

# MANDATING UNPROVEN TECHNOLOGIES

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## **Background: Approval and Regulation of Therapeutic Goods**

In the early 1980s, the pharmaceutical industry outsourced the running of its clinical trials to Contract Research Organizations (CROs) and outsourced the preparation of manuscripts on their clinical trial results to medical writing companies.

As a result of this, physicians and academics running clinical trials of drugs and vaccines lost access to clinical trial data. Even the apparent authors on the manuscripts representing the results of those trials no longer had access to and could not interrogate the data or stand as guarantors for the accuracy of the published record of these trials.

Study 329, a study comparing paroxetine to placebo in depressed minors conducted in the mid-1990s, illustrates the changes then taking place. A 2001 article with a distinguished authorship line, in the journal with the highest impact factor in child psychiatry, claimed paroxetine worked well and was safe. It led to a considerable increase in the prescribing of paroxetine to minors<sup>1</sup>.

Based on documents I provided, in 2004 New York State took a fraud action against the makers of paroxetine, GlaxoSmithKline (GSK), which was resolved with a promise to make company trial data more available. This high-profile action led to Black Box Warnings on antidepressants. It made clear that the entire published literature on randomized controlled trials (RCTs) of antidepressants in children at that time was ghostwritten – the names on the authorship lines for medical paper reporting the results of RCTs do not write those papers. It also laid bare a comprehensive mismatch between the published claims and the data when accessed.

Study 329 and paroxetine were also the centrepiece of an action the US Dept of Justice took against GSK that was resolved in 2012 with a payment of \$3 billion then the largest such payment in corporate history.

Study 329 was not an aberration. It represents standard industry modus operandi as of the mid-1990s. It was performed in the best academic centres with good oversight, and to higher standards than most trials are now.

These legal actions made Study 329 trial data uniquely available. This permitted colleagues and I some years later, to demonstrate the range of tricks companies use in hiding harms<sup>2</sup>.

Most of the tricks companies now deploy to hide harms and fudge efficacy were being worked out at the time this trial took place. Company abilities to hoodwink us have improved greatly since then and there is likely more fraud now than then.

A recent BMJ publication on Pfizer's vaccine trials illustrates that these trials are affected by the practices that were becoming standard in the 1990s<sup>3</sup>.

Besides company tricks, even if done by angels, as pointed out by Austin Bradford Hill who ran the first randomized trial, RCTs can be helpful in evaluating one of the more than one hundred

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<sup>1</sup> For more on Study 329, see Healy D et al Children of the Cure. Samizdat Press, Toronto (2020).

<sup>2</sup> Le Noury J, Nardo J, Healy D et al. Restoring Study 329: A randomised, controlled trial of the efficacy and harms of paroxetine and imipramine in the treatment of adolescent major depression BMJ 2015; 351: h4320

<sup>3</sup> Thacker P. Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial. BMJ 2021;375:n2635

things every drug does but this, by definition, makes them a poor way to evaluate a drug or vaccine overall<sup>4</sup>.

The need to supplement RCTs with other evaluative approaches can be brought out by a simple example. Before the selective serotonin reuptake inhibiting (SSRI) group of antidepressants were put into clinical trials, it was known these drugs affect sexual functioning in close to 100% of us within 30 minutes of a first pill. But in RCTs of these drugs undertaken for the purposes of establishing the existence of a much less common benefit for nervous problems, the focus on a primary endpoint that RCTs require meant these sexual effects essentially vanished.

The vanishing-effects problem is even greater in current vaccine trials, where participants have been presented with a prepopulated list of a small number of side effects that might happen to them as a result of the vaccine (see appendices 2 and 3). This is like a company claiming an improvement in its consumer satisfaction levels after eliminating the complaints department.

### **Consent**

Two issues arise when treatment effects, other than those of commercial interest, vanish. Because of a premium now put on RCTs, companies claim that the only things that happen on a drug or vaccine are things that happen to a statistically significant effect in an RCT. Everything else is anecdotal or psychogenic.

Statistical significance testing, however, should only be applied to the primary endpoint of a trial. It should not be applied to effects that are not being investigated.

As a result, the consent forms for people taking Covid vaccines, in the UK for instance, now present people with a strong steer that the only things likely to happen them after injection are a sore arm, headaches or other aches, fatigue, stomach upset, or a mild fever.

Pfizer knew about the effects of SSRIs on sexual functioning and risk of triggering suicidality before launching sertraline. The company similarly knew about the risks of its vaccine to individuals with pre-existing neurological conditions such as multiple sclerosis, or the more general risk of effects on the nervous system such as Guillain-Barre Syndrome, Bell's Palsy, demyelinating disorders or transverse myelitis, all of which people should be warned about prior to deciding whether to take the vaccine or not.

### **Risk-Benefit**

A second issue stems from the current misreading of what RCT data demonstrate, namely that it is not possible on the basis of RCTs to establish a Risk-Benefit ratio for a drug or a vaccine.

Regulators routinely claim that the Risk-Benefit ratio favours the approval of this drug or vaccine or failure to warn about harms, basing this claim on company RCT data and assuming the primary endpoint is by far the commonest effect of treatment with all other effects being rare or idiosyncratic or developing outside the time frame of the trial.

But if RCTs can make effects of a drug or vaccine that are as common or even more common than the primary endpoint vanish, or if other effects are rare or idiosyncratic but serious, then the basis for claiming a favourable Risk-Benefit ratio for drugs or vaccines vanishes.

