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Covid-19 Vaccines: Isn't it Time for Real Truth Telling?

The FDA, Shock Troops for the Pharmaceutical Industrial Complex

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As of this week, over 194 million doses of the Covid-19 vaccines have been administered in the US. Consequently, a growing majority of Americans are delighted that life may return to normal because most believe they are now protected from infection. Clearly that is not the case. Bill Maher tested positive for Covid last week and had to cancel his television show for his first time since 1993. This was despite Maher having been fully vaccinated. Moreover the vaccines' serious adverse effects are being downplayed by health officials and the media. Who will experience an adverse effect appears to be arbitrary; therefore, it is a game of Russian Roulette as to whether a person will be critically injured or be protected from the virus. One of the world's most accomplished rock guitar musicians Eric Clapton received both doses of AstraZeneca's Covid vaccine and had such severe reactions he feared he might never play the guitar again. Clapton posted a message:

> "About six weeks later [after receiving the first shot] I was offered and took the second AZ shot, but with a little more knowledge of the dangers. Needless to say the reactions were disastrous, my hands and feet were either frozen, numb or burning, and pretty much useless for two weeks, I feared I would never play again, (I suffer with peripheral neuropathy and should never have gone near the needle.) But the propaganda said the vaccine was safe for everyone."

However it is not simply a miniscule few who are suffering undesirable Covid-vaccine events such as blood clots and other cardiovascular complications, anaphylaxis, severe allergic reactions, various neuropathies, abnormal menstrual bleeding and suspected miscarriages, extreme muscle weakness, fatigue, etc. If this were the case, an argument could be made for siding with benefits over risks. Covid vaccines have only been administered for less than six months, and it is becoming increasingly clear that the risks may outweigh the benefits. Suspected numbers of miscarriages following Covid vaccines is especially worrisome. A government study published in the *New England Journal of Medicine* attempted to analyze and downplay the risk. Yet at the same time, the study observed a trend of 11.6% of spontaneous abortions occurring less than 13 weeks after the mRNA vaccination. It is becoming increasingly obvious that these vaccines' safety profiles are far less than Anthony Fauci, the FDA and the CDC are touting.

More younger adults are experiencing adverse vaccine symptoms than from the risks due to acquiring a wild coronavirus. Worldwide reported adverse effects and deaths are escalating dramatically. In the CDC's Vaccine Adverse Events Reporting System (VAERS), reported Covid-19 vaccine deaths have now reached 4.434 as of May 13th 2021 which is more vaccine-related deaths from conventional vaccines recorded in VAERS during the past 21 years. Since VAERS is a passive reporting system, the actual serious adverse effect rate may be as high as 1in 10 shots. No other vaccine on the CDC's vaccination schedule has such a poor record of safety.

As with Bill Maher, fully vaccinated people are still being infected and testing positive. Younger healthy adults, who earlier had an insignificant chance of becoming sick or dying from the SARS-CoV-2 virus, are now being injured and in some cases dying from the vaccines.

A recent study published in *JAMA* observed delayed hypersensitivity vaccine reactions well after injections. The University of Pennsylvania estimates that between 5 to 10 percent of recipients of the mRNA vaccines have "severe adverse reactions" – an inordinately high percent compared to every other non-Covid vaccine. And a group of medical institutions including the University of Greifswald School of Medicine, and the Medical University of Vienna are proposing a new medical condition, "vaccine-induced prothrombotic immune thrombocytopenia," now be associated with the AstraZeneca and Johnson and Johnson vaccines.

A recent paper warns about the dangers of vaccine-induced prion disease. The list of adverse effects continues to mount. A Pfizer document refers to the possibility of Covid vaccine shedding to the unvaccinated. Doctors are coming forward and accusing the CDC of scrubbing the statistics of actual vaccine-related deaths. The risks were quite obvious in the vaccine makers' own clinical trial documents before the FDA awarded Covid vaccines with emergency use approval to launch a nation-wide vaccination program. Whether or not health officials at the CDC or FDA thoroughly deliberated on the many warnings or simply ignored them is open to debate. But the evidence strongly leans towards the latter.

