistic dynamic allows pharmaceutical companies to resist the imposition of conditions and to strike licencing agreements that are not in the public interest.

Furthermore, industry funded clinical trials have a demonstrable bias in their results.[21] They often fail to provide appropriate evidence of efficacy—for example using surrogate endpoints that tell us little about how effective a drug is at extending life or improving the quality of life of patients. All too often they don't tell us enough about how a drug compares to the other medicines on the market.[22] And they frequently delay innovation by failing to test important drug combinations ahead of marketing authorisation.[23]

Public involvement in later stage clinical trials could address many of these problems. By funding later clinical trials, the public sector could drive up standards forcing pharmaceutical companies to accept pro-public conditions if they want to secure the licences to promising research. It could ensure more robust and independent trial design and results. And it could push for earlier testing of likely beneficial combinations of drugs with different patent holders.

While this could be done through funding alone, there is the potential for the creation of a democratically owned public clinical research organisation that could conduct these trials. By building on the incredible resource of the NHS, this organisation could harness many of the incomparable advantages of the publicly owned and delivered health service to deliver large and complex trials for the benefit of NHS patients and broader scientific advancement. This could stand to benefit the NHS as it moves into a new era of data-driven health, which is currently dominated by private corporations with little accountability. Furthermore, it could ensure that one of the primary drivers behind the privatisation of public research can be avoided.

(ii) Patent pooling

The last Labour government was instrumental in establishing the Medicines Patent Pool (MPP) through its leadership at the multilateral global health organisation Unitaid.[24,25] The Patent Pool facilitates the efficient, transparent, and equitable licencing of intellectual property to generic drug manufacturers to facilitate affordable access across the developing world. Initially focused on HIV, it has now expanded to tuberculosis, hepatitis C, and other conditions.

The MPP is a successful example of how an alternative approach to licencing could deliver more affordable and equitable access to medicines. Patent pools could also help to accelerate collaborative innovation by ensuring promising compounds can be worked on by scientists across multiple institutions and in combination at much earlier stages of the innovation cycle.

By creating a democratically owned patent pool, or a series of pools across relevant and distinct research areas, the UK could ensure publicly funded research is fairly accessed by multiple actors. This could be housed within the public clinical research organisation proposed above. The licensees—pharmaceutical companies, democratically-owned drug manufacturers, not-for-profit drug development organisations, and research bodies—would all have to commit to conditions around collaboration, access, and transparency in order to secure the intellectual property rights. In this way we can increase the leverage the public sector has to secure deals in the public interest.

(iii) State funding for research spinoffs

At present, university and other forms of promising publicly funded biomedical research frequently become spun out into small, start-up biotech firms. They commonly secure venture capital investment to further their research to the point where they have one or a small number of promising compounds which present a viable bet for big pharmaceutical companies. As the funding required to conduct large-scale clinical trials often only comes from larger pharmaceutical companies, a common next step is for the promising biotech to be acquired by one of the big multinational corporations, which then completes the later-stage clinical trials and brings the drug to market at a very high price.

This highlights many of the problems with the status quo. Large pharmaceutical companies are increasingly ineffective at innovation, yet their mergers and acquisitions strategies ensure they are rewarded for research conducted in large part by the public sector.

A state investment bank or revolving loan fund housed within an existing government agency could take the role of venture capitalists by investing in small start-ups spun out from university or other publicly funded research. This could be done on the condition that a cooperative or democratic ownership model is established, with guarantees on public interest, returns, and access. The state would be able to retain an interest in the IP it has developed, ensuring that conditions are placed on any entity which seeks to buy them out—or preventing such buy-outs from happening—which would ensure that the public funding for later stage clinical trials can allow small UK tech startups can stay independent and grow as viable new enterprises.

3.2 Ensuring full engagement: transparency and participation

A fundamental flaw in our current medical innovation model is that the power to determine which medicines (which are a global public good) are developed resides in the hands of a small number pharmaceutical industry executives who base their decisions largely on what will best serve the interests of another small elite—their shareholders. Neither the patients who need the medicines, the doctors who prescribe them, the researchers who develop the drugs, the health systems that use them, or the public health experts and epidemiologists who understand diseases and their interaction with our culture and society have much of a say.

