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Plan B Public Health Infrastructure and Operations Oversight Reform for America

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Abstract

It's not the public that needs more monitoring and oversight: it is the US regulatory agency of public health network and the pharmaceutical companies that run them. In this paper, I provide a blueprint for a bona fide public health infrastructure based on independence of freedom from corporatism.

Introduction

Since the US CDC was founded, an unholy alliance has infiltrated public health in the US — euphemistically referred to as "industry/government partnerships" and "Not-for-Profit" government entities — the wicked marriage has infused profit motives into US government agencies charged with regulating medical and pharmaceutical industries. Those involved view themselves as agents working toward a "greater good" — notwithstanding, the trappings of perverse incentives and presumed moral dictates, agencies designed by past generations to protect the US population from harm from corporatist tendencies have been completely captured and subverted. Apologists for regulatory capture even laud the "benefits" of collusion between corporations and the agencies that have been designed — and are funded to — provide regulatory oversight (Reiss, 2011). It seems surreal to consider the brazen use and even celebration of the combination of pharmaceutical influences and matters of state. The "revolving door" between corporations and agencies has been widely recognized for some time – including the FDA (Piller, 2018; Kaplan, 2016), CDC (Reuters, 2009; National Public Radio, 2009). Thirty-nine percent of National Institutes of Health (NIH) COVID-19 Treatment Guidelines Panel had tied to Pharmaceutical or Biotechnology companies – this was the committee that recommended the expensive Remdesivir over the inexpensive hydroxychloroquine for treatment of COVID-19. Remdesivir is made by Gilead — and eight of the COVID-19 Treatment Guidelines Panel had ties to Gilead.

As well documented as these abuses are, nothing comes of them — even if public health suffers. The scope of its influence on the quality of science that is supposed to inform public health and medical policy is only just now becoming painfully apparent. The US media is likewise utterly

captured due to revenue from direct-to-consumer marketing of pharmaceutical products; this quite literally means that the US does not have a free and independent press.

Corporatism Leads to a Regulatory Vacuum

Because corporatism is the prime target of US regulatory agencies, a regulatory vacuum has been created only to be immediately filled by profiteering government "watchdogs" expanding their own political, financial, and regulatory mandate against all challengers, especially the public population they are supposed to be protecting. The need for completely independent "untouchable" research institutions has never been higher, and yet some who have nominated themselves to protect the public interests, actually provide refuge for biased corporate science (e.g., Monsanto reaching into studies by allegedly independent researchers on the safety of glyphosate; McClellan-Roger Exhibit 5, 2019).

The lack of real regulatory backbone is absolute. Incredibly, for example, FDA only required an inert saline placebo in the Moderna's mRNA m1273 vaccine clinical trial after a citizen's group, The "I Can Decide Network" (ICAN.org), petitioned them with a thoroughly referenced piece of work that aimed to improved vaccine safety science by setting it back on its original track.

There is a bulwark system of defenses built up around vaccines (see Oller in this issue) that is patently unscientific to its core. Sadly, the US public have had to resort to litigation to seek justice and compensation for harm caused by corporate products, and such cases are adjudicated on legal merits informed by an increasingly biased body of scientific literature, and in the face of almost insurmountable legal obstacles that have only been increasingly strengthened in favor of vaccine manufacturers since the notorious National Childhood Vaccine Injury Act of 1986 that did nothing to protect children from injuries but did everything to guard vaccine producers from citizen initiated lawsuits. This bias is enhanced by **targeted retraction** — the act of systematic targeting of research studies with results that draw the safety of corporate products into question (Shaw and Oller, 2020). I personally have been involved in the defense of a number of studies that are on par with or superior compared to previous published studies in their rigor of design, execution and analysis. It is readily apparent that 'retraction' of studies has replaced rational discourse in many journals — bringing the validity and reputation of those journals into question.

The bulwark of defenses around vaccines are not defending vaccines themselves — they are defending the power to control the public's perception of vaccine safety, and are thus erected specifically to bias the scientific, medical and lay populations' perception of the quality and rigor of vaccine "safety", actually vaccine "risk and danger", studies. The emergence of organizations such as ICAN — which has chronicled in detail their successes in holding CDC, HHS and the FDA accountable to best practices of clinical research — is the result of harms visited upon the US population caused by regulatory negligence. Without first-hand experience with vaccine injury, the messages of such organizations could not possibly resonate with the public, leading the recent surge in vaccine risk awareness, mass protests, and resistance to mandatory vaccinations without exemptions.

