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IS INCOME INEQUALITY THE CENTRAL ECONOMIC PROBLEM? by Oliver Heydorn/ Wally Klinck

In a blog entry that is well worth reading entitled "What Choice Do We Have?", Charles Hugh Smith discusses the extreme and ever-increasing income inequality that characterizes economic life in the modern world (amongst other closely related issues): http://www.oftwominds.com/blogdec14/no-choice12-14.html. As I discuss at some length in my book *Social Credit Economics*, the 'Monopoly of Credit' induces a pyramidal economic structure in which people are rewarded or punished depending on how effectively they serve financial interests. The result is a gross and ever-intensifying gap between the richest segments of the population and the rest of us. Indeed, the disparity has become so great (please see Smith's 'long tail distribution' graph) that many might be led to believe, quite naturally, that income inequality is the central economic problem and that a re-distributive socialism of one variety or another is necessary as a corrective. As disproportionate as present income distributions can be, the Douglas Social Credit diagnosis points in another and deeper direction. Addressing this more fundamental problem in keeping with the Douglas Social Credit remedial proposals, is likely, all by itself and without the intrusion of a command system, to re-order patterns of income distribution along more reasonable lines. In direct response to Smith's blog entry, Wally Klinck has submitted the following comments:

"Social Credit would alter this trend toward wealth concentration without in anyway suggesting that incomes should be equal. As technology replaces human effort as a factor of production the "wages of the machine" would be paid equally to all citizens. This would provide a sustainable consumer demand and provide a stable outlook for competent businesses. Quantitative easing cannot provide a remedy because the deficiency is on the consumption side. Naturally, if business outlook is not good, banks will be reluctant to release credit for more production. The economy is, as has been, said, 'costive'. It is overloaded and plugged up with un-liquidated financial costs which cannot be liquidated because the rate of flow of financial incomes increasingly falls short of the rate of flow of financial costs and prices. It matters not that adequate incomes may have been paid out it in the past. Money that has been prematurely recovered in respect of allocated capital charges is cancelled as effective purchasing-power. It does not matter how much money has been distributed, all of it, of course, being accounted as a financial cost. If it has been cancelled or placed to reserve it is not available as consumer purchasingpower—and it's use to produce additional goods further increases costs and prices. There is no solution other than an exogenous supply of consumer money which does not create additional financial costs but is capable of liquidating previous ones. It is not a testimony to human intelligence that we seem incapable of realizing that the economy exists to serve consumption and that in order to allow it to function smoothly we must provide for the consumption that supports production. Human labour is a shrinking factor in production but we have demonstrated, nevertheless, our ability to produce a surfeit of goods. But we cannot have them without drowning in debt and incurring wanton waste and war. What then? Shall we commit suicide?

"Our Bank of Canada is telling us that consumers are precipitously in debt and that we should curtail this trend. What else is either new or possible? So we curtail credit buying, deny ourselves the use of what demonstrably has been and can be produced, and collapse the economy so that the strong (including especially the banks as primary issuers of financial credit) can foreclose on the weak and appropriate our past efforts. What an evil system! It can't be brainless—no one could be that stupid. But, I am afraid the masses are so—not really, just pathetically brainwashed and misinformed. It is tragic. It is the Social Credit mission to change this sad state of affairs.

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(continued from previous page) "There is a lot of propaganda out there about the top 1%. This is an oversimplification and tends to support the dangerous and revolutionary socialist/communist idea of expropriation of incomes and assets. Studies have been done long ago to show that if you divided the financial incomes of the upper class

amongst the overall population this would do little to enhance the income of each individual. The problem is much more complex, involving a gross error in national cost-accountancy creating a widening chasm between collective effective financial incomes and collective prices. Two very different issues."

CRYPTOCURRENCY - SOMETHING NEW OR MORE OF THE SAME? by M. Oliver Heydorn

A few months ago I visited a friend of a friend at the new home he had recently purchased. The house itself was a suburban stand-alone dwelling in a quiet and, by all impressions, pleasant neighbourhood. As we entered through the front door, there, on the ground, stood a computer, or rather a series of computers, all hooked up together with countless wires. The main screen revealed that these computers were busy, feverishly busy, engaged as they were in all sorts of apparently endless computations. In an instant, I realized what I was witnessing: a mining operation, as in "mining for cryptocurrency". And, sure enough, this friend of a friend was "mining" Ethereum, a cryptocurrency that was introduced in 2015.