Earlier, we presented the historical evidence of widespread corruption at the CDC; however, the FDA is far more influential because it is the final watchdog that determines a drug's efficacy and safety profile. In the most perverse scenario, the FDA relies upon outside experts to sit on its advisory committees to review a drug's or a vaccine's safety. Many of these experts have a gross conflict of interests with the pharmaceutical industry. This institutional dilemma is steeped into the FDA's very DNA. As far back as 2006, Public Citizen discovered that 1 out of 3 of outside consultants and advisory members to the FDA had financial conflicts. The situation has only worsened over the years.

A Pogo investigation in October last year, uncovered several advisers on the FDA's Vaccines and Related Biological Products Advisory Committee who had direct ties with the Covid-vaccine companies, including direct payments for consulting fees. Dr. Archana Chatterjee, for example, has received over $200,000 from agreements with these companies. The same is true for the Committee's chairman, University of Michigan Dr. Arnold Monto who received fees from the largest vaccine firms including Pfizer, Sanofi, GlaxoSmithKline and Novartis. The previous chair, Dr. Hana El Sahly from Baylor University, had to recuse herself due to her role in supervising Moderna's Covid-19 vaccine clinical trials. Earlier, Monto was the principal investigator for Sanofi's influenza vaccine. Another is the president of Meharry

Medical College where coronavirus clinical trials were conducted. Three other Committee members likewise held close conflict-of-interest relationships with vaccine makers. Shortly before issuing emergency use approval, a second Pogo analysis concluded that the FDA Committee whitewashed the warnings indicated by the Covid-19 vaccine trials. The meeting was adjourned by the FDA director for the Office of Vaccines Research and Review in favor of green-lighting the vaccines before Committee members suspicious of the clinical results could weigh-in. Prof. Carl Elliott, a medical ethicist at the University of Minnesota, summarized the problem of corporate bias now plaguing the FDA. "You do something positive for a company that you feel confident is going to pay you back for it later on," Elliot stated. "And they do." The FDA's current rules regarding conflict of interest is strictly limited to the honor system. In Europe, on the other hand, the European Medicines Agency strictly prohibits experts with ties to private industry from sitting on its advisory committees.

Even with FDA efforts to crack down on conflicts of interests due to Congressional pressure, the industry has found other means to get their representatives onto advisory panels. And the heads of the agency willingly turn a blind eye. A *Science* exposé reported on the growing strategy of "pay after" conflicts of interests. Outside advisors will declare no conflicts but then rule in favor of a drug or vaccine only to be reimbursed afterwards. The journal's review of compensation records uncovered "pay after" schemes for the approval of 28 psychopharmacologic, arthritis, cardiac and renal drugs." The investigation also uncovered:

> "Of the more than $24 million in personal payments or research support from industry to the 16 top-earning advisers—who received more than $300,000 each—93% came from the makers of drugs those advisers previously reviewed or from competitors."

Probing still deeper, the Pacific Legal Foundation released an analytical review of 2,952 rules issued by the Department of Health and Human Services over a 17-year period. The Foundation determined that 75 percent of these rules were unconstitutional and "issued by low-level officials and employees with no authority to issue rules." With respect to the FDA dozens had no democratic controls and involved tens of millions of dollars ruled over by career bureaucrats.

Every American who is prescribed a drug by a physician has the belief that the pill has undergone rigorous trials to scrutinize its safety and will be effective. And when there are known potential adverse effects, we blindly assume the attending physician knows these dangers. However, this is a myth perpetuated not only by drug makers but also by our own federal health agencies.

As we have reported on many occasions, iatrogenic deaths, deaths caused by medical error and prescribed medications is now the third leading cause of mortality in the US. The Institute of Medicine has warned about "the nation's epidemic of medical errors." A large percent of these errors are related to adverse drug events (ADEs). The FDA states, "ADRs are one of the leading causes of morbidity and mortality in healthcare." Dr. Curt Furburg published an article in the *Archives of Internal Medicine* proposing sweeping changes throughout the FDA. Furburg and his colleagues wrote, "We see eight major problems with the current system of assessment and assurance of drug safety at the FDA." A fundamental problem is the FDA's initial review for drug approval that often fails to detect serious ADRs: "A study by the US General Accountability Office (GAO) concluded that 51% of all approved drugs had at least one serious ADR that was not recognized during the approval process."