Career "Scientists" Favor Corporate Interests Over Public Health

Over the past three decades, as regulatory capture has increased, a massive public health crisis has emerged. In the US, over 54% of children have a chronic illness – for which they "require" life-long pharmaceutical interventions. Public health disasters such as rampant metabolic disease and diabetes, ADHD, autism, autoimmune disorders, and the rapid spread of COVID-19 due to CDC's failed testing program in March, 2020 – all occurred on the watch of paraprofessional government careerist "Scientists" who have routinely made ill-founded calls for specific public health measures that defy all reason and logic. For example, Francis Collins of the NIH recently called for an early end to COVID-19 randomized trials by vaccination of the placebo group because, in his view "we owe them" the vaccine. This of course would obviate the entire reason for the clinical trials – which includes, to monitor for disease enhancement – ill health caused by pathogenic priming of individuals by prior exposure to a vaccine or an infection – as was seen in all past animal vaccine trials for SARS and MERS. A more rational and scientifically literate ad-hoc WHO committee published an article calling for continuance of the trials specifically because vaccinating the placebo group would make long-term safety signal detection impossible (WHO Ad-Hoc Expert Group, 2020).

In April, Dr. Birx of the Whitehouse COVID Response Team announced that all deaths of individuals with COVID-19 were to be counted as death from COVID-19, blunting the public health tool of reporting and tracking. The assumption that more testing is always better was matched with a corresponding drive to make the medical community and the public believe that RT-PCR tests cannot lead to false positive results, a claim falsified by numerous studies with empirical field false positive estimates that include 11% (Basile et al., 2020), 30% (Lee et al., 2020).

Public health in the US is one -hundred percent focused on the manipulation and control of public perception; they are obsessed with burying any evidence of vaccine risks, and thus our collection of vaccines themselves have become more and more blunted instruments loaded with more and more unforeseen and unstudied risks: we are left with unscientific, irrational responses to COVID-19 leading to staggering economic losses projected to be on the scale of US$16 Trillion dollars – a full ¾ of our GDP (Cutler and Summer, 2020; also see the CHD article in this issue of *IJVTPR*).

Regulatory Capture Means Loss of Liability for Flawed Products

As we now see with COVID-19 vaccines, corporations have learned that making their products appear to be essential to public health can place them closer to the goose that lays a continuous stream of golden eggs – ownership of monopolistic or near-monopolistic of government-contract mandated products free from liability. Right now, liability for vaccine injury in the United States falls to the Department of Health and Human Services— with specific cases adjudicated by Special Masters in the National Vaccine Injury Compensation Program. My personal experiences in the NVICP as an expert have left me simply aghast at how patently unfair that hornswoggle program is: the HHS is at once the defendant and administers the HRSA Table of Vaccine Injuries; their experts and Special Masters remain ignorant of advances in science on aluminum toxicity and in matters of the use of aluminum hydroxide to induce autoimmunity even after being presented with the balance of the research literature. Indeed, one Special Master attempted to bribe me to change my testimony; when I submitted new testimony to the case that included mention that among the materials I

examined, I was morally obliged to include the audio recording of the message tempting me with reimbursement if I took a different approach, the case was dismissed. The lawyer involved was subsequently disbarred due to another matter outside the NVICP.

The opposite model in which vaccine manufacturers, not the HHS, are held liable for vaccine injuries would provide them with critical quality control feedback on the suitability of their product and at the very least protect against product quality decay. It would herald the return of a free market. In the case of vaccines, products such as Merck's MMR vaccines continued to be marketed full in the face of data that made loss of efficacy absolutely clear: entire schools with 100% of students up-to-date on MMR vaccination per the CDC's recommended schedule still experienced mumps outbreak (Hogan et al., 2020).

In the age of COVID-19, we now see vaccine makers seeking additional liability protections — and in some cases being denied those additional protections — and we also see medical facilities seeking passage of legislation protecting them from liability associated with COVID-19 infections. In Pennsylvania, Governor Tom Wolf vetoed legislation that passed the house and senate affording hospitals with liability protections from COVID-19-related illnesses. The rationale for the veto was that it could cause hospitals to lower their safety standards related to COVID-19 transmission — just as pharmaceutical companies have lowered their standards of safety (increasing corresponding risks) related to vaccines. The cycle of unlabeled forward-looking statements without sufficient transparency on the data have led to pump-and-dump stock cycles, allowing company owners to increase their personal wealth without sufficient accountability, not to mention actual oversight, of the often deleterious effects of their products on public health.