The fellow's motive for getting involved in Ethereum was simple enough and it is probably the most common motive that people have for taking an interest in cryptocurrencies: the potential for speculative gain. People buy cryptocurrencies by exchanging real money for them in the hopes that these acquisitions would, over time, increase in value as the demand for them increases. They can then sell their crypto holdings once they have reached this higher price, convert them thereby back into the currency of the realm, and make a profit. The securing of additional units of cryptocurrency via "mining" operations, which involves the use of computers and electricity, is an added bonus which certain cryptocurrencies afford the consumer.

From a Douglas Social Credit perspective, it should be pointed out that this type of speculative gain involves using money to make money without contributing anything of equivalent value in terms of real goods and services. It's a form of usury based on a Ponzi scheme. In order for it to maintain its momentum, later investors must have confidence that they will also see the same sorts of benefits that have been enjoyed by previous investors. The fact that, in this case, the speculators are "investing" in a digital or virtual currency that has no existence outside of the internet merely underscores how far or divorced from reality speculative activities can become as opposed to genuine investment (which, by contrast, is always aimed at some concrete result in the real world).

The nature of this speculative gain is even more inverted, or, if you prefer, perverted, when one considers

that not only do crypto-currency investors use money to make more money without contributing anything of equivalent value in the form of real goods and services, they can actually, through the various "mining" operations, consume enormous quantities of electrical energy. In other words, a real good and service, in this case, electricity, which could be used instead for more meaningful production and consumption activities answering to real human needs, is being completely squandered, dissipated, so that some investors in an intangible crypto-currency can "make money" without providing any real benefit to the human beings with whom they are in economic association.

It should likewise be pointed out that this waste of an important real resource by means of crypto-currency "mining" can be phenomenally large in its extent. In the case of bitcoin, for example, it has been estimated that the "mining" operations associated with it use up 91 terra-watt hours of electricity per year, which is more than the annual consumption of Finland, constituting, as it does, 0.5% of the world's total supply of electricity per annum.²

Now, in a partial defence or apologia for our cryptocurrency investors, we must likewise acknowledge that if it were not for the inefficacy, inefficiency, and unfairness of the present financial and economic systems, the desire for speculative gain of whatever kind would be greatly attenuated. In other words, people who seek to make a profit by investing in cryptocurrencies do so very largely because they feel the urgent need to "get ahead" (or at least stay ahead) by any means, fair or foul. When the cost of living is continually increasing (especially in more recent times), when it becomes harder and harder to afford a home, when wages and salaries are continually falling behind in the rat-race of our present economic order, it is quite understandable that many people will look for a magic solution that will make them rich and finally secure. Like a lottery win, cryptocurrency investments promise a leg up, or at least a keeping up, with the insane financial pressure which the existing economic dispensation imposes on all of us. This aspect of the cryptocurrency phenomenon is another nail in the coffin, another confirmation of the suboptimal nature of the existing economic system and the pressing need for its radical reform. (continued next page)

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So much for the bad or the "more of the same" side of the crypto-currency phenomenon. Might there also be something in it that is genuinely positive where economic and civilisational progress are concerned?

Well, as a matter of fact, there are certain technological developments inherent to the crypto-currency world which may have wider applications and which could be employed as part and parcel of an eventual Douglas Social Credit monetary reform of the existing financial system.

Crypto-currencies, by employing cryptography and a network that is distributed across a large number of privately held computers, make it impossible or nearly impossible for monetary tokens to be counterfeited. This is always a bonus in any money system. But the same technology also renders it easy to instantaneously transfer funds from peer to peer without having to rely on a trusted third-party, such as a bank or similar financial institution. Eliminating the middle man in this way reduces the risk of illegitimate external interference in transactions and it saves times, effort, and money. Crypto-currency transfers constitute, thereby, a costeffective mode of transaction. Finally, crypto-currency systems offer their users a type of privacy and security that cannot be presently superseded by any another type of electronic exchange system. The mathematical puzzles built into the blockchain ledger are hard to decode and pseudonyms can be used that are not linked to any user account. It is also possible to prevent any stored data from being attached to a profile.