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This leads to perverse outcomes, with critical but unprofitable research like antimicrobial resistance going unfunded by industry, whilst billions are sunk into replicating existing medicines which will make money but offer little improvement in health outcomes. A much more diverse stakeholder group needs to have a voice in these decisions, both through representation in decision making forums, and through the creation of funding streams which challenge industry's monopoly in later stage research funding and delivery.

Public investment and funding for later-stage clinical trials should be delivered according to investment criteria agreed in a transparent consultation process involving researchers, public health experts, doctors and patients. These criteria, and the decisions they inform, should be publicly shared and open to review. They should incorporate a commitment to publicly

acknowledge failure in a proactive effort to learn from mistakes and improve future investment decisions.

All of this relies upon a dramatic increase in transparency of decision making and data (which we discuss further in section four), and for which we believe the UK should become a global champion.

3.3 Governance and operations

Whilst many aspects of health and pharmaceutical policy can be made at a decentralised level, there is a logic to maximising policy coherence on UK medical R&D investments and centralising the majority of decision making authority with regards to pharmaceutical innovation.

Specifically, while there is significant scope for a pluralistic medical innovation sector to flourish with diverse forms of entities delivering research and drug development, a coherent national framework for research investment priorities is likely to help give researchers clarity and maximise the chances of delivering strategic and societally beneficial innovation.

For example, under proposals developed by the World Health Organisation (WHO) on how to overcome the failure to develop new medicines for diseases of poverty,[26] it was envisioned that an expert committee would advise on how global funds should be allocated to priority health research investments. A similar structure, which would include publicly accountable research, drug development, public health, and other relevant experts, as well as clinicians and patient representatives, should be created to inform investment in medical R&D, later stage clinical trial funding, and government investment in democratically-owned drug development entities.

Furthermore, the patent pooling we envision should replicate and strengthen the structures of the Medicines Patent Pool—which includes a formal board plus an advisory board made up of policy experts and patient representatives of the relevant disease area—that reviews the licencing agreements signed between originator and generic drug companies.

Finally, the democratically-owned start-up firms, which we envision the UK government funding, should have the formalised involvement of workers, clinicians, patients, and other stakeholders on its board and in other relevant decision-making structures. The government should retain a controlling interest in the entity to ensure that it is not sold out to private sector interests on terms that would undermine the public interest.

4. Democratic public ownership of generics manufacturing

4.1 Why we need public generics manufacturing

Generic medications account for the majority of prescriptions written and dispensed in the UK and are crucial to our healthcare system.[27] However, repeated drug shortages and massive price spikes on these medications illustrate a fundamental problem with relying on for-profit industry to provide public goods: the incentives are misaligned. Despite our best efforts to create the market incentives necessary to ensure the safe and adequate supply of all the medications our health system requires, we continue to experience costly and dangerous supply chain issues. There is a clear opportunity for democratic public ownership in pharmaceutical manufacturing to address these issues. Furthermore, a publicly owned pharmaceutical manufacturer could be the source of good public sector jobs and help create greater transparency in and across the pharmaceutical supply chain.

There is already broad recognition that essential goods and services like healthcare should be owned by, and responsive to, society as a whole. In fact, many believe that the establishment of the NHS is our greatest achievement as a society. It would be natural, cost effective, and strategic to extend public ownership and control of healthcare into the pharmaceutical sector. Publicly owned drug manufacturers could be tasked with not only serving the needs of our healthcare system, but also creating greater participation, transparency, and accountability in an industry central to human health and wellbeing.