Campaign Finance Reform Caused Restrictions and Loss of Human Rights

Corporations with vaccines already on the market are highly motivated to continue their liability-free near-monopolistic hold on the market. Thus, they initiate legislation to restrict existing rights to exemptions (religious and medical). They have gone so far as to pursue, harass, and threaten to disrupt or halt the practice of medicine by doctors who follow federal requirements for informed consent for medical procedures and for human experimentation. Dr. John Piesse's offices in Australia were raided and private medical records were seized so a Pharma-captured medical board could review the exemptions he permitted. In their review, they inadvertently delegitimized their own attempt to legitimize their persecution by finding one — just one, out of all of the past exemptions — to be valid.

Mass Vaccination Programs Are Not Founded on Solid Ethics

The vaccinologists have seized an unearned moral high ground when, in reality, the depravity and disregard they exhibit for the sanctity of human life seems unmatched in modern times.

In a custody court case in Oakland County Court in Michigan, USA, Dr. Stanley Plotkin testified that he had preferentially experimented upon individuals with intellectual disability. The transcript of the testimony (TSG Reporting, 2018), which was never entered into evidence, shows that he participated in multiple vaccine experiments of various groups of disempowered persons without their consent. The relevant part of the transcript reads as follows:

Counselor (Q): Have you ever used orphans to study an experimental vaccine?

Stanley Plotkin, M.D. (A): Yes.

Q Have you ever used the mentally handicapped to study an experimental vaccine?

A I don't recollect ever doing studies in mentally handicapped individuals. At the time in the 1960s, it was not an uncommon practice.

Q So you're saying -- I'm not clear on your answer. I'm sorry. Have you ever used mentally handicapped to study an experimental vaccine?

A What I'm saying is I don't recall specifically having done that, but that in the 1960s, it was not unusual to do that. And I wouldn't deny that I may have done so.

Q Well, in any event, you're not denying that you, that you -- well, there's an article entitled "Attenuation of RA 27/3 Rubella Virus in WI-38 Human Diploid Cells." Are you familiar with that article?

A Yes.

Q In that article, one of the things it says is: "Seronegative mentally retarded children were given RA 27/3 vaccine?"

A Okay. Well, then that's, in that case that's what I did.

Q Have you ever expressed that it's better to perform experiments on those less likely to be able to contribute to society, such as children with handicap, than with children without or adults without handicaps?

A I don't remember specifically, but it's possible. And, again, I repeat that in the 1960s, that was more or less common practice. I've since changed my mind. But those were, that was a long time ago.

Q Do you remember ever writing to the editor of "Ethics on Human Experimentation"?

A I don't remember specifically, but I may well have.

Q …Do you recognize this letter you wrote to the editor?

A Yes.

Q Did you write this letter?

A Yes.

Q Is one of the things you wrote: "The question is whether we are to have experiments performed on fully functioning adults and on children who are potentially contributors to society or to perform initial studies in children and adults who are human in form but not in social potential? (A: Yes) "It may be objected that this question implies a Nazi philosophy, but I do not think that it is difficult to distinguish nonfunctioning persons from members of ethnic, racial, economic, or other groups."?

A. Mmmhmm.

Q Have you ever used babies of mothers in prison to study an experimental vaccine?

A Yes.

Q Have you ever used individuals under colonial rule to study an experimental vaccine?

A Yes.

Q Did you do so in the Belgian Congo?

A Yes.

Q Did that experiment involve almost a million people?

A Well -- well, all right, yes.

The full testimony transcript, available online (ReformedHealth.net, 2020), reveals that the foundation of the vaccine industry and the vaccinologists' disregard for the sanctity of human life was, at the onset of such studies, either missing in action or dead on arrival. Dr. Plotkin's name is emblazoned on the gavel used in ACIP meetings — a committee imbued with direct financial conflicts of interest nearly to a person — whose "recommendations" now carry the weight of the rule of law. Who are these people? They are not elected officials who answer to the voting public. Due to the loss of exemptions to vaccine mandates, their recommendations have become unquestionable decrees — a form of rule over the population that went out of style in 1066 and that was firmly routed from the United State of America in 1776.