A 2003 investigation published in *The Independent* in the UK reported "under pressure from the pharmaceutical industry, the FDA routinely conceals information it considers commercially sensitive, leaving medical specialists unable to assess the true risks [of approved drugs]." One case involved a very popular over-the-counter drug, the painkiller ibuprofen. The investigators' search uncovered concealed data showing that ibuprofen increased heart attack risks by 25 percent. Even Freedom of Information (FOI) filings to the FDA do not produce all the information being requested. For example, a group of Swiss investigators filed an FOI to procure trial data about the musculoskeletal pain drug Celecoxib and received back only 16 of the 27 trials conducted on it. A separate FOI concerning a similar drug, Valdecoxib, had pages and paragraphs deleted because sections of the document were marked as "trade secrets." An even worse case involving a leaked report concerning internal memos and secret FDA reports provided detailed evidence that the FDA approved 9 different antidepressants, representing a total of 22 studies enrolling 4,250 children, while knowing full well that the risk of "suicide-related events" was twice as high as children taking a placebo. These are just several examples among numerous others, which may best be summarized by a *Forbes* article entitled "The FDA is Basically Approving Everything."

Isnt it time for real truth telling? The FDA, which was budgeted for $5.9 billion in FY 2019, is ruled and governed by a small group of political scientists who have abdicated their ethical responsibilities as physicians and medical professionals. With all the controversy and debate over the efficacy and safety of new mRNA vaccines and the aggressive emergency approval of the ineffective anti-Covid drug remdesivir, we may consider a Harvard University article published in the *Journal of Law, Medicine and Ethics* entitled "Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs." For the past four decades, the paper states,

> "patients have suffered from a largely hidden epidemic of side effects from drugs that usually have few offsetting benefits. The pharmaceutical industry has corrupted the practice of medicine through its influence over what drugs are developed, how they are tested, and how medical knowledge is created. Since 1906, heavy commercial influence has compromised Congressional legislation to protect the public from unsafe drugs. The authorization of user fees in 1992 has turned drug companies into the FDA's prime clients, deepening the regulatory and cultural capture of the agency."

We are witnessing the pharmaceutical industry increasing its demands for shorter than average times for the FDA to review new drug submissions; alternatively they have an option to pay the FDA costly fees to have these drugs fast-tracked under its Accelerated Approval Program, thereby jumping over many regulatory hurdles to bring their products to market more quickly. According to a 2019 review of the Program, conducted by the University of Nebraska's Institute for Operations Research, "from 1992 to 2008, 36% of post-market studies had not been completed, and 50% of the uncompleted studies took on average of 5 years to even begin." Yet throughout the duration of years, these drugs continued to be prescribed and reap enormous profits for the companies benefiting from the FDA's loopholes.

As a consequence, the FDA's entire regulatory protocol has consistently deteriorated with each passing year. From a system originally mandated to function as a guardian to protect patients from dubious industry commercial interests, it has been transformed into an anti-preventative pipeline favoring drug companies' bottom line and their shareholders.

In 2013, the Union of Concerned Scientists released its investigative report, four years after the Obama administration launched a process to increase transparency in the federal sciences agencies — another well-meaning Obama initiative that failed to make any fundamental change. The Union concluded that the FDA had created a culture lacking scientific integrity, including no formal procedures for investigating scientific misconduct.