There is, then, a whole decentralised aspect to the crypto-currency world which, while potentially increasing the efficiency of the financial system, could also mirror on an administrative plane the decentralisation of financial power which the Douglas Social Credit proposals wish to effect on the level of financial policy. If a crypto-currency were to become the currency of a country, all of the citizens would, by holding, using, recording, and verifying the currency with their computers, collectively become a decentralised banking network where each person would be actively involved in maintaining the integrity of the currency and of the system as a whole. Perhaps, by making the citizens personally responsible for a Douglas Social Credit system via the introduction of a state-sanctioned cryptocurrency, it would be more difficult for the system, once it had been established, to be usurped or corrupted later on by predatory interests. The end result may be a system that would be beyond the reach of any political vested interests to tamper with in any anti-constitutional manner. That, in itself, would be a substantial achievement.

References:

1. Jake Frankenfeld recently explained the nature and purpose of crypto-mining in reference to the bitcoin cyrpto-currency as follows: "Bitcoin mining is the process of creating new bitcoin by solving puzzles. It consists of computing systems equipped with specialized chips competing to solve mathematical puzzles. The first bitcoin miner, as these systems are called, to solve the puzzle is rewarded with Bitcoin. The mining process also confirms transactions on the cryptocurrency's network and makes them trustworthy.

"For a short time after Bitcoin was launched, it was mined on deskton computers with regular central processing units (CPLI)

desktop computers with regular central processing units (CPU). But the process was extremely slow. Now the cryptocurrency is generated using large mining pools spread across many geographies. Bitcoin miners aggregate mining systems that consume massive amounts of electricity to mine the cryptocurrency.

"In regions where electricity is generated using fossil fuels, bitcoin mining is considered detrimental to the environment. As a result, many bitcoin miners have moved operations to places with renewable sources of energy to reduce Bitcoin's impact on climate change."

https://www.investopedia.com/terms/b/bitcoin-mining.asp

2. Cf. https://www.businessinsider.com.au/bitcoin-mining-electricity-usage-more-than-google-2021-9

IS OMICRON ANOTHER LAB CREATION? by Dr. Joseph Mercola https://articles.mercola.com/sites/articles/archive/2021/12/14/omicron-lab-leak.aspx

December 14th 2021

In Bannons War Room interview above, Dr. Robert Malone, inventor of the mRNA and DNA vaccine core platform technology, reviews what we know so far about the so-called Omicron variant of SARS-CoV-2. As noted by Malone, the latest media hype actually began with reports of Africa having far lower case rates than the rest of the world, despite its comparatively low COVID jab rate. That was followed by reports in the local press that South Africa was asking Pfizer to halt its shipments of the shots, as they still had plenty and most adults were refusing to take it.

The very next day, "we suddenly had this huge kerfuffle about this new virus strain, and the press was announcing it was coming out of South Africa," Malone says. The U.K. almost immediately responded by shutting its borders to most of South Africa.

According to media reports, the Omicron variant was discovered in Botswana, in four fully "vaccinated" individuals. Physicians in South Africa responded saying that while the variant has been detected, they are not seeing significant illness from it. All cases so far have been mild and none has required hospitalization.

Coordinated Fear Porn Campaign

In rapid succession, news articles were published proposing the virus evolved in an AIDS patient and appears to spread far easier than previous variants. Calls for concern and the need for new restrictions flooded the airways. As noted by Malone, the press was talking about "everything except for the obvious, which is that this is a 'vaccine'-escaped mutant."

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Indeed, the variant appears highly resistant to the COVID shots, which is a sign of it having mutated within one or more COVID-jabbed individuals, not in someone with no antibodies at all to attack it.

Remember, viruses mutate primarily in response to insufficient immune responses. Yet among the first recommendations from the mental giants in charge of COVID responses was to push COVID booster shots, which is as irrational as it is unscientific.