The embedded and oft-repeated justification of "the greater good" actually begs the question of utility of vaccines in the prevention and control of disease in the population because, while transmission may be controlled by some vaccines and symptoms merely reduced by others, the true cost of vaccine adverse events is unknowable: to bring forward evidence of vaccine injury might reduce vaccine uptake, threatening the utility of the vaccine in the first place, and the profits of the manufacturers and their now fully captured regulatory partners.

Thus, the net balance of risk is never experimentally tested or demonstrated but is merely presumed to fall in favor of population-wide vaccination. With any ACIP-approved vaccine, the possibility of generating any information to the contrary is stymied at every turn — including meaningful post-market "surveillance". These measures include the use of vaccines or adjuvants as "placebos" during clinical trials. Where the researchers involved in clinical trials of vaccines ought to be using inert saline as a comparison treatment, as shown by the team at ICAN.org (2020) in their report leading to what was called "Placebogate" — the vaccine promoters rely on misleading statements by physicians and the bullying of parents into accepting all the vaccines and "mandates".

They aim to prevent them from gaining access to data on vaccine adverse events. Instead they force reliance on retrospective observational studies which provide association and correlation but which will also eternally deny the discovery of adverse events caused by vaccines. They have placed limits on the Vaccine Safety Datalink, requiring intimidating over-the-shoulder supervision of anyone accessing the data (CDC, 2020). They have also engaged in post-hoc changing of study designs and analysis following result-peeking as in the Destefano et al. study, chronicled in the revelations of such heinous crimes of pseudoscience reported to Hooker by William Thompson (Hooker, 2016). My own in-depth analysis of all of the studies on the vaccine and autism question sent by AAP to President Trump revealed that all of the studies but one were underpowered to detect even a weak correlation, and that one of the studies was likely the product of outright fraud. I even calculated the

number of patients that had to be moved from one group to another to achieve the association given the national prevalence of autism in the population under study.

COVID-19 Has Stimied Progress Toward Reform

By August 2019, the shockingly poor state of vaccine safety science in the US was thoroughly chronicled and the door was opened for discussions. In 2018, Robert F. Kennedy, Jr. had been considered for position in the White House on a Vaccine Safety Commission, an initiative that was turfed by interference by Bill Gates (Newsweek, 2018), who is neither a physician nor a scientist. Attempts by Pharma to repeal exemption laws in numerous states were failing. An attempt to mandate HPV Vaccines in Allegheny County, PA was fought in a lawsuit and ruled null and void ab initio (*Lyons-Weiler vs. Allegheny County Board of Health*, Stipulation). COVID-19 has taken over virtually every inch of legible real estate online. The lives of people around the world are being held hostage with pronouncements "no return to normalcy" by unelected public health servants. These individuals enjoy seriously troubling financial entanglements of their intellectual property and national public health measures. These persons are the same individuals who

- foundered at COVID-19 control with a misleading test in February (see my other paper in this issue)
- flip-flopped on public health measures like masking,
- failed to rigorously follow Federal law in reporting cases and deaths of COVID-19 (Heneley et al., 2020),
- facilitated skipping early COVID-19 vaccine animal trials to avoid vaccine-induced disease enhancement;
- altered standard Phase 2 and Phase 3 trials into Phase 2/3 to reduce the chance of finding adverse events;
- failed to provide rigorous oversight on the false positive rates of qRT-PCR tests for SARS-CoV-2 virus (11%-30%), and
- worked diligently to bury the evidence of efficacy of hydroxychloroquine if used early (see studies compiled at c19study.com).

Together, these efforts work ensure that the public *perception* that COVID-19 vaccines will have saved the day- these same public health servants have done so at great indirect costs. With Francis Collins now calling for the end of clinical trials by vaccination of the placebo group, leaving the detection of long-term health consequences of the COVID-19 vaccine program to post-market "surveillance" studies using already failed passive reporting systems (public reporting to VAERS or the VSD), the public health and medical agencies in the US government themselves can be seen as a dire threat to public health.

All of these facts point to a warping of rational translational research to the end of defending the reputation of vaccine science – and, more broadly, the reputation of the abysmal failure of the US public health infrastructure.

When a precursor article to this one was published on the LinkedIn social media website, I was locked out of my account and offered access back into my account if I agreed to surrender my first Amendment rights. I refused, and lost access to 16,000 professional contacts from around the world.