The FDA's serious failures to carry out its duties to monitor and regulate drug companies are well exemplified in the case of the North Carolina outsourcing firm Cetero. After several years of gross negligence to thoroughly review pharmaceutical drugs, mostly generic knock-offs submitted for licensure, the agency finally uncovered Cetero's five-year history of faking documents and data or early clinical trials and bioanalytics. While we expect contractors who carry out clinical trials for large drug companies to be busy at work conducting research on the recorded trial data, on over 1,900 occasions there were no personnel in the Cetero facilities. Approximately 1,400 trials for roughly 100 drugs were faked. Whereas the FDA did little to conduct a thorough investigation, the European Medicines Agency on the other hand discovered that Cetero and its Big Pharm partners, including Roche and Genentech, failed to submit 80,000 reports on American approved drugs that killed over 15,000 Europeans. We need to consider that the Mayo Clinic is on record stating that the last ten years of cancer research are utterly useless due to systemic fraud.

To understand the systemic rot eating away the FDA, we may take note of the research of Dr. Charles Seife and his students at New York University. Seife and his team undertook the task to investigate and analyze the extent to which the FDA covers up evidence of fraud and corruption in medical drug trials. They reviewed FDA documents for about 600 clinical trials. One of Seife's primary questions was the frequency that FDA officials discover flagrant and intentional misconduct and subsequently decide to bury the evidence and prevent it from becoming public to the medical community. He discovered such actions to be an official pattern within the agency. Given the high rate of content deleted or blacked out from the documents the FDA provided, the investigators could only determine which pharmaceutical company or drug was involved in 1 of 6 of the reviewed trials. For one trial alone, where FDA inspectors found significant fraud and misconduct, 78 different medical publications printed articles based upon that single study. In an article for *Slate*, Seife writes,

> "Nobody ever finds out which data is bogus, which experiments are tainted, and which drugs might be on the market under false pretenses. The FDA has repeatedly hidden evidence of scientific fraud not just from the public, but also from its most trusted scientific advisers, even as they were deciding whether or not a new drug should be allowed on the market. Even a congressional panel investigating a case of fraud regarding a dangerous drug couldn't get forthright answers."

In one case, a new anti-blood clotting drug, rivaroxaban, involved four large trials recruiting thousands of patients in clinical sites in over a dozen countries. According to Seife, one of the trials "was a fiasco." In half of the sixteen clinical sites, the FDA discovered "misconduct, fraud, fishy behavior or other practices so objectionable that the data had to be thrown out." One Colorado site falsified data. At the Mexican site, there was "systematic discarding of medical records." Despite these overwhelming problems, the drug trial was published favorably in the prestigious British journal *The Lancet*. The FDA found similar problems in the three other trials; in one the data was ruled "worthless." The FDA advisory committee of "expert" reviewers were only informed that inspectors discovered only "significant issues" at two sites in one of the trials. Rivaroxaban was nevertheless approved in 2011. Since then lawsuits for wrongful death from the drug continue to increase.

One of the deeper flaws within the FDA's mode of operations is that it solely relies on the studies and clinical trials conducted by drug makers without conducting any studies of its own. Consequently these private firms have complete control over the clinical data and can provide such data or not at their own discretion. For example, if a company conducts 20 clinical trials on a potential new drug and15 trials conclude it is absolutely useless or results in serious reactions and deaths, the company is only required to submit documentation for the 5 trials that are favorable.

Over the years, Congressional subcommittees have voiced warnings to FDA officials to clean up their act. A House Government Reform Committee reported that both the CDC's and FDA's advisory committees for vaccines were thoroughly compromised with pharmaceutical conflicts of interest.

One of the most glaring examples of FDA misconduct, deceit and cover-up to protect pharmaceutical interests in the agency's history was the federal case against Merck and its anti-inflammatory drug Vioxx. Dr. David Graham, a former Associate Director for Science and Medicine in the FDA's Office of Drug Safety, testified before the US Senate. Dr. Graham has impeccable credentials qualifying him as an expert on the failures of pharmaceutical drugs. He graduated from the Johns Hopkins University School of Medicine, and trained in Internal Medicine at Yale and in adult Neurology at the University of Pennsylvania.