"The boosters are a perfect way to bias our immune system so we're LESS able to respond to this new variant," Malone explains. "This is [like] jabbing everybody with a flu vaccine from three seasons ago and expecting it to have effects against the current [flu strains]."

Is Omicron Another Lab Creation?

As for the nature and origin of Omicron, Malone says:

"It has the hallmark of a viral agent under tight genetic selection for evolution to escape the 'vaccine' responses against the receptor bonding domain. The question that is outstanding right now is — because this is so different from the other strains that are being tracked; it's in its own separate little evolutionary branch — how did this happen? Why did this suddenly pop up with all these new mutations?"

The mainstream press is pushing the narrative that Omicron's mutations are due to the low COVID jab rate in South Africa, possibly in combination with it mutating within someone with AIDS. The solution, we're told, is to blanket Africa with COVID shots, even though the continent has enjoyed a phenomenally low case rate and mortality rate without the jabs. So, clearly, this narrative is trying to achieve an end that simply isn't warranted by the real-world data.

Aside from shaming South Africa into getting more COVID shots, another potential reason for this narrative is that they want to hide that it's another lab created virus. As noted by Malone, we have "the looming specter of this being further engineered in some way." In all, Omicron is said to have some 50 mutations from the original Alpha strain, many of which specifically allow it to circumvent COVID shot-induced antibody defenses.

While Malone admits he is not closely tracking the mutations of the virus, and is not qualified to speculate on its evolution, he points out there is a subset of experts who believe it may have undergone lab modification because, genetically, it "doesn't look like it's part of the prior evolutionary process that we're seeing with many other strains."

Until and unless we end up with conclusive proof of its origin, we need to keep all options open, Malone says, and that includes the possibility of Omicron being cooked up in a lab from a previous strain.

Omicron Cases Double in Less Than Five Days

So far, we know as little about Omicron as we did the original SARS-CoV-2 virus when it first emerged. What we do know is that it appears highly infectious, doubling in a median time of 4.8 days, and has significant "vaccine" evasion capabilities.

According to the Economist, which cites data from South Africa's National Institute for Communicable Diseases, Omicron "appears to have rapidly outcompeted Delta" in South Africa, as of the first week of December 2021 accounting for nearly all positive cases.

Omicron Is a Major Oddity

One particularly odd feature of Omicron is that the closest genetic sequences date back to mid-2020. It doesn't seem to belong to any of the evolutionary branches that have emerged since. As noted by professor Trevor Bedford, a computational virologist interviewed by NPR, "This is very rare to see."

In a Twitter post, a user named Chief Nerd, shows a time-lapse graphic he created that illustrates the genomic epidemiology of SARS-CoV-2 from the original strain until now, using data from nextstrain.org.

It's a great illustration of just how odd an unnatural Omicron's emergence really is. As the time-lapse gets toward the end of 2021, suddenly there's Omicron, emerging like a straight line from a mid-2020 strain, having no semblance to any of the other strains.

There's no precedent for this oddity occurring in nature. There is, however, precedent for this in lab-leaked pandemics, such as the 1977 Russian influenza, caused by an H1N1 flu strain that strongly resembled a strain in circulation between 1946 and 1957. There have been persistent rumors that the Russian flu might have been the result of a live-vaccine trial escape.

Omicron, also known by the designation B.1.1.529., has a ratio of nonsynonymous to synonymous mutations of 25 to 1. According to molecular biologist and cancer geneticist Philip Buckhaults, Ph.D., Omicron has 25 nonsynonymous and only one synonymous spike mutation compared to its most recent common ancestor, AV.1. Were it a natural occurrence, that ratio ought to be somewhere between 25 to 50 and 25 to 100.

Three Hypotheses of Omicron's Origin

Researchers have tried to explain this phenomenon in a variety of ways. Bedford has suggested the mid-2020 strain might have infected and evolved within some unknown animal population before spilling back into the human population.

It's an unlikely scenario though, Bedford says, because there ought then to be signs of the animal genetic material in the genome, and we're not seeing that. Instead, there's human RNA insertions, which suggests a human host.