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<sup>4</sup> Healy D. Shipwreck of the Singular. Healthcare's Castaways. Samizdat Press, Toronto, 2021. Healy D, Mangin D, (2019). Clinical judgments, not algorithms, are key to patient safety. BMJ 367: I5777

This clearly is likely to be even more the case for novel mRNA technologies.

There is furthermore no metric, or algorithm, for making Risk-Benefit judgements on a population level. These are a matter of individual decision.

## **Pharmacovigilance**

The development of modern therapeutics has put pharmacovigilance at the heart of medicine. While there are epidemiological and other processes that pharmacovigilance can turn to, the central discipline involves a doctor and patient deciding on the basis of an examination of the patient what is happening when the patient reports some change after taking a medicine. The event being considered could be a benefit in which case doctor and patient will opt to continue treatment. Unless such decisions are ordinarily correct, medical practice could not continue.

Or the event could be that the treatment is not working or is causing a harm.

This assessment by doctor and patient is or should be a judicial process. Judicial processes are commonly viewed as something distinct from science. A judicial process, however, necessarily adheres to available data, and only available data, just as closely as science does. Judicial processes have rules of evidence as strict as science. Speculation has no part in a judicial process. Nor since the execution of Walter Raleigh in 1618 does hearsay. If a witness cannot be brought into the examination room and cross-examined, their evidence is discounted.

The explanation, the verdict, must match the facts presented. It must also achieve a consensus that overcomes the biases of 12 different jurors.

In a clinical encounter, just as in a legal process, the answer is provisional, as are all answers in science. Further facts may come to light that challenge a provisionally accepted view.

As outlined here, this is a process that is as scientific as any of the demonstrations of physical or chemical phenomena undertaken in the Royal Society from 1660 onwards that we view as establishing the scientific paradigm, namely that science seeks to explain observable data, that it challenges bias by sticking to this rule and that all its verdicts are intentionally provisional with the process encouraging others to experiment further.

Good clinical practice, when undertaken as outlined here, is inherently scientific. More scientific than any practice shaped by unavailable RCT data, misleadingly represented in ghostwritten publications that hype the benefits of a treatment and hide the hazards.

Clinicians, who attempt to be scientific in this manner, however, are increasingly called on to account for the mismatch between their judgements based on what they see in and hear from patients, for instance that this SSRI made this person suicidal, and what an apparently scientific literature, along with the NICE or other guidelines that are based on this literature, claim.

## **Regulation and Pharmacovigilance**

The goal of medicines regulation, as in traffic, financial, or airline regulation, is to enhance safety. It is not to enhance efficacy.

A set of Amendments to the US Food and Drugs Act put in place in 1962 introduced RCTs to the regulation of medicines for the contribution they might make to assessing therapeutic efficacy, in the hope that eliminating ineffective treatments might contribute to safety.

Safety however has not been enhanced by these regulations, at least not since the 1980s. Prior to 1962, the benefits of treatment had to be evident to clinicians and patients, whereas now, if a sufficiently large number of patients are recruited to a trial, statistically significant effects can be

established on surrogate outcomes with these leading to approvals without any doctors or patients seeing an evident benefit, and with more deaths on treatment than if the patient were left untreated.

It was thought in 1962 that clinicians would remain, as they had been before, the principal agents in medicines' regulation, with the bureaucrats we now call regulators continuing to occupy a relatively minor role.

In contrast to clinicians, the bureaucrats working in the United States Food and Drug Administration (FDA) and Britain's Medicines and Healthcare Regulatory Agency (MHRA) do not engage with the judicial processes outlined above for four reasons.

1). When doctors or patients report adverse events to MHRA, the first step, if the reporting process has not already achieved this, is for the bureaucrat to strip the names of patients from any communication – ostensibly to comply with clinical confidentiality requirements. This transforms reports from doctors (or patients) into Hearsay.

Anonymization makes the evidence from injured patients and their doctors inadmissible as evidence in court in a way that case reports with a doctor and patient's name on them remain admissible. A patient who has been injured by treatment, and further injured by anonymization, cannot be examined and cross-examined and it is not possible to establish cause and effect.

In the case of the Covid vaccines, MHRA, despite huffing and puffing about searching night and day for the needles of causation in a haystack of reports, are faced with a needlestack of reports but are unable to determine any cause-and-effect relationships. While regulators have conceded a link between current vaccines and both thromboses and myocarditis, this was only after clinicians established that these are happening based on their assessment of patients in front of them. To save face regulators have had to agree.

In the event of reports to them, pharmaceutical companies, in contrast to regulators, are legally obliged to follow up patients and their doctors over time to establish whether the company's drug might be causing a problem. Companies do this and decide their drug has caused a harm and add this harm to their drugs label, while regulators stack up thousands of reports and claim they have never made a causal link in a single case.

2). A further factor inhibits MHRA from making causal determinations in respect of deaths on vaccines and drugs. In the case of deaths, MHRA ordinarily wait for inquests, before coming to a view. These inquests have inputs from the patient's doctor. There is also a coroner in place who comes to a view as to what the cause of death has been.

While coroners can indicate a street drug has been a cause of death, they do not have an option (a box to tick) to indicate that a prescription drug or vaccine has caused a death.