I had and herein again propose a major overhaul of the public health infrastructure in the United States designed to specifically meet the following criteria:

(1) assurance of independent, objective scientific research on all threats to public health;

(2) de-politicization of the matters of public health;

(3) de-centralization of public health to avoid the flaws inherent to centralization, including

   a. limited scope,

   b. groupthink,

   c. and regulatory capture,

(4) full representation of considerations of the impact of public health priorities and measures on all aspects of society;

(5) full, fair, and objective consideration of all reasonable public health measures to public health crises, including certain details of the practice of allopathic medicine;

(6) and assurances of robust and rigorous scientific studies on all manner of public health issues.

Plan B. Decentralization and Depoliticization

Under the current configuration, the HHS Secretary provides administrative oversight to CDC and related operations (ACIP, NVICP) as well has FDA. This configuration not only leads to geographic centralization of public health interests, a certain military risk, but also to restricted allowance of thoughts and paradigms, including groupthink and authority-based reasoning. It also lends itself well to regulatory capture. This configuration, which can be considered Plan A, has failed to provide a vibrant and healthy stewardship of crucial aspects of public health. Minority viewpoints and dissent are quashed. Plan A lacks adaptive flexibility and resilience. Most of it is patently and irreversibly corrupted.

Under Plan B, 80 independent research organizations, all funded directly by the US Senate, geographically located across the United States, would establish a broad base of expertise and provide a full compendium of cultural representation on priority issues of public health. Each research node would serve independently of the others. Redundancy is the point. The charter of each node will be to focus on public health issues relevant to the local, regional and national populations. Independent research focused on all source of high mortality and chronic illness – not just infectious diseases – would be the priority activities. The prime directive of each node would be determined autonomously, reflecting a sampling procedure of public health matters that command attention, guided only by direction toward the goal of understanding the causes and mitigating human pain and suffering.

Each node would exist either independently or in connection to a larger organization, however, its finances must be completely independent. No involvement, partnership, or sponsorship of activities of any kind can be funded by any source other than the US Senate. The net product of these nodes will be an annual independent report on the state of public health in the United States and North America highlighting the issues that cause American citizens to suffer acute or chronic illness of any kind and mortality.