Generic drug shortages have been increasing in recent years and Brexit may bring even further supply chain disruptions.[28] These shortages are not only dangerous — as delayed treatment or use of second-line medications may cause adverse and even deadly reactions— they are also very costly. NHS England estimated that increased prices on generic drugs related to shortages cost the system £362 million in 2017-18.[29] Pharmacists incur further costs in these instances as they are often reimbursed at lower rates than those they were forced to pay to procure a medication in shortage, despite the 'concession pricing' the NHS grants in such cases.[30]

We have also seen massive price spikes on generic medications not in short supply. In the case of pharmaceutical company 'divestment' for example, proprietary medicines are de-branded and re-introduced to the market as high-cost generics. A few de-branding cases in recent years have seen prices hiked up

to 12,000% and individual drugs experiencing such price increases have cost the NHS tens of millions of pounds each year.[31] Though some companies incur fines for this sort of price gouging, the industry contests such decisions, locking the country into expensive litigation for years. The sanctions levied by the Competition and Markets Authority (CMA) in one of these cases led the manufacturer to publish a statement claiming that it would provoke "unintended consequences on future investment in, and availability of, generics," implying that for-profit generics manufacturers might just pull out of the UK market if they were to deem it not profitable enough.[32]

Additionally, divestment is only one of the anti-competitive behaviours that impacts our ability to procure cost-effective generic drugs for our healthcare system. Collusion and pay-offs are used to keep competitors out of the market all-together, essentially securing monopoly pricing rights for some generic manufacturers.[33] At the time of writing, the CMA showed twelve open cases against pharmaceutical companies for various forms of anti-competitive behaviour that can affect our economy, health, and democracy.[34]

Together these forces put undue strain on our healthcare system and illustrate a key failure of the for-profit pharmaceutical sector to effectively meet our public health needs. They also make a strong case for public ownership in the pharmaceutical manufacturing sector. In private, for-profit ownership, fiduciary duty compels corporate boards to seek profit maximisation above all else which leads to unnecessary costs imposed on our healthcare system, pharmacists and patients. But public ownership is more flexible and can be the vehicle for the designs we need to ensure that public health needs are prioritised in this key industry.

Public ownership in general can contribute to the return of revenue to public balance sheets and be the source of good jobs and greater public oversight of important industries. In the pharmaceutical sector in particular, the sort of democratic public ownership we propose can also assure that public funds are directed towards the most critical public health needs, that relevant stakeholders are included in decision-making, and that greater transparency is gained around generic medicine pricing.

Publicly owned drug manufacturers could be tasked with not only serving the needs of our healthcare system, but also creating greater participation, transparency, and accountability in an industry central to human health and wellbeing.

Without exorbitant CEO salaries to pay and shareholders' demands for ever increasing profits to satisfy, publicly owned pharmaceutical manufacturers are well-placed to supply our healthcare system with low-cost, high quality generic medications according to public health needs, rather than market imperatives. A public generics manufacturer could further be designed to assure that all profits are reinvested in the company, helping create a self-sustaining entity whose budget is not subject to the whims of any particular administration. Alternatively, profits could be reinvested further 'upstream' in the healthcare system and deployed for primary and preventative care or channeled into programs that address social determinants like housing and education. Close coordination with the NHS and the Medicines and Healthcare Products Regulatory Agency could help eliminate inefficiencies in the supply chain and assure the most critical medications are prioritised for production.

4.2 Ensuring full engagement: transparency and participation

Only when citizens have access to information can they fully participate in both the political process and the economy. As the pharmaceutical industry in

its current form is substantially removed from direct democratic control, transparency becomes even more important in empowering the public with the information that allows them to hold elected officials and public institutions to account in their regulation and oversight of such business.

Among the key items on the agenda at this May's World Health Assembly (WHA) meeting was a comprehensive proposal from the Italian Minister of Health on transparency measures as a key contribution to the planned discussion on Addressing the global shortage of, and access to, medicines and vaccines.[35] The proposal was hotly debated and the UK government played a significant role in watering down the proposal. The UK then publicly announced it was dissociating itself from the final (weaker) proposal that was approved. The UK government should reconsider this stance and could re-build the international case for genuine transparency by drawing on the consensus of like-minded countries.