Physicians, meanwhile, if asked to attend an inquest or prepare a report on a death, will be advised by their medical insurer to deny a link to any treatment to which they were party. Doctors at inquests are routinely advised in this manner, by the representatives of a business, whose interests lie in not incurring further costs. Containing a medical insurer's costs is done by deflecting attention from a treatment to an illness.

Coroners, who are normally not medically qualified, are not in a position to gainsay a treating physician who denies a link to treatment. If a coroner is very concerned about a problem, s/he can make a regulation 28 report to MHRA, who will ordinarily opt not to gainsay the view of the treating doctor.

Even the press reporting on inquests are caught in this web, as advice to journalists from the Independent Press Standards Organization (IPSO) on reporting suicides, for instance, makes clear. IPSO explicitly tells journalists not to go against the conclusion of the coroner, which for the reasons outlined will never implicate a treatment.

3). Regulators support the mantra that RCTs provide gold standard evidence on drugs, partly because RCTs make the bureaucratic job easier. This faith in RCTs extends to claiming that if an effect has not been shown to happen to a statistically significant extent in an RCT, then no matter how plausible it might be, we simply do not know that it happens.

Ian Hudson, the recent CEO of MHRA, said exactly this under oath in the 2001 Tobin v SmithKline trial, when he was working for GSK. The jury rejected the argument.

4). In line with Hudson's approach, when considering adverse events, FDA and other regulators claim to have dedicated epidemiologists for this task. Epidemiologists have very little role in pharmacovigilance other than in monitoring the risk of birth defects on treatment.

Neither FDA, nor MHRA, have any clinicians trained in assessing adverse event causality. They lack procedures to assess causality. If were they to establish a link between treatment and an event, pharmaceutical companies effectively maintain a drugs label and have to agree before anything happens. Finally, there is reluctance to acknowledge a Suspected Unexpected Serious Adverse Reaction (SUSAR) because of all the work this leads to.

### **Hearsay**

The anonymized reports of deaths and injuries on vaccines are worthless from an evidential point of view in legal and scientific settings, although some value can be extracted from proportional reporting rates.

In contrast, for sixty years the results of RCTs have been taken in legal settings as meeting a Hearsay exemption.

For the first thirty of those sixty years, however, the courts could request the presence of physician authors on the papers reporting the result of company trials, where authorship meant physicians who treated patients who existed with the physician in a position to evaluate the full effect of these drugs in patients.

For the subsequent thirty years, few of the authors on papers reporting on company RCTs will have met any of the patients in trials and several authors have ended up in jail for recruiting non-existent patients to trials. Between non-existent patients, and lack of access to the patients who do exist, the results of RCTs arguably should no longer qualify for a Hearsay Exemption.

### **Regulation and Trial Data**

As per scientific norms, there is an assumption that regulators, investigators, and the authors whose names appear on publications of RCT results, see the clinical trial data. None do.

Instead, the regulation of pharmaceutical company products is a business process where commercial confidentiality counts for more than the norms of science. Unlike drugs, company involvement in the case of vaccines is relatively recent. Vaccines were made by countries, who were not constrained by profit considerations.

Companies hold the trial data and submit Clinical Study Reports (CSRs) to the regulator. These are the company representation of what its clinical trial has shown. The CSR will often contain large amounts of largely irrelevant figures set out in Tables. The Tables are in principle

transcribed from Clinical Report Forms (CRFs), which, until a recent turn to electronic capture of figures, might have up to 100,000 pages for a 300–400-person trial<sup>5</sup>.

FDA insist they get everything from companies, but even FDA do not read these CRFs other than for audit purposes – checking to see if there are any hints that every 12<sup>th</sup> patient might not exist.

As I can attest, based on a more detailed examination of CRFs than FDA undertake, if a significant question mark arises about some harms, FDA will invite the company to revisit its records and tell the regulator what the score is in the light of some concern that has arisen. When matters get this serious, companies are still liable to mislead regulators.

(FDA is mentioned here rather than other regulators because of their claims to thoroughness rather than because they offer a gold-standard in regulation).

More recently FDA led the way in getting what they refer to as individual patient level data (IPD). IPD gives the impression a regulator is getting to grips with something like the raw data but in fact IPD is essentially a spreadsheet with figures primarily linked to efficacy that allow FDA to check on some of the claims for benefits, based on selected data provided. It does not allow FDA or any other regulator to explore hazards or interrogate subjects from trials.

The CSR does include some individual patient level data in the form of narrative reports on serious adverse events (SAE) – events that result in hospitalization or death.

From these narratives, it might be possible to guess that the man whose death was coded as death by burns died because he poured petrol over himself intending to kill himself but only died 5 days later and question the company as to whether this death occurring on a new psychotropic drug rather than placebo might have been better coded as suicide.

But companies have found ways around the obligation to write narratives for SAEs. Patients who drop out of trials because of an adverse event can be designated as having intercurrent illness or some related term. There is no obligation to write a narrative on a patient like this, which leaves anyone who might get to see the records none the wiser as to what has gone on.

In Study 329, a 15-year-old boy was picked up by the police on the street waving a gun and threatening to kill people. He was brought to hospital. This was almost certainly a paroxetine related adverse event. It vanished under an intercurrent illness coding – as did events that befell three other children in this trial, all of whom were on paroxetine and none on placebo.