Dr. Graham told the Senate:

> "During my career, I believe I have made a real difference for the cause of patient safety. My research and efforts within the FDA led to the withdrawal from the US market of Omniflox, an antibiotic that caused hemolytic anemia; Rezulin, a diabetes drug that caused acute liver failure; Fen-Phen and Redux, weight loss drugs that caused heart valve injury; and PPA (phenylpropanolamine), an over- the-counter decongestant and weight loss product that caused hemorrhagic stroke in young women.
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> "My research also led to the withdrawal from outpatient use of Trovan, an antibiotic that caused acute liver failure and death. I also contributed to the team effort that led to the withdrawal of Lotronex, a drug for irritable bowel syndrome that causes ischemic colitis; Baycol, a cholesterol-lowering drug that caused severe muscle injury, kidney failure and death; Seldane, an antihistamine that caused heart arrhythmias and death; and Propulsid, a drug for night-time heartburn that caused heart arrhythmias and death. . . .
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> "I have done extensive work concerning the issue of pregnancy exposure to Accutane, a drug that is used to treat acne but can cause birth defects in some children who are exposed in utero if their mothers take the drug during the first trimester. During my career, I have recommended the market withdrawal of twelve drugs. Only two of these remain on the market today—Accutane and Arava, a drug for the treatment of rheumatoid arthritis that I and a co-worker believe causes an unacceptably high risk of acute liver failure and death."

The Los Angeles Times reported that witnesses told the Senate panel that Merck and the FDA knowingly had data well before the approval and licensure of Merck's Vioxx painkiller that proved the drug's serious cardiovascular health risks. Nevertheless, the FDA granted it approval without resolving the risks, and Vioxx was aggressively marketed.

Testifying about Merck's Vioxx, Dr. Graham states:

> Today . . . you, we, are faced with what may be the single greatest drug safety catastrophe in the history of this country or the history of the world. We are talking about a catastrophe that I strongly believe could have, should have been largely or completely avoided. But it wasn't, and over 100,000 Americans have paid dearly for this failure. In my opinion, the FDA has let the American people down, and sadly, betrayed a public trust.

According to Dr. Graham. "Not only did the FDA ignore known risks from Vioxx and related drugs but . . . it tried to prevent Graham and others from publicizing their own research that proved the extent of these risks."

Members of Congress have echoed Graham's concerns. Charles Grassley (R–Iowa) said he was concerned that the FDA "has a relationship with drug companies that is too cozy." Sen. Jeff Bingaman (D–New Mexico) said the problem was within the FDA's own culture." This culture is one whereby the pharmaceutical industry, which the FDA is mandated to regulate, is the FDA's most favored and lucrative client.

Sixteen years have passed since Dr. Graham's public statements exposing the life-threatening policies and corruption that infest the FDA. It's difficult to comprehend why the agency has been unable to clean up its act. Instead the FDA's culture of deceit has only worsened. Nevertheless, the evidence clearly shows that our government health officials would rather support pharmaceutical profiteering than the health and safety and American citizens. In fact, 45 percent or $2.7 billion of its budget derives from private pharmaceutical "user fees."

The disturbing data suggest that the FDA's evaluation of pharmaceuticals for safety and efficacy may be so flawed that only 4% of all trial results are identified as such. As a result, FDA scientists and officials responsible for approving drugs to the market are kept largely uninformed about the egregious scientific misconduct involved in obtaining study data. Further, these erroneous and fraudulent studies are published in peer-reviewed scientific literature and accepted as valid science. The American public is 'virtually defenseless' if another medication proves to be unsafe after it is approved.

But it gets worse. The agency has been warning against highly effective off-patent drugs to treat early SARS-CoV-2 infections such as hydroxychloroquine (HCQ) and ivermectin. Shortly after the pandemic was formally announced, and with no promising treatment in sight, the FDA recommended HCQ but then reversed its decision in June after Anthony Fauci publicly announced the coming arrival of Gilead's novel drug remdesivir. The FDA's approval of remdesivir baffled many scientists, according to the journal *Science*, who were keeping a close watch on the drug's clinical reports, which showed a "disproportionally high number of reports of liver and kidney problems" Nor did remdesivir lessen hospital stays or lower mortality rates.