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Another hypothesis is so-called "cryptic spread" in an unmonitored region. In other words, the mid-2020 strain may have circulated in an area where testing and monitoring of cases were low or absent, allowing it to evolve under the radar, until finally becoming transmissible enough to spread into more monitored regions.

Alas, Bedford finds fault with this explanation as well, "Because it would seem that as [this strain of the virus] was on its path to becoming Omicron and becoming a quite transmissible virus, [the earlier versions] would have started to spread more widely before just now."

What's missing from this list of hypotheses is the most obvious one, which is that the virus mutated in response to the pressure of widespread COVID injections. Also missing is the hypothesis that Omicron was genetically manipulated from a mid-2020 strain, and in one way or another entered into circulation.

A third hypothesis involves the incubation in an immunocompromised patient, such as an AIDS patient. If the patient's immune system was just robust enough to prevent death, but not complete clearance, the virus may have lingered for many months, slowly mutating over time.

The crux here is that the virus ought to have spread from that person earlier. Why did it take well over a year for it to finally be transmitted? Intermediate variants should have emerged, but didn't. It just suddenly emerged with dozens of mutations already baked in that have no precedent.

Bedford told NPR, "That's a good question and a legitimate one. I don't have an obvious answer besides chance." Despite the lack of plausible answers, Bedford believes this scenario may be the most plausible.

Two Elephants in the Room — The Missing Hypotheses

Of course, getting back to Malone's observation, what's missing from this list of hypotheses is the most obvious one, which is that the virus mutated in response to the pressure of widespread COVID injections. Also missing is the hypothesis that Omicron was genetically manipulated from a mid-2020 strain, and in one way or another entered into circulation.

Irrationally, Bedford and others are now stressing the importance on ramping up HIV treatment to prevent mutations from occurring in untreated individuals with low immune function, rather than taking a long hard look at how the mass "vaccination" campaign is driving the evolution of this virus and putting COVID jabbed individuals at ever-increasing risk of serious infection.

At present, one of the most plausible theories appears to be that scientists enabled an early SARS-CoV-2 variant to build antibody resistance, possibly by passaging them through human or humanized cell lines in the presence of convalescent plasma.

The Lab in South Africa Experimented on SARS-CoV-2

If Omicron is another lab creation, what lab might be responsible for its creation? A number of internet sleuths have pointed fingers at the biosafety level 3 (BSL3) lab in Durban, South Africa, where research on SARS-CoV-2 was taking place.

A paper titled "Escape of SARS-CoV-2 50IY.V2 from Neutralization by Convalescent Plasma" was published in the journal *Nature* at the end of March 2021. This appears to be just the kind of research that might train the virus to evade COVID antibodies.

The research, funded by the Bill & Melinda Gates Foundation, was conducted by a conglomerate of researchers, most from South Africa, but also one American and several with research credentials at both South African and German, British or American research facilities. Affiliates listed include several research facilities in South Africa, as well as research institutes in Israel, the U.K., U.S., Germany and Brazil.

In a series of December 3, 2021, Twitter posts, Yuri Deigin, a drug developer and biotech entrepreneur, points out that the initial emergence of Omicron was in Durban, where the BSL3 lab happens to be located, and where that study was done.

As yet, the Omicron lab leak theory is loosely held together, but if recent history is any indication, we're bound to start seeing more extensive discussions and reviews of the evidence as we go along.

As noted in an October 10, 2021, *New York Post* editorial, the lab leak theory, referring to the original SARS-CoV-2 virus, "is now almost certainly proved" — and according to David Martin, Ph.D., proved beyond all doubt based on the patent trail, dating back two decades — but it took well over a year and a half to get to this point.

While the Omicron origin question is likely to grow, our fear of this variant doesn't have to. So far, all indications are that Omicron is among the mildest of the variants — highly infectious with rapid spread, but very mild in terms of symptoms.

References (from The Folly of Full Employment by Oliver Heydorn, p6.):

1. Unfortunately, outside of Social Credit circles, no one seems to grasp any of this. The distributists, for example, are still obsessing about providing 'jobs for all' rather than 'incomes for all'. How can we have jobs for all, when machines are doing more and more of the work? Shall we have people dig holes and fill them up again? As noted, a large proportion of existing jobs are already tantamount to such purposeless, redundant activity.