Ultimately people are the data in clinical trials. Without access to their names and contact details, which should be possible in a vaccine trial where volunteers are not being treated for an illness, no-one can establish what has happened in a clinical trial.

It takes a clinical interview to establish if the person in the trial likely became suicidal as a result of their illness or their drug. The clinical interview is the only place where all the data is present – the later trial database loses data as a result of a semi-automatic allocation of features that an illness and a treatment might share in common, such as suicidality, to the illness.

Up to half of the symptoms that people have in a trial may be features shared in common between a treatment and an illness. This can be teased out in healthy volunteer trials of drugs which remove the illness confounder. In vaccine trials, everyone is a healthy volunteer but companies have found ways to discount the injuries that have happened.

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<sup>5</sup> Healy D, Le Noury J, Wood J. Children of the Cure. Samizdat Press, Toronto 2020.

## Pre-Vaccine Summary

1. Clinicians do not have access to clinical trial data on medicines or vaccines.
2. Close to all of the medical literature reporting trial results for on-patent drugs and vaccines is ghostwritten, hyping the benefits and hiding the harms.
3. Clinical trials of these treatments that are negative on their primary or their most common outcomes are often published in prestigious journals as positive.
4. Clinical trials have their harms airbrushed out of ghostwritten publications.
5. Regulators (FDA, Health Canada, MHRA, EMA) do not get to see the full trial data.
6. Regulators approve treatments as working even when more people die on active treatment than on placebo.
7. Regulators approve medicines on the basis of negative studies and agree not to let the wider world know about this.
8. Regulators say nothing when companies publish negative studies as positive and make adverse effects of treatment, including death, vanish.
9. For many trials there are more deaths on active treatment than on placebo, but this does not lead regulators to warn about hazards as to do so would in their stated view deter people from seeking a benefit (even when the benefit is better characterized as a commercial benefit to a company rather than a benefit to the individual in terms of a life saved or a restoration of function).
10. Regulators do not have pharmacovigilance expertise and a variety of factors inhibit them from linking a treatment to a hazard after that treatment comes on the market.

Before Covid, there was growing evidence that life expectancies were falling, or improvements in life expectancy had stalled, in many Western countries, including the UK and US. While poverty and inequality kill, we also know that a polypharmacy, made possible by the business and regulatory processes outlined above, also kills<sup>6</sup>.

Few of us were on more than a brief course of one medicine per day in the 1980s. Now heading toward 50% of us over the age of 45 are on 3 medicines per day and approaching 50% of us over 65 are on 5 medicines or more per day. The evidence that reducing medication burdens can increase life expectancy, reduce hospitalizations and improve quality of life is strong enough for the Department of Health to support efforts in this area.

An unwillingness to tackle the issues raised here, however, semi-mandates an increase in medication burdens. These points are ones that those in favour of vaccine mandates might consider more carefully.

Points 1-10 above have been made to regulators, Ministers of Health, Chief Medical Officers, guideline makers, the editors of medical journals and others. Much of the correspondence is available [Here](https://davidhealy.org/from-stephen-oneill-to-the-crack-of-doom/) - <https://davidhealy.org/from-stephen-oneill-to-the-crack-of-doom/>

They have been presented at academic meetings on all continents, featured in articles in major journals and in University Press books without being contested or leading to legal action.

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<sup>6</sup> For references see Healy D. Shipwreck of the Singular. Healthcare's Castaways. Samizdat Press, Toronto, 2021.



## **MANDATING 'VACCINES'**

The government is considering the mandating of an unproven technology, against a background of vaccine approval and pharmacovigilance processes that leave a lot to be desired even in the case of proven technologies.

The technologies, now designated as vaccines, are novel, so much so that they led in 2021 to a change in the dictionary definition of a vaccine.

The techniques used to evaluate these novel agents are not new but have been corrupted and no longer meet the norms of science. The points made in the background section about the evidence regulators, and investigators get to see hold for these new technologies also.

Icon is the CRO that co-ordinated the trial of a vaccine that is sometimes now called Comirnaty, and more generally called Pfizer<sup>7</sup>. Icon subcontracted to other companies, at some point engaging Platinum Research Ltd, which includes Ventavia, the CRO with concerning trial practices that was the subject of the Nov 2<sup>nd</sup> BMJ paper. Icon boast that the main trial was conducted with unprecedented speed and pitch for further business based on this.

Icon staff wrote the papers reporting the results of these trials submitted with BioNTech as the sponsor. Of the 29 listed 'authors' on the main trial, there are 3 Americans, 4 who run for profit clinical trial centres overseas, and 19 company people of whom 17 are linked to Pfizer and 2 to BioNTech. There are few clinicians on these papers, and likely none have met any of the trial subjects, particularly those who have been harmed.

These novel agents were authorized for emergency use (EUA) starting with Icon/Pfizer's RCT. They were later approved without additional safety or efficacy data. Approval made mandates possible; these are not possible under an EUA.

My argument offers no views on Covid, other than it is an infection to be managed.

It offers a view on processes. Government, regulators, and guidelines makers have agreed with, or not contested, the points being made here about clinical trial data sequestration and their agreement is the basis for this letter.

To disprove the case, government would have to be able to show there is access to the clinical trial data for these new technologies, that there are processes in place to establish what harms these technologies are causing, and there is ongoing research on treatment options for those who are harmed by vaccines.