Two months ago the agency issued a warning statement against the use of ivermectin. "The very next day," reported the Alliance for Natural Health, "Merck announced positive results from a clinical trial on a new drug called molnupiravir in eliminating the virus in infected patients." Again, the FDA had been working in concert with the pharmaceutical industry to advance expensive experimental drugs rather than cheaper and proven drugs with decades of research to back their safety records.

In addition, the FDA has waged a war against alternative medical systems for many

decades, including natural supplements. Last September, the agency attempted to ban N-acetylcysteine (NAC) after it showed promise to reduce cytokine storms associated with SARS-CoV-2 infection. The supplement had already been shown to improve lung problems due to respiratory infections such as pneumonia and acute respiratory distress symptom. Three years ago, an FDA advisory committee met to consider banning five supplements made by specialized compounding pharmacies: alpha lipoic acid, CoQ10, pyridoxal-5-phosphate, creatine monohydrate and quercetin dehydrate. Earlier the FDA had banned curcumin, boswellia and aloe vera from pharmacologic compounding. One of the key executors of the agency's revitalized assault against supplements and the natural health industry was Trump's appointment of Scott Gottlieb as FDA Commissioner. Following his two years at the FDA's helm, Gottlieb quit and joined Pfizer's Board of Directors.

The FDA's argument is rather straightforward, albeit dubious; since supplements, including Vitamin C and D, Omega-3 fatty acids, and even minerals such as magnesium and zinc have not been formally submitted to the FDA for evaluation to be registered as "approved drugs," it is against the law to make any health claims about their health benefits. This is despite the thousands of peer-reviewed studies in the National Library of Medicine to support their efficacy. The average median cost to conduct clinical trials to meet FDA standards for approval, according to a Johns Hopkins University evaluation, is $19 million and upwards to $2-3 billion. In other words to get Vitamin D officially recommended as a viable preventative defense against Covid-19 would require a minimum of $19 million in addition to numerous fees and other legal costs prior to and after submission. And that doesn't even address the problem of ownership since Vitamin D is a natural substance and excluded from patenting. In the meantime, supplement manufacturers are prohibited from stating the vitamin's benefit to the public thereby contributing to a gross disservice.

"Clearly these are the actions of an agency looking to restrict the supplement market," according to the Alliance for Natural Health, "and remove as many products as possible in as many ways as possible." One reason is that if a vitamin or supplement were to go through the FDA licensure treadmill, the agency could potentially require a supplement's access by prescription only. It would no longer be available over the counter. And this in turn would be another boon for the drug industry, which is already developing synthetic supplemental knock-offs that are patentable.

Much of the blame lies on the shoulders of politicians on both sides of the aisle and the mainstream media who have enabled the FDA and CDC to run amok and then propagate the pharmaceutical industry's nonsense. A recent Harvard University and Robert Wood Johnson Foundation survey reported that public trust in America's health care system has rapidly fallen during the pandemic to 34 percent. Only 37 percent stated they had much trust in the FDA.

This trend may very likely continue as a growing number of physicians and medical experts are sounding alarms over the flagrant incompetence of our federal officials leading the national efforts against Covid-19 and the approval vaccines with highly questionable safety records and expensive novel drugs that fail to warrant use. Worldwide, tens of thousands of otherwise orthodox medical professionals are charging Anthony Fauci, the CDC, FDA and the World Health Organization with gross mishandling of the pandemic. Lawsuits are underway against national health ministries around the world for deceiving their populations with fraudulent PCR testing, fake mortality rates and unwarranted public health policies that have produced extreme harm and suffering. As the situation deteriorates more suits will be anticipated.

Sadly there is no reason to expect the FDA to undergo a structural change. For decades Congressional committees have warned the agency about it's ignoring the public health of Americans and its revolving door policies with drug makers. Yet matters continue to worsen. A complete overhaul by adopting policies similar to the European Medicines Agency such as independent leadership divorced from the pharmaceutical complex and full public funding, would be a decent start. Another solution could be the creation of separate and independent National Drug Safety Board without ties to private industry or overlapping conflicts of interest with the existing health agencies in dire need of reform. However that tipping point has not been reached to expect any of our politicians to switch sides and for once serve the public's health interests.

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