2. C.H. Douglas, *Programme for the Third World War* (Liverpool: K.R.P. Publications Limited, 1943), 6.

THE FOLLY OF FULL EMPLOYMENT by M. Oliver Heydorn

One of the axioms of the existing economic order is the policy of 'Full Employment' (FE). Everyone must work for his daily bread or be dependent on those who do (*via* either redistributive taxation or increased public borrowings meted out in the form of welfare, unemployment insurance, pensions, etc.) when he is unable to work or when insufficient work is available.

Such a policy makes absolutely no sense. It is neither necessary nor possible to realize it.

It is not necessary because we are physically capable of producing everything that people can use with profit to themselves while only calling on a minority of the available labour force and the situation is steadily improving or deteriorating – depending on your point of view. Because of continuing (not to say 'accelerating') technological advancements, we can produce more and/ or better with fewer and fewer people working. Indeed, it has been predicted that 50% of existing jobs in the US will be automated within 20 years. This is a hard fact of life. Insisting on full employment in the face of the fourth industrial revolution is simply puritanical foolishness which is bound to increase unnecessary strains and stresses until we reach a breaking point ... from which they may be no return.

The policy is apparently not capable of being realized either because, outside of wartime demands and conditions, there is no economy that has managed to create enough jobs to meet the demand (largely artificial in nature) for jobs. It is already the case that a good proportion of the jobs that the economy does create has no meaningful or direct connection with the flow of real goods and services that answer to *bona fide* human needs. In other words, many of the existing jobs are useless, witless, redundant, and/or destructive.

Economists are supposed to be keen on efficiency. Well, the first and most important form of efficiency has to do with getting the goods and services we need to survive and flourish with the least amount of labour and resource consumption. Any other arrangement is simply madness. Right now, the system is set up in such a way that we get the least amount of goods and services in exchange for the most amount of effort (as measured in financial terms). It's upside down and embodies an incredible amount of waste, both material and human. Much of our economic activity is pure economic sabotage.

Instead of 'Full Employment', the 'Minimum Employment Needed' (MEN, the feminists should be bemused!) should be the goal of public policy where employment is concerned. Indeed, the policy of the minimum employment necessary is one of the distinguishing features of the Social Credit proposals. Social Credit's National Dividend and National Discount

would make this objective realizable by providing increased purchasing power to all, and especially by providing purchasing power to those whose labour is not required by the formal economy. ¹

Make no mistake, however, 'Full Employment' is not some innocent economic error, it also serves political purposes. It keeps people busy struggling to meet the weekly bills so that they have no time to reflect on political questions or energy to do anything more meaningful than act as cheerleaders for the latest star candidate:

"... if you can control economics, you can keep the business of getting a living the dominant factor of life, and so keep your control of politics – just that long, and no longer." ²

The policy of full employment is the prime method of making "the business of getting a living the dominant factor of life". We fight to pay the bills, when, from a purely physical assessment of the economy's potential, we should be living in easy abundance.

But there is another aspect at play. The policy also keeps people in a position of perpetual insecurity, dependent as they are on employment-givers. Under these conditions, people are naturally disinclined to take stands on controversial issues, lest their 'rocking of the boat' threaten their jobs or interfere with promotions, etc. For the sake of 'playing it safe' people naturally tend to go along with whatever the majority of people in their milieu seem to believe is right or, at the very least, they do not raise their voices in protest against the mob consensus. This way they won't stand out and their jobs are more easily protected. At that point, all that is necessary for oligarchy to triumph is to provide the script for the mass mind to follow, through the centralized control of media, entertainment, education, etc. (all made possible by the universal dependence on the banks' monopoly of credit) and the regrettable human tendency to blindly follow the pack will do the rest. The bulk of the sheeple do not even recognize what is happening, believing that all the frenetic and previously unthinkable changes to social life are somehow part of an organic evolution, rather than instances of a revolution orchestrated from above.

