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Sustainable Human Development

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COVID-19 and Marketocracy

Confronting the pandemic in the context of the market's supremacy over the welfare of people and planet

Álvaro J. de Regil

Introduction

This paper is an excerpt of "Marketocracy and the Capture of People and Planet", published in June 2021, which provides a holistic assessment of the unsustainable trajectory that humanity has been following since the First Industrial Revolution and the capture of democracy by capitalism.[1]

An innate feature of capitalism has been the endless pursuit of an ethos with the least possible intervention of the state in its unrelenting quest for the reproduction and accumulation of capital, at the expense of all other participants in the economic activity prominently including the planet. Capitalism always demands to be in the driver's seat of the economy. Only when its activities are threatened by communities and nations opposing the expropriation of their natural resources and the imposition of structures that extract the vast majority of the value of labour—the surplus-value—, capitalism demands the intervention of the states; these include their armed forces, to protect the exploits of the owners of the system. This is all the more evident in the global South. Across centuries of imperialism and colonialism, the practice of invasion, conquering, expropriation and exploitation by capitalist enterprises—with the full support of their states—has always been more vicious and predatory in the system's periphery than in its core. Labour exploitation and resource depredation also occur systematically in the system's metropolises, albeit under less pernicious and predatory practices. Hence, as the norm, capitalism demands from the state the establishment of a sheer laissez-faire ethos, to leave everything to Adam Smith's naive idea of the

[1] ↩ Álvaro J. de Regil: Marketocracy and the Capture of People and Planet – The acceleration of Twenty-First Century Monopoly Capital Fascism through the pandemic and the Great Reset — The Jus Semper Global Alliance, June 2021

market's invisible hand,[2] which, as a demigod, would wisely dispense good fortunes to everyone, allocating the resources in the most efficient fashion, in pursuit of achieving the maximum level of general welfare for the community.[3]

Capitalism demands the ideal conditions for the infinite reproduction and accumulation of capital through the consumption of resources, their transformation into goods and services and the renewed and unlimited accumulation of wealth for the owners of the means of production. To materialise this, it requires an unending growth spiral in the consumption of natural resources to catapult, in turn, an unending spiral of growth in the rate of reproduction. Nothing else matters; not in the least the welfare of the communities (capital's markets) that make possible the reproduction and accumulation of wealth, for this is the only quintessential raison d'être of capitalism. Capitalism, the epitome expression of selfishness, greed and individualism of the human species, has waged myriad wars on the unrelenting pursuit of its mantra at the cost of hundreds of millions of people, the destruction of entire nations and the ravage of ecosystems across the planet. It has no limits, and it will never will. Capital on one side and limits, boundaries, maximums and control on the other is an oxymoron. Our planet Earth can be exhausted by capitalism, but there is no remorse, no reckoning on the social, economic, environmental and moral implications of such an unsustainable and destructive system. There is no rational sense of the possibilities that such a system will drive us to our self-annihilation.

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We live under an irrational vision of how societies should run our Oeconomicus—the management of our home. In order to build truly sustainable societies, human activity must be pre-eminently centred on the sustainability of our planet to determine the levels of resource consumption and material welfare that our home can sustain. However, given that capitalism's only raison d'être is endless accumulation of wealth per se at the expense of anything else, including prominently the consumption of resources and human labour, there is a blatant and irreconcilable incompatibility between capitalism and the long-term sustainability of our planet, to which we belong as part of nature and without which we cannot exist. Nonetheless, the system's owners could not care less, and in a display of extreme arrogance and self-delusion, they unrelentingly pursue the maximisation of their wealth. Essentially, their enthralment to wealth and power obnubilates any possibility of rational thinking. Hence, in their self-interest, they pursue a path that would provide them with the sustainability of their passions, a sort of "sustainable inequality"; albeit any limits to their passions are unacceptable since their greed drives them to have more wealth-power than ever.

To build truly sustainable societies, human activity must be pre-eminently centred on the sustainability of our planet to determine the levels of resource consumption and material welfare that our home can sustain.

With the emergence of neoliberalism in the last quarter of the twentieth century, capitalism increased its hold on societies' lives by making so-called liberal democracy a mockery and replacing it with Marketocracy or the dictatorship of the market. This has reached a level where the system's owners—the plutocrats representing much less than the 1% of the world's population—have captured states and made politicians their market agents with the mission to ensure that

[2] ↩ Adam Smith, An Inquiry Into the Nature and Causes of the Wealth of Nations, Edwin Cannan, from the fifth ed. (1776; New York: Random House, 1994) p. 485.

