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Why Is the Gates Foundation Funding the UK's Medicines Regulator?

Just as importantly, why is the regulator laying off 20-25% of its workforce in the midst of a global pandemic?

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*On August 13, the UK government published a response to a freedom of information request in relation to the **Medicine and Healthcare products Regulatory Agency (MHRA)** — the UK's equivalent of the FDA. The question it was in response to enquired as to whether or not the agency had received funding from the Bill and Melinda Gates Foundation. The answer was yes:*

> We do receive funding from the Bill and Melinda Gates Foundation as well as other sources outside government such as WHO. This funding mainly supports work to strengthen regulatory systems in other countries...
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> The current level of grant funding received from the Gates Foundation amounts to approximately $3 million. This covers a number of projects and the funding is spread across 3-4 financial years. We are an executive agency of the Department of Health and Social Care.

The story didn't attract much attention at the time. In fact, not a single newspaper or broadcaster even bothered to cover it, perhaps because there didn't see much in it. After all, $3 million (with an "m") is not even that much money these days. And the Gates Foundation (GF) is a charitable organization — the biggest of its kind, with roughly $60 billion in assets — so what could possibly be wrong with it granting funds to an organization in charge of deciding which pharmaceutical products and medical devices reach the market and which don't? Well, quite a lot, actually.

Blatant Conflict of Interest

Firstly, $3 million may not be a lot of money to the GF but it's still a substantial sum to the cash-strapped MHRA. Secondly, the Gates Foundation's roughly $60 billion in assets include, among other things, shares and other forms of investments in some of the world's largest pharmaceutical companies, whose products the MHRA has to regulate on a regular basis. Those companies include Sanofi, Merck, Eli Lilly and Company and Abbott Laboratories, all

of which have developed or are developing covid-19 treatments and/or vaccines that are yet to receive authorisation in the UK. They also include Pfizer and its German partner BioNTech, which together have developed and marketed the most profitable vaccine in history.

This is a blatant conflict of interest. It's also worth noting that the MHRA's former CEO, **Ian Hudson**, now works as a senior advisor at the GF.

When it comes to global healthcare, the GF is anything but a disinterested third party. Its co-founder, **Bill Gates**, is as committed as ever to intellectual property rights. In January we learned that Gates had played a key role in convincing Oxford University to drop a prior commitment to donate the rights to its vaccine to any global drug maker. The idea was was to provide the vaccine to poorer countries at a low cost or even free of charge. But Gates persuaded the British university to sign a vaccine deal with AstraZeneca instead that gave the pharmaceutical behemoth exclusive rights and no guarantee of low prices.

We have also learnt that Gates was instrumental in blocking attempts by a coalition of countries led by South Africa and India to bring a patent waiver proposal to the World Trade Organization's TRIPS (Trade Related Aspects of Intellectual Property Rights) Council. A waiver would allow poorer countries to produce the vaccines themselves. And that would massively accelerate global take-up of vaccines, which could help in the global fight against Covid. But Gates argued that poor countries were not prepared to scale up manufacturing. A waiver would also eliminate incentives for future research, he said. His argument won the day and even today the TRIPS waiver is still under discussion at the WTO, going nowhere slowly.

In an article for Wired magazine Mohit Mookim, a former researcher at the Stanford Center for Ethics in Society, asks whether we should be surprised that a monopolist-turned-philanthropist maintains his commitment to monopoly patent rights as a philanthropist too?

> "Throughout the last two decades, Gates has repeatedly advocated for public health policies that bolster companies' ability to exclude others from producing lifesaving drugs, including allowing the Gates Foundation itself to acquire substantial intellectual property. This continues through the Covid-19 pandemic."

Now we learn that the foundation, with its vast holdings in pharmaceutical companies and substantial intellectual property interests, **has also been helping to fund the MHRA for the past four years.** In other words, an organization that has poured billions of dollars into the research and development of vaccines, other novel treatments and medical devices has also been funding the UK agency responsible for approving those vaccines, novel treatments and medical devices. .

The MHRA is not the only public health agency in the UK to have benefited from the foundation's largess:

- **Public Health England, a health watchdog set up by the Government in 2013 to protect and improve health and wellbeing and combat health inequalities, has received $7,785,336 from the Gates foundation.** The agency is set to close in the coming months and will be replaced by the Orwellian-titled "UK Health Security Agency".
- **Health Data Research UK has received $3.5 million from the GF since**

the pandemic began. The organisation has courted controversy in recent months for its role in bringing together the health and biometric data of all 55 million of the NHS' patients. That data was then supposed to be flogged to any interested third parties, but the plan was scrapped at the last minute due to public opposition.