In this context, the UK would be poised to be a global leader in pharmaceutical transparency by embedding the practices proposed to at the WHA in the operations of their new publicly owned pharmaceutical enterprises. As per the Italian proposal, drug manufacturers could make a significant contribution to global transparency efforts by making public annual reports that include sales revenue, prices, the quantity of sales, and outlays on marketing. By integrating such transparency measures into the charter of a publicly owned drug manufacturer, citizens and lawmakers would gain important insights into the true costs of drug production empowering them with information which helps hold the industry accountable. Furthermore, such insights would put the country in a better position to negotiate prices with for-profit manufacturers and could be leveraged to pressure more manufacturers to disclose their own costs and expenditures.

A publicly owned generics manufacturer would also be subject to existing transparency laws and practices such as Freedom of Information Act but additional requirements, such as open meetings, should also be explored. These transparency mechanisms themselves create opportunities for citizen participation and oversight, and further mechanisms for participation can and should be embedded in the design of the governance of public manufacturers, as discussed below.

4.3 Governance and operations

Citizen participation in activities associated with healthcare planning and health services are already widely regarded as essential to improving public health. This provides an extra incentive to assure the participatory governance of an enterprise that forms part of a key sector of our economy, such as pharmaceuticals. The governing board of a public manufacturer, then, should be designed to include key stakeholders such as workers, patient advocates, medical professionals, and environmental organisations.[36] There are a number of models from the healthcare sector that provide examples of what this might look like.

The California Institute for Regenerative Medicine (CIRM), a public research lab for stem-cell research created by voters in 2004, provides one example which could be further developed to further the goal of a more democratised economy. The CIRM is governed by a 29-member board of Californians with expertise in biomedical research, biotechnology, management, federal drug regulation processes, patient advocacy and ethics. Representation for a number of disease groups most affected by the institute's work is required by statute, including diabetes, neurodegenerative diseases, spinal cord injuries, HIV/AIDS, and mental health disorders. CIRM's board does not include worker environmental representation, however, both of which would be critical to achieving goals related to empowering workers, addressing environmental destruction and hastening the green transition.

The thousands of community health centres operating throughout the United States offer another model. While each health centre can develop its own process for selecting board members, the majority of board

members (at least 51%) must be patients served by the health centre and, as a group, must reflect the demographics of the area served. For the health centres which additionally receive a special designation to serve a particular medically underserved population (such as homeless or migrant worker populations), that population must be represented on the board as well.[37] The non-patient board members are selected for their expertise in relevant areas like social services, finance, and local government.

Both these examples show how local communities and individuals directly affected by the operations of these institutes (patients) can be directly involved in strategic oversight of enterprises alongside stakeholders with technical expertise and specialised experience relevant to the enterprise's mission and operations. Other avenues for popular participation in decision-making should be explored. For instance, popular consultation or referenda may be appropriate in the case of certain major decisions that directly affect the populace (i.e. the decision to relocate or close a factory).

Regarding the issue of scale, which impacts how and where decisions get made, different nodes on the pharmaceutical supply chain lend themselves better to different scales. In a fully public pharmaceutical supply chain, we might have R&D centralised at the national level for purposes of strategic planning and investment, with manufacturing and wholesale at the regional level and retail at the local level.

In the UK context, public manufacturing could conceivably be organised at a variety of levels with a number of political and economic considerations determining the ideal configuration of enterprises. We can imagine a number of different arrangements whereby public manufacturing companies are owned and operated by the different nations of the UK at the level of the devolved governments, or in any of a variety of regional arrangements between localities. These could then be organised either as a single networked system working across sectoral production lines, or each as independent companies focusing on the production of different types of medicines (i.e. traditional chemical drugs, vaccines and biologics, etc). Whatever the exact conformation, we recommend some variant of regional ownership and management of manufacturing companies which would allow for a balance between the economies of scale required by the industry and the desire to devolve decision-making to the lowest level possible and contribute to local economies.[38]