As it stands, my view cannot be pitched against opposing views, with a government who has to manage a crisis being let by the legal system use its discretion to choose which set of views to believe. As a matter of logic, no scientists can endorse withholding trial data. And if harms are denied, no-one can assert research is being done on how to recognise and treat them.

The government does not have a right to substitute business considerations or hocus-pocus for science and mandate on this basis, especially in a time of crisis when trust is important.

### **Vaccine Efficacy**

Rather than establish the effectiveness of a treatment, many clinical trials use surrogate outcomes as a measure of efficacy. Thus, with SSRI antidepressants, while there are falls in

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<sup>7</sup> <https://www.biopharma-reporter.com/Article/2021/03/03/Inside-the-Pfizer-BioNTech-COVID-19-vaccine-trial-Insights-on-speed-agility-and-digital-development>

depression rating scale scores, there are more lives lost and suicide attempts on treatment than on placebo, suggesting rating scale changes are surrogates for the outcomes we want.

Based on the trial results reported for these new technologies on measures of effectiveness, such as death, we know that in the Icon trial there were more deaths on vaccines and placebo. In all trials, other measures of what most people might regard as effectiveness, such as hospitalization for serious illness or admission to intensive care units, are not reported.

The measures reported are symptomatic infection confirmed by PCR test<sup>8</sup>. Now this might not seem like a surrogate, any more than depression rating scales scores do, but it is now clear that these agents do not block infection or transmission and so cannot help us achieve herd immunity, which along with lives saved and an avoidance of significant disability, is a measure of 'vaccine' effectiveness.

Agents that possibly treat rather than immunize, such as ivermectin, hydroxychloroquine, molnupiravir, or paxlovid, could produce comparable results.

Subjects on active treatment in trials who developed Covid after the first dose and prior to 14 days after a second dose were not counted, as this would be unfair to the vaccine, when a strict Intention-to-Treat analysis would include them.

Health Canada makes a CSR for the Pfizer trial available<sup>9</sup>. In this multiple tables give slightly different figures for those recruited and dropping out of the trial. Over 1000 subjects appear to have dropped out in both the vaccine and placebo arms having contracted an infection. Analysing the outcomes with these left in would make a difference to the conclusions.

The PCR testing used to establish who was infected offers further ambiguity. There is no consensus on what threshold for these tests reliably distinguishes a Covid infection from viral fragments. The commonly used cycle thresholds for PCR are greater than 30 and tests positive on this basis commonly do not support viral cultures<sup>10</sup>.

Another large number of people appear to have disappeared into a gap between a first dose of the vaccine and 14, or more, days after the second dose – in this case many more on the vaccine (300+) than placebo (60), with a similar excess in Pfizer's children's trial.

Companies have a track record in making safety events disappear into gaps like this. Given the BMJ Nov 2<sup>nd</sup> report about how these trials were conducted, and in the absence of details on the centres in which drop-outs happened, there can be no guarantees the reported reasons for dropouts hold water.

One might argue that safety events can be left out of a consideration of efficacy, but clearly in the case of suicide on SSRIs this should not be the case. Where the relationship between efficacy and effectiveness is as loose as with SSRIs, as it appears to be for these new technologies, leaving serious safety events like death out of both efficacy and safety analyses is problematic and particularly problematic when serious safety events are portrayed widely as occurring in those who are unvaccinated, during the weeks after a first injection.

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<sup>8</sup> Doshi P. Will covid-19 vaccines save lives? Current trials aren't designed to tell us. BMJ 2020;371:m4037

<sup>9</sup> <https://clinical-information.canada.ca/ci-rc/terms?id=244906>

<sup>10</sup> Jefferson T, Spencer EA, Brasseley J, Heneghan C. Viral cultures for COVID-19 infectivity assessment – a systematic review. MedRxiv preprint doi: <https://doi.org/10.1101/2020.08.04.20167932>

(The SSRI trials offer a precedent for what companies have done in their vaccine trials, and in that case company conduct has been recognized as inappropriate – see Appendix 1).

### **RCTs and Real-World Evidence**

The available data offers slender evidence for vaccine efficacy and none for effectiveness. Without full access to the data, especially in the light of the BMJ report about the behaviour of Ventavia, the sub-contracted CRO helping to run the Icon/Pfizer trial<sup>11</sup>, it is impossible to establish what happened in these trials.

In the case of the SSRIs, when it became possible to pierce through company obfuscations and show that evidence from company RCTs demonstrated a link between SSRIs and suicide, companies and others turned to real world evidence to deny this link. This evidence was used to claim that what appeared to be a hazard from RCTs was not one in the real-world. SSRI real world equivalents to mRNA harms are detailed further in Appendix 1.

As with SSRIs, it is only when we establish what happened in the core RCTs that we can begin to establish how the apparent real-world evidence might have arisen.

For instance, if SSRIs work wonderfully well, then real world evidence of falling suicide rates might well map on to their effectiveness. When, however, in trials SSRI were shown to offer scant benefits and an increased risk of suicide, researchers began to note that suicide rates were falling before SSRIs emerged and correlate better with falling autopsy rates than with increased SSRI use. In addition, they found that increased SSRI treatment correlates well with increased rates for deaths of undetermined cause.

Similarly, knowing exactly what happened in vaccine RCTs is key to establishing what is happening in the real world.

There are many possible explanations for what is happening following vaccination. An enduring lack of consensus about what a case of Covid is opens a gap through which all kinds of claims can be marched.