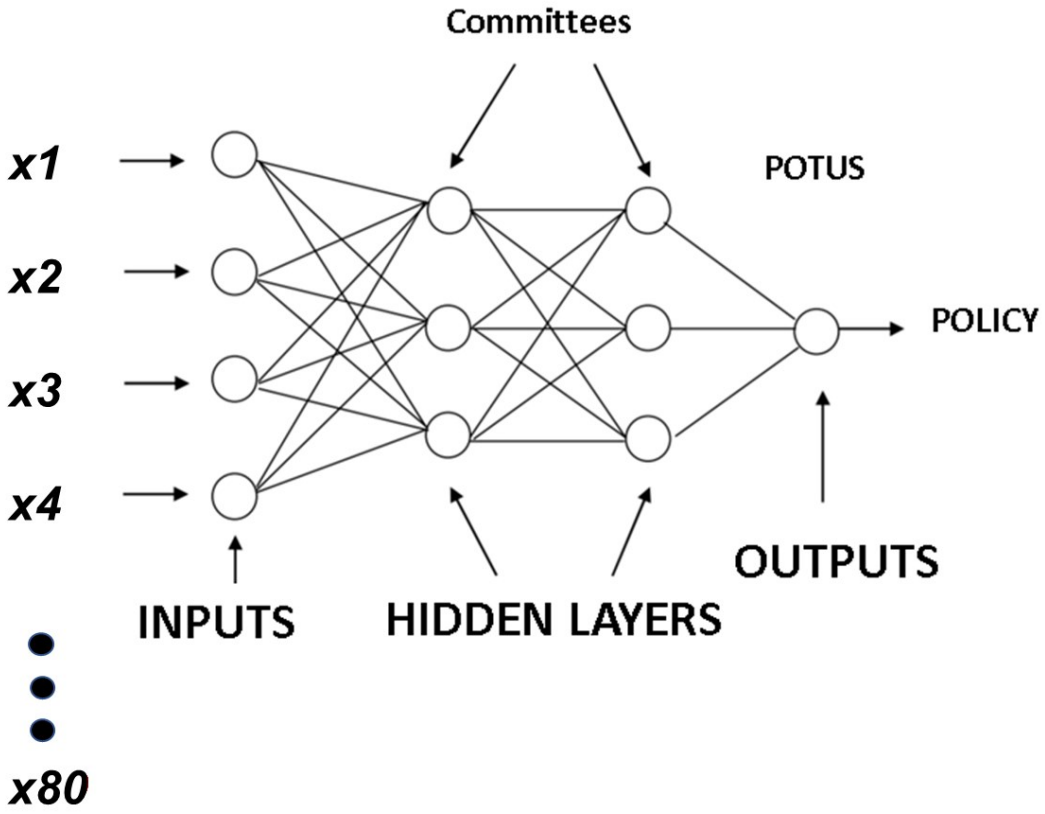

Figure 1. Schematic of the Core Design of Plan B Public Health Infrastructure.

Each independent annual report (IAR) from each node will be provided separately to each US Senate Committee by December 15th of each year. Each US Senate Committee will review each report and issue, by February 15th of each year, their own summary report reflecting the interests represented by that Committee. These Committee Annual Reports (CARs) will be provided the US Senate Intelligence Committee for review by March 15th of each year. The Senate Intelligence Committee will then send a Notice of Intent Report (NIR) to the Governors of each state, the President of the United States, the Speaker of the House of Representatives and to the President of the Senate issuing the determination of the Senate for prioritize actions to address the predominant public health issues threatening the US Public. The House of Representatives will address these issues with Bills as needed.

The decentralized process limits the authority of public health officials and broadens the focus of public health from infectious disease to the most common causes of serious acute and chronic

illness and mortality in a manner that utilize the full intelligencia inherent to representative government. The structure of the proposed process itself is that of a neural network, and thus the entire process is designed to be intelligent and flexibly adaptive to changes in priorities in public health.

Rules Enforcement

All studies undertaken should have a pre-published Data Analysis Plan encrypted for privacy with the key published in a single public blockchain resource following publication. This will allow an external data analysis review that matches the final data analysis plan that was executed to the data analysis plan that was published. Funding to each node should be contingent on independence and freedom from conflicts of interest. Any participating node found to embark on misadventures of profit-based incentives, internally or externally, of any type, including collusion or seeking input from any for-profit entity, should be cut from the network and replaced with a new node in a new geographic location.

The goal is to provide a self-correcting process that replaces the current public health infrastructure, which has gone off the rails. This was foreseen in 2010 by Justice Sotomayor, who wrote, in the dissenting view of the Supreme Court ruling of *Brusewitz et al., vs. Wyeth*, (SCOTUS, 2010), that

"[the court's] decision leaves a regulatory vacuum in which no one ensures that vaccine manufacturers adequately take account of scientific and technological advancements when designing or distributing their products."

It is abundantly clear that there is no free market regulation of vaccines; medical doctors are alleged to serve as "learned intermediaries" between vaccine manufacturers and patients, and they are incentivized to maximum vaccine uptake, and penalized if they do not.

The lack of independence of the regulatory and "research" agencies is blatant, and massive. CDC receives >$25Million per year from Pharmaceutical companies via their "CDC Foundation" In 2000, CDC held a conference to which members of the Pharmaceutical and medical industry were invited – but to which members of the public were not invited – at which it was decided that results showing increase in risk in autism related to vaccination had to be reconfigured before publication. The results were finally published after the data had been tortured extensively (Verstraeten et al., 2003). The product of this so-called "science" – no association – has been used to justify the meeting, but that, of course begs the question of how flawed science can justify an illegal meeting. It's the process of doing the science that is corrupted – and nothing good can come from corrupted processes.

NIH is similarly compromised via the "NIH Foundation", and issues directives on how its employees can "manage" their conflicts of interest.

We know from the crisis in Science that perverse incentives can warp the mentality of some involved in a particular line of scientific inquiry; we also learned from that same coming-of-age realization of the tools used to bias scientific studies such as p-hacking, result peeking. We know from Ioannidis of Stanford University that observational studies can be manipulated by design and analysis to ensure any particular desired result.

It is time to apply across the entire public health enterprise what we already know about the corruption of the pharmaceutical industry and its government regulators and profiteering collaborators. In our mission to return objectivity to science and to the media, we are reminded of the wisdom of Buckminster Fuller:

> *You never change things by fighting the existing reality.*
> *To change something, build a new model that makes the existing model obsolete.*

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