For both these reasons, full employment is the policy that is primarily responsible for our intensifying dispossession and disenfranchisement. The various economic, political, and cultural policies that subvert society and further centralize power in the hands of an international elite cannot be effectively opposed and neutralized by a servile public.

*For References, see bottom of previous page, (p5.)

COVID-19 VACCINES AND TREATMENTS: WE MUST HAVE RAW DATA, NOW [THIS BOMBSHELL FROM THE HIGHLY PRESTIGIOUS BRITISH MEDICAL JOURNAL IS DIFFICULT TO UNDERSTATE. – THE EDITOR] https://www.bmj.com/content/376/bmj.o102

In the pages of *The BMJ* a decade ago, in the middle of a different pandemic, it came to light that governments around the world had spent billions stockpiling antivirals for influenza that had not been shown to reduce the risk of complications, hospital admissions, or death. The majority of trials that underpinned regulatory approval and government stockpiling of oseltamivir (Tamiflu) were sponsored by the manufacturer; most were unpublished, those that were published were ghostwritten by writers paid by the manufacturer, the people listed as principal authors lacked access to the raw data, and academics who requested access to the data for independent analysis were denied.₁₂₃₄

The Tamiflu saga heralded a decade of unprecedented attention to the importance of sharing clinical trial data.56 Public battles for drug company data,78 transparency campaigns with thousands of signatures,910 strengthened journal data sharing requirements,1112 explicit commitments from companies to share data,13 new data access website portals,8 and landmark transparency policies from medicines regulators1415 all promised a new era in data transparency.

Progress was made, but clearly not enough. The errors of the last pandemic are being repeated. Memories are short. Today, despite the global rollout of covid-19 vaccines and treatments, the anonymised participant level data underlying the trials for these new products remain inaccessible to doctors, researchers, and the public—and are likely to remain that way for years to come. 16 This is morally indefensible for all trials, but especially for those involving major public health interventions.

Unacceptable delay

Pfizer's pivotal covid vaccine trial was funded by the company and designed, run, analysed, and authored by Pfizer employees. The company and the contract research organisations that carried out the trial hold all the data. 17 And Pfizer has indicated that it will not begin entertaining requests for trial data until May 2025, 24 months after the primary study completion date, which is listed on ClinicalTrials.gov as 15 May 2023 (NCT04368728).

The lack of access to data is consistent across vaccine manufacturers. 16 Moderna says data "may be available ... with publication of the final study results in 2022." 18 Datasets will be available "upon request and subject to review once the trial is complete," which has an estimated primary completion date of 27 October 2022 (NCT04470427).

As of 31 December 2021, AstraZeneca may be ready to entertain requests for data from several of its large

phase III trials. 19 But actually obtaining data could be slow going. As its website explains, "timelines vary per request and can take up to a year upon full submission of the request." 20

Underlying data for covid-19 therapeutics are similarly hard to find. Published reports of Regeneron's phase III trial of its monoclonal antibody therapy REGEN-COV flatly state that participant level data will not be made available to others. 21 Should the drug be approved (and not just emergency authorised), sharing "will be considered." For remdesivir, the US National Institutes of Health, which funded the trial, created a new portal to share data (https://accessclinicaldata.niaid.nih.gov/), but the dataset on offer is limited. An accompanying document explains: "The longitudinal data set only contains a small subset of the protocol and statistical analysis plan objectives."

We are left with publications but no access to the underlying data on reasonable request. This is worrying for trial participants, researchers, clinicians, journal editors, policy makers, and the public. The journals that have published these primary studies may argue that they faced an awkward dilemma, caught between making the summary findings available quickly and upholding the best ethical values that support timely access to underlying data. In our view, there is no dilemma; the anonymised individual participant data from clinical trials must be made available for independent scrutiny.

Journal editors, systematic reviewers, and the writers of clinical practice guideline generally obtain little beyond a journal publication, but regulatory agencies receive far more granular data as part of the regulatory review process. In the words of the European Medicine Agency's former executive director and senior medical officer, "relying solely on the publications of clinical trials in scientific journals as the basis of healthcare decisions is not a good idea ... Drug regulators have been aware of this limitation for a long time and routinely obtain and assess the full documentation (rather than just publications)."22

Among regulators, the US Food and Drug Administration is believed to receive the most raw data but does not proactively release them. After a freedom of information request to the agency for Pfizer's vaccine data, the FDA offered to release 500 pages a month, a process that would take decades to complete, arguing in court that publicly releasing data was slow owing to the need to first redact sensitive information. 23 This month, however, a judge rejected the FDA's offer and ordered the data be released at a rate of 55 000 pages a month.