There is scope to confuse deaths with concomitant Covid and Covid deaths. In one large UK sample involving children 60% of Covid positive deaths were not Covid deaths<sup>12</sup>.

In seeking to nudge people toward a treatment they genuinely believe might be helpful, public health officers may have been economical with the truth. They need to be allowed some latitude in a pandemic but latitude risks toppling over into lying.

Another option is that rather than immunize people, which it is hard to say these agents do, some of these agents may 'treat' – that is act like a drug with a beneficial effect of reducing the likelihood of a Covid pneumonia and consequent death.

Access to the RCT data will encourage a range of experts to put serious thought into explaining the real-world data. It seems likely that access will make it more difficult to attribute all good real-world data to vaccine effectiveness and safety.

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<sup>11</sup> Thacker P. Covid-19: Researcher blows the whistle on data integrity issues in Pfizer's vaccine trial. BMJ 2021;375:n2635

<sup>12</sup> Smith C, Odd D, Harwood R et al Deaths in children and young people in England after SARS-CoV-2 infection during the first pandemic year. Nature Medicine doi.org/10.1038/s41591-021-01578-1.

Beyond this, there remains a lot of real-world evidence still to come in. In the case of Di-Ethyl-Stilbestrol (DES) it took thirty years before clinicians spotted its major hazard – vaginal cancer in the daughters of women who took it during pregnancy.

In contrast, in the case of most drugs now, from SSRIs to leukotriene antagonists, the ghostwriting of clinical trials and sequestration of trial data mean that thirty years after clinicians first described these hazards companies can get away with denying the hazards exist.

In the case of vaccines, we likely face decades before unexpected hazards emerge and in addition decades before there is a recognition of serious hazards clinicians are currently reporting.

### **Vaccine Safety**

The companies deny there were serious adverse events (SAE), events that result in hospitalization or death or have the potential to do so, in their trials.

In the Astra-Zeneca vaccine trial, the resulting Falsey et al New England Journal of Medicine (NEJM) publication mentioned that people who withdrew from the study have not been included in the analysis. Brianne Dressen was a subject in this trial who was not included in the analysis, but she did not withdraw. Ms. Dressen would be happy to be contacted by you.

She wrote a letter for publication to NEJM making clear that, after Astra-Zeneca broke the blind and confirmed she was on active treatment, they told her not to take a second dose. They also removed the electronic device given to her for reporting ongoing adverse events (Appendix 2).

The NEJM editor, Eric Rubin, responded to Dressen that NEJM would not be publishing the letter. On Nov 15, 2021, at 3:19 PM, he further emailed:

Dear Ms. Dressen,

The best we could do is forward your letter to the manufacturer. **Only they** are in a position to see the primary data. But you can do that yourself and I would encourage you to do so. Only you can provide the information that they can use to investigate.

Eric

Brianne Dressen subsequently made it clear to Dr Rubin that she was not the only A-Z trial participant to whom this happened and that the NEJM's Falsey publication breaches good clinical trial reporting guidelines. Rubin still refused to budge.

The Astra-Zeneca trial gave electronic devices to volunteers for safety monitoring. This had a set of prepopulated events that subjects in the trial could respond to – they could report on headaches, or fever, but not on the early signs of a transverse myelitis, Guillain-Barre Syndrome, a myopathic disorder, myocarditis or thromboses.

In the Icon/Pfizer trial of 12–15-year-olds, 13-year-old Maddie De Garay spent close to two months in hospital after suffering adverse reactions that left her in a wheelchair and fed by nasogastric tube. I have examined Ms. De Garay and all her medical records.

The NEJM publication of this trial (Frenck et al) states there were no serious vaccine related adverse events. In the De Garay case, the investigators in their publication appear to depend on the report of an allergist, who introduced the idea of a functional disorder, to claim that Maddie De Garay has a functional illness. This implies she had a predisposition to hysteria and therefore the vaccine cannot be said to have caused this. The allergist consulted the lead investigator, Dr Frenck, before committing this entry to the medical record. His entry included the detail that he had consulted with Dr Frenck, who is based in the hospital Ms De Garay was

being seen in - that the trial monitors insisted she be taken to rather than a hospital nearer home.

My examination of Ms. De Garay and review of her medical record suggests this trial designation is not just wrong but quite unbelievable. It is perhaps even sociopathic as it appears that, in order to maintain Pfizer's position, this young woman is not getting the treatment that would be ordinarily indicated for the kind of problems she has. Instead based on a claimed functional disorder, she has been directed to a mental health facility.

There seems little point writing to Dr Rubin about this. On October 26<sup>th</sup>, three weeks before his email to Brianne Dressen, Eric Rubin was a member of the FDA Vaccines and Related Biological Products Advisory Committee convened to review the data on Pfizer's application, based on Icon trials, to approve their vaccine for 5–11-year-olds. He voted for approval saying<sup>13</sup>:

**“We are never going to learn how safe this vaccine is unless we start giving it. That's just the way it goes. That's how we found out about rare complications of other vaccines”.**

Given Dr Rubin told Brianne Dressen that NEJM don't publish case reports, it is difficult to see that NEJM will ever contribute to the safety profile of these agents.