Key precedents

A number of other countries including Brazil, Thailand, Cuba and China have invested in public production of medicines as a way to combat supply chain issues and assure their health systems can access high quality, cost effective essential medicines. Public manufacturing has also formed part of a number of nations' industrial strategies and contributed to economic independence. In the United States, federal legislation was introduced in 2018 that would create a public Office of Drug Manufacturing within the Department of Health and Human Services in order to reduce costs, address shortages, and increase access to essential medicines.[39,40]

Public production capacity could also provide state actors with leverage in negotiating drug prices with the private industry in some cases. Additionally, public manufacturers can take on the important role of producing medications for domestic distribution in cases of compulsory licensing. Both Thailand and Brazil have utilised their public manufacturing capacity to produce and distribute low cost antiretrovirals pursuant to compulsory licenses, making cost effective access to these essential medicines widely available and reducing overall health system expenditures in treating HIV/AIDS.

A new initiative in the United States may also be paving the way for future public manufacturers. CivicaRx is a non-profit generics manufacturer founded in 2018 with the mission to "reduce chronic generic drug shortages" in the U.S. and "stabilising supply of

essential generic medications in a hospital setting."[41] The company will produce generic medications for in-patient use and sell them to member hospitals as well as wholesalers at a unitary price. The model is so promising that it attracted $30 million in philanthropic start-up funds, and now counts more than 800 hospitals as part of its network.

At Civica, member hospital systems form an important part of the Drug Selection Advisory Committee which prioritises medicines for production. This ensures that urgent clinical needs are met and locks-in a market for the medications produced before manufacturing even begins. In order to address the issue of shortages in critical generic medications, Civica is pursuing a strategy that would be just as applicable to public producers as well: 1) Contracting multiple existing manufacturers that operate regulator-approved manufacturing facilities, 2) Pursuing regulatory approval for its own generics, and 3) Simultaneously building in-house manufacturing capacity to further streamline and integrate the supply chain. Additionally, as part of their strategy to combat shortages, Civica plans to both build redundancy into its supply chain, and enter into long-term contracts to assure a stable supply over time.[42]

While it is still early days, the company has already entered into contracts to produce the first two drugs from its list—both antibiotics critical to hospital care. They have partnered with the Danish supplier Xellia Pharmaceuticals to supply these medications. Within five years, they expect to be providing member hospitals with up to 100 different generic medications.[43] If successful, their initiative will show that large-scale not-for-profit drug manufacturing can thrive even within what is likely the world's most favorable regulatory environment for private pharmaceutical production, a powerful precedent for any seeking to establish public manufacturing enterprises.

5. Conclusions

The development of new, lifesaving drugs should be directed by public health objectives that prioritise patient access—both in the UK and across the world. Today's system of privatised medicines has led to extortionate prices and patients denied access to life-saving drugs. It is also not delivering the innovative, breakthrough drugs that society needs (such as new antibiotics). Instead, pharmaceutical corporations divert their investments into tweaking existing compounds for short-term returns and pour capital into share buybacks to improve shareholder value.

Bringing research, development and production of drugs into democratic, public ownership would not only lead to more innovative and affordable medical care but could also increase accountability and participation in the delivery of products that are key to the right to health. Creating enterprises driven by public interests would be the first step to ensure that our NHS can sustainably treat patients as well as deliver the large-scale investment and economic development needed as part of the wider industrial strategy to create high-quality jobs in the future.

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About the Authors

Dana Brown is director of The Next System Project at The Democracy Collaborative and Thomas M. Hanna is its director of research. The Democracy Collaborative (democracycollaborative.org) works to bring into being a democratic economy built on shared ownership and control, equity and inclusion, and ecological sustainability.

Heidi Chow leads the pharmaceutical access campaign at Global Justice Now (globaljustice.org.uk), which produces research and engages in campaigns to address structural inequities that drive poverty and injustice.

Diarmaid McDonald is the founder and lead organizer of Just Treatment (justtreatment.org), which mobilizes patients to advocate for lower drug prices for the National Health Service.