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The data are to be made (continued from previous page) available on the requesting organisation's website (phmpt.org). In releasing thousands of pages of clinical trial documents, Health Canada and the EMA have also provided a degree of transparency that deserves acknowledgment.2425 Until recently, however, the data remained of limited utility, with copious redactions aimed at protecting trial blinding. But study reports with fewer redactions have been available since September 2021,2425 and missing appendices may be accessible through freedom of information requests. Even so, anyone looking for participant level datasets may be disappointed because Health Canada and the EMA do not receive or analyse these data, and it remains to be seen how the FDA responds to the court order. Moreover, the FDA is producing data only for Pfizer's vaccine; other manufacturers' data cannot be requested until the vaccines are approved, which the Moderna and Johnson & Johnson vaccines are not. Industry, which holds the raw data, is not legally required to honour requests for access from independent researchers.

Like the FDA, and unlike its Canadian and European counterparts, the UK's regulator—the Medicines and Healthcare Products Regulatory Agency—does not proactively release clinical trial documents, and it has also stopped posting information released in response to freedom of information requests on its website. 26

Transparency and trust

As well as access to the underlying data, transparent decision making is essential. Regulators and public health bodies could release details²⁷ such as why vaccine trials were not designed to test efficacy against infection and spread of SARS-CoV-2.²⁸ Had regulators insisted on this outcome, countries would have learnt sooner about the effect of vaccines on transmission and been able to plan accordingly.²⁹ Big pharma is the least trusted industry.³⁰ At least three of the many companies making covid-19 vaccines have past criminal and civil settlements costing them billions of dollars.³¹

One pleaded guilty to fraud.31 Other companies have no pre-covid track record. Now the covid pandemic has minted many new pharma billionaires, and vaccine manufacturers have reported tens of billions in revenue.32 *The BMJ* supports vaccination policies based on sound evidence. As the global vaccine rollout continues, it cannot be justifiable or in the best interests of patients and the public that we are left to just trust "in the system," with the distant hope that the underlying data may become available for independent scrutiny at some point in the future. The same applies to treatments for covid-19. Transparency is the key to building trust and an important route to answering people's legitimate questions about the efficacy and safety of vaccines and treatments and the clinical and public health policies established for their use.

Twelve years ago we called for the immediate release of raw data from clinical trials. We reiterate that call now. Data must be available when trial results are announced, published, or used to justify regulatory decisions. There is no place for wholesale exemptions from good practice during a pandemic. The public has paid for covid-19 vaccines through vast public funding of research, and it is the public that takes on the balance of benefits and harms that accompany vaccination. The public, therefore, has a right and entitlement to those data, as well as to the interrogation of those data by experts.

Pharmaceutical companies are reaping vast profits without adequate independent scrutiny of their scientific claims. 33 The purpose of regulators is not to dance to the tune of rich global corporations and enrich them further; it is to protect the health of their populations. We need complete data transparency for all studies, we need it in the public interest, and we need it now.

Footnotes

- Competing interests: We have read and understood BMJ policy on declaration of interests and declare that The BMJ is a co-founder of the AllTrials campaign. PD was one of the Cochrane reviewers studying influenza antivirals beginning in 2009, who campaigned for access to data. He also helped organise the Coalition Advocating for Adequately Licensed Medicines (CAALM), which formally petitioned the FDA to refrain from fully approving any covid-19 vaccine this year (docket FDA-2021-P-0786). PD is also a member of Public Health and Medical Professionals for Transparency, which has sued the FDA to obtain the Pfizer covid-19 vaccine data. The views and opinions do not necessarily reflect the official policy or position of the University of Maryland.
- Provenance and peer review: Commissioned; externally peer reviewed.

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