The treatment of Ms De Garay raises another prospect. In the case of vaccinated minors, with neurological problems of the type she has, few if any paediatricians or family doctors have seen older people's disorders such as demyelinating events and strokes in the young. Accordingly, many will not know what they are seeing or how to respond, making a turn to a diagnosis like hysteria (functional neurological disorder) more likely.

As with Brianne Dressen, Maddie De Garay had a prepopulated electronic device that only let her record indicators like headache, fever etc but none of the clinical problems she has ended up with. (See Appendix 3 for details of the De Garay case and the Frenck NEJM publication).

The CSRs on these Icon trials, possibly written by Icon, have numerous tables of adverse events reported in the course of the trial. Prepopulated electronic devices make these tables meaningless.

The safety arms of the Icon/Pfizer trials were dismantled, two months after recruitment stopped. The blind was broken and all of those who had been on placebo were invited to have the vaccination.

In other trials of related biological products, the existence of mandates and the need to get vaccine passports have encouraged others of those who have been in trials, to get extra jabs after the trial ended in order to be able to get vaccine passports – supporting their individual liberties but compromising communal safety.

Finally, while Icon congratulated themselves on co-ordinating 152 recruitment sites, 130 in the US, to deliver a speedy result, anyone familiar with a trial of aripiprazole as a maintenance treatment in bipolar disorder might wonder about these sites, especially trial business operations. Aripiprazole showed no benefit over placebo in 30 US sites, but was wonderfully

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<sup>13</sup> Eric Rubin starts at 6 hours 51 minutes: [https://youtu.be/laaL0\\_xKmmA?t=24733](https://youtu.be/laaL0_xKmmA?t=24733)

effective in 3 non-US sites, the results from which made the overall result positive. FDA noted this odd pattern of results but did nothing<sup>14</sup>.

## Pharmacovigilance

The Covid vaccines make clear that our current pharmacovigilance systems do not work.

In less than a year, there have been several fold more deaths following Covid vaccines reported to MHRA in the UK and CDC in the US than after all other vaccines combined over the last 20 years but regulators have not conceded a link between any of these deaths and the vaccines.

There are certainly a great number of deaths from Covid. These primarily involve pneumonias and occur in hospital settings and allow clinicians to link many to Covid and to register these deaths and maintain figures that have some validity.

A Nature Medicine paper, referenced above, however, looking at all deaths in British children linked to Covid found that 60 % of children who died and were Covid positive did not have a Covid caused death.

Deaths from the vaccine, in contrast, happen at home or in settings other than hospitals. No attempts are made to link the deaths to the vaccine (other than in Norway where 10% of deaths after vaccination in residential homes were deemed to be likely linked to the vaccine and 26% possibly linked.<sup>15</sup> No register of deaths lets us know how common vaccine deaths are relative to Covid deaths.

The issues of myocarditis, especially in younger people, and thrombotic events have been brought to the fore by clinicians. In Britain, where most reports to regulators come from doctors, there have been 10-times more reports of neurological events than from myocarditis and thromboses combined. There are few hints of these neurological difficulties in the published articles on these trials, even though cases of transverse myelitis led to a temporary halt of the Astra-Zeneca trial.

Brianne Dressen was an early volunteer for this trial when it resumed. Her case and Maddie De Garay above illustrate how companies can manage to lose seriously injured people.

Some countries like Norway, Sweden, and France have more robust pharmacovigilance systems than the UK, often employing clinicians distributed around a country rather than operating as a central bureaucracy. These countries have done better than Britain has in this pandemic in recognising myocarditis and thromboses, and recognizing vaccine related adverse events, such as narcolepsy, in previous pandemics.

For therapeutic agents in general, the United States has depended on companies to undertake the pharmacovigilance and to take steps to ward off the liabilities they face if injured patients

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<sup>14</sup> Rosenlicht N, Tsai AC, Parry PI, Spielmans G, Jureidini J, Healy D (2011). Aripiprazole in the maintenance treatment of bipolar disorder: A critical review of the evidence and its dissemination into the scientific literature. PLoS Medicine, 8, e10000434.

<sup>15</sup> BMJ <https://doi.org/10.1136/bmj.n1372> ; Norway study: <https://doi.org/10.4045/tidsskr.21.0383>; Norway regulator press release: <https://legemiddelverket.no/nyheter/expert-group-has-assessed-deaths-amongst-the-frail-elderly-following-covid-19-vaccination>

take legal actions, as they can in the US. Companies have been far more likely to make a cause-and-effect link to their product than FDA or CDC have been.

The increasing control these companies have over the medical literature, however, means that in the case of clear adverse events, as the SSRI story (appendix 1) indicates, they stonewall on warnings to an ever-greater extent, and are confident that, if warnings are put in place, they can deploy real-world 'evidence' or other methods to ensure clinicians ignore them.

With vaccines, and the removal of liabilities, companies have been able to focus on hard-nosed contract negotiations, rather than on pharmacovigilance, leaving CDC and FDA, agencies with little expertise or motivation in this area, holding the pharmacovigilance baby. Mandates further increase the pressure on regulators to partner with companies rather than pursue safety.

Even though FDA do little pharmacovigilance, when they approve new products with recognized or potential hazards, they commonly invite companies to craft Risk Evaluation and Mitigation Strategies (REMS). Not so in this case.

REMS packages are a step up from a toothless set of Phase IV trials, notionally designed for pharmacovigilance purposes but more often used to market the product. These have not been requested either.