- **The GF has also partnered with the UK Government's UK Research and Innovation (UKRI), which began life in 2018 with a budget of £6 billion, ostensibly to support science and research in the UK.**

Funding Crisis

As I wrote last week, the UK Government is ramping up its plans to privatise the NHS. This is leaving many parts of the health system starved of funds, which in turn opens up fresh opportunities for private-sector companies, trusts and foundations. The MHRA, like the FDA, is primarily funded by the "user fees" it charges its "customers" (i.e., the companies it regulates).

In the US, user fees fund account for around 65% of the FDA's operating budget for regulating prescription drugs. In the case of the MHRA, 100% of its budget for regulating medicines comes from user fees. Its other activities are funded by a combination of private and public sources. The MHRA's regulation of devices is primarily financed by the Department of Health and Social Care (DHSC), with approximately 10% of its revenue derived from fees. The National Institute for Biological Standards and Control (NIBSC) raises around half of its revenue from fees charged for services.

Nonetheless, the MHRA is facing a funding crisis. And it's largely a result of Brexit. Before the UK's departure from the EU, in January this year, the MHRA formed part of the European system of medicines approval. Under that system, national regulators can serve as rapporteur or co-rapporteur for any given pharmaceutical application, providing most of the verification work on behalf of all members. It was an important source of fee-income but now it's dried up. And the government is not replacing it.

As a consequence, the regulator has announced plans to lay off between a fifth and a quarter of its 1,200-strong workforce as part of cost-cutting measures. According to the FT, the goal is to transform how the MHRA operates by redeploying staff to new areas of regulation and science. Documents leaked to the *British Medical Journal* reveal that the MHRA is offering early redundancy packages to staff from its divisions on vigilance and risk management of medicines (not exactly comforting), licensing, devices, inspection enforcement and standards (also not comforting), as well as its committee secretariat. The document, marked "official sensitive," also notes that the MHRA's income is forecast to fall by 15-20% in the next financial year and beyond.

Despite the drastic downsizing, the MHRA says it wants to still serve as a world-class regulator that delivers positive outcomes for patients while modernizing the services it provides to industry. With 15-20 percent less operating income and 20-25 percent fewer workers, that's likely to be a tall order.

User Fees: A Principal-Agency Problem

User fees are being used more and more to fund medicine regulators around the world. They are seen as a way of shifting some of the financial burden to manufacturers who stand

to benefit from the sale of of medicines. But they also raise serious ethical issues. In a 2017 blog post for the *BMJ*, Joel Lexchin, a professor emeritus at the School of Health Policy and Management at York University, warned that the widespread introduction of user fees had created a principal-agent problem.

When the FDA's operating budget used to be funded exclusively by the government (up til the early '90s), there was essentially one principle and one agent in each interaction. Each of their roles was relatively clear. The principle needed something done (in this case, patients in the US needed effective, safe medicines to be approved and ineffective and/or unsafe medicines to be blocked) and the agent (in this case, the FDA) was contracted to do the task. However, since the introduction of user fees a new principal has been added (the pharmaceutical industry) and now the regulatory agency has two principals with directly competing values:

> In the case of the public, the primary value is to have effective and safe drugs, but in the case of the pharmaceutical industry, its primary goal is to get its products through the approval system as quickly as possible and to sell those products to as wide an audience as possible. At times, it seems that regulatory agencies prioritize the latter at the expense of the former. Shortly after Canada introduced user fees, the head of the part of Health Canada that regulates prescription drugs issued a memo in which he said that "the client is the direct recipient of your services. In many cases this is the person or company who pays for the service." The one page document focused on service to industry and relegated the public to the secondary status of "stakeholder" or "beneficiary"…
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> User fees are reauthorized in the US on a five year cycle. When they came up for renewal in 2007, a number of prominent American commentators, including Marcia Angell, a former editor of the *New England Journal of Medicine* and Jerry Avorn, a leading pharmacoepidemiologist, opposed its reauthorization and instead called for increased Congressional appropriations in order to allow the FDA to undertake its responsibilities free from any apparent conflict-of-interest.

"Safety in a world of user fees" is of paramount concern, concluded Lexchin. That was was back in 2017. Four years on, we are in the biggest health crisis of our lifetimes and the tasks performed by medicines regulators are more important than ever. New experimental vaccines and therapeutic treatments are rolling off the line in record time. But they're also being authorised in record time — in some cases despite scant evidence of benefits (e.g., Remdesivir). And they're earning record profits for their manufacturers. At the same time, promising repurposed off-patent medicines that do not offer lucrative financial returns are largely being ignored or are even being demonised by our medicines regulators.

In its quest to remain globally relevant as it loses money and staff and in the absence of increased government support, the MHRA will need to raise even more funds from the companies it regulates. Further handouts from the likes of the Gates Foundation will also be welcome, one can imagine. But that, one can imagine, will come with even more strings attached.

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