If something goes wrong with these new technologies, the costs will fall on governments, who are even less likely than pharmaceutical companies to accept there might be harms. In Britain taxpayers will foot the bill and it is in our interests to have harms recognized as soon as possible – something that mandates inhibit.

Governments have known about the data sequestration in company trials and ghostwriting problems outlined here for several decades but have done nothing. They appear to be thinking magically rather than rationally.

We have been here before with Tamiflu and a previous viral pandemic<sup>16</sup>. On the back of hidden data on both efficacy and harms, and a ghostwritten literature, governments stockpiled billions of dollars' worth of Tamiflu, a drug now recognised as harmful junk. The exigencies of needing to be seen to do something in the face of a pandemic, and having already spent large amounts of money, appear to have inhibited bureaucrats and politicians from recognizing a con.

Unfortunately, to this day, while many doctors are semi-aware that Tamiflu is ineffective, faced with someone with a viral illness they prescribe it saying: "well what else can we do".

Their wish to help is commendable. Their failure to appreciate the hazards is frightening.

### **Mandates**

The arguments put forward in favour of mandates by clinicians, ethicists, politicians, and others depend heavily on assumptions about the integrity of the clinical trial data in respect of the efficacy and safety of these novel technologies, the integrity of the regulatory process, the integrity of pharmacovigilance processes, as well as a belief that if people are harmed by the vaccine they will be received sympathetically by healthcare systems and their injuries will be both remediable and remedied.

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<sup>16</sup> <https://www.bmj.com/tamiflu>

None of these positions can be held with confidence in the light of the uncontested evidence about the underlying processes detailed here.

During the 10 months these new technologies have been in use before approval and subsequent mandating, we should have had:

1. Mandatory adverse event reporting systems in place.
2. Mandatory assessments of causality by people trained to assess adverse events.
3. Mandatory assessments of causality with protocols designed to support this.
4. A free flow of information between companies making these new technologies and medical organizations likely to be faced with any harms.
5. Research on treatments for the injuries companies knew were likely before the first jab.

None of the arguments in favour of mandates recognize any of these issues.

Instead, arguments for mandates claim it is the duty of clinicians to first do no harm<sup>17</sup>, but these arguments fall aside with the now accepted evidence that those who are vaccinated can be infected and transmit that infection. Nor is it possible to make an evidence-based case against the proposal that those who are infected naturally are more likely to be immune and less likely to do harm to others than those who are vaccinated.

None of the many opinions in favour of mandates take account of the climate mandates create. A growing number of deaths, and significant harms on these technologies are being denied and discounted. The denial of these harms mean that healthcare staff fail to treat these patients decently and are not able to treat them effectively.

A recognition of the harms we are causing with our treatments should be at the centre of medical practice. Inhibiting doctors from recognizing harms risks altering medicine radically.

While the key reason to recognize these harms is the Hippocratic injunction to avoid making things worse for our patients, doctors might also consider this:

If our treatments are marvellously effective and free of harms, it would be reasonable for those who run health services today to decide that prescribing could be done by much less expensive staff or technicians. There is already a significant push in this direction.

Those against mandates are characterized as asserting a prior importance of individual liberties. My argument hinges on the centrality of science to modern medicine, our values, and our civilization. It is an argument based on the freedom we achieve through communal striving rather than a claim based on individual liberty.

Medicine in the last thirty years has retreated from this common ground. Far from mandates securing a safe retreat, they further imperil the common good and support corporate libertinism.

At present healthcare staff do not have the option to refuse vaccination. An option to take a vaccine, as these have until recently been understood – that is not based on mRNA or DNA technology - is now possible if the government made it available. Government could transform healthcare if they approved a product provided by a company committed to transparency.

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<sup>17</sup> Sokol D. Covid vaccination should be mandatory for healthcare workers. BMJ 2021; 375: n2670



## Summary

We have a Covid crisis.

The process factors outlined here, clinical trial data sequestration and ghostwriting, cannot but have contributed to deaths in this crisis, and a turn to mandates as a solution.

Life expectancy in several Western countries had stalled or was falling before Covid struck. This is also a crisis to which the process factors outlined here cannot but have contributed.

While inequality and poverty contribute to reduced life expectancy for some, the factors outlined here cannot but have contributed to a huge widely acknowledged increase in medication intake and the emergence of a phenomenon, polypharmacy, only recently described, and even more recently noted as a contributor to stalling or falling life expectancies.

The process factors have contributed to both crises in general and likely specifically contributed to the Covid debacle in care homes for older people where polypharmacy is pronounced.

Early in the pandemic, a colleague and I wrote a short paper on the desirability of reviewing the medication burdens of older people in residential care. All our major journals turned this paper down, without review. Three epidemiological studies have since confirmed our proposal, placing medication burden, second only to age, as a risk factor for death<sup>18</sup>.

Our falling life expectancies are a parallel crisis to the Covid crisis, contributing to a greater morbidity and mortality than Covid but receiving less attention.

There is no science that can be used to support mandatory 'vaccines' for healthcare staff.

The sequestration of trial data makes valid consent impossible.

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<sup>18</sup> See <https://rxisk.org/medications-compromising-covid-infections/>

Ottenhoff MC, Ramos LA, Potters W et al Predicting mortality of individual patients with COVID-19: a multicentre Dutch cohort. *BMJ Open* 2021; 11: e047347.

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