[3] ↩ Álvaro J. de Regil: The Neo-Capitalist Assault: Essay Two of Part I (The Economics of Reference) — The Historical Background in the XVIII and XIX Centuries, The Jus Semper Global Alliance, April 2001, pp. 2-5.

the public agenda always remains in control of the plutocratic elite. In this way, since the 1990s, capitalism has enjoyed full control of the driver's seat of economic policy and dictates the conditions it regards as ideal for maximising the rate of reproduction and accumulation. To achieve this, it has gradually encroached on the public sphere. It takes over the halls of government, transforming most of the public sphere into a new commodity amenable to the reproduction and accumulation of wealth. This includes the natural resources vital to life and our bodies. This encroachment brings the planet to the brink of planetary tipping points that complete the metabolic rift[4] between our species and the planet. We do not know yet, but this may have already forced us to cross a threshold of no return and placed us on a direct trajectory to destroy life on our planet for all living things, including our species as we know it.

We have past more than a year and a half battling a pandemic that, in the best case, is due to the product of the incursion of capitalist activity in otherwise pristine environments, where traders unknowingly carried out pathogens that were endemic to those ecosystems in search of products demanded by markets emerging for the human consumption of these new products.[5] In the worst case, there is the possibility that those in power provoked this pandemic to advance a very perverse agenda to consolidate the complete submission of humanity to their will in pursuit of life as dictated by a tiny elite of psychopaths. In either case, there is already ample evidence that the global elite of the much less than 1% is taking advantage of the pandemic to accelerate the imposition of a new world order of the 'fourth industrial revolution", through what they call "The Great Reset", prominently advanced by Klaus Schwab, the leader and Executive Chairman of the World Economic Forum at Davos, Switzerland.[6]

The purpose of “Marketocracy and the Capture of People and Planet” is to examine the trajectory that the world has been following since neoliberalism was imposed on humanity half a century ago. Its specific aim is assessing the ulterior motivations—and their consequences on humanity and the planet as a whole—of key groups and individuals of the global elite with powerful influence on the world’s governments and multilateral institutions. Among these are the Bill & Melinda Gates Foundation, Elon Musk, Jeff Bezos and, last but not least, the World Economic Forum (from now on WEF), and the purpose of its proclaimed “Fourth Industrial Revolution” through “The Great Reset”. I believe that, on the one hand, we are enduring perilous times for life on our planet, as the direct result of the capitalistic-driven Anthropocene[7] that has put the planet on the brink of crossing a tipping point with dramatic transformations that can become cataclysmic and that threaten the future of all living things. On the other hand, we have a dangerous global elite that has captured our so-called “democratic governments” and unilaterally pretends to impose their agenda, which true intentions are a future they deliberately keep opaque but are advancing in the most undemocratic manner. It should be extremely evident that the common citizenry is never asked to participate in the discussions and decisions that the elite pretends to advance and implement on behalf of humanity. Hence, this is my contribution to raising the questions and finding the answers to critical events that we are witnessing as I write. This should help the common citizenry gain knowledge, take consciousness, and empower themselves to

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4 ↩ John Bellamy Foster: Marx’s Ecology, Monthly Review Press, New York, 2000, p. 19 (ePub).

5 ↩ For a detail explanation of the origin of these pathogens see: Rob Wallace, Alex Liebman, Luis Fernando Chaves and Rodrick Wallace: COVID-19 and Circuits of Capital — New York to China and Back, The Jus Semper Global Alliance, August 2020.

6 ↩ World Economic Forum

7 ↩ The anthropocene is a new geological epoch displacing the Holocene epoch of the last 10000 to 12000 years to represent what has been called an “anthropogenic rift” in the history of the planet, see John Bellamy Foster: The Anthropocene Crisis, The Jus Semper Global Alliance, July 2017, p.1.

make well-informed decisions that can contribute in turn to organise and put in check the agenda pursued by the global elite of the less than one per cent. The current events must make saving our species and our planet the fundamental issue and the overarching and quintessential cornerstone of our effort to transition to a new sustainable paradigm. It cannot be one of many vital issues, but the single element that drives our vision to achieve sustainability that fundamentally determines how we draft our new paradigm. It is in our self-interest to become cognisant about the damning catastrophe that we are facing, stop our numbness and individualism and coalesce to change the current doomed trajectory and veer to what Paul Burkett calls an eco-revolutionary tipping point. This is the cross-sectoral defensive struggles of ecological, communitarian and urban movements coalescing as an ecological socialist movement against *this system of monopoly-finance capital and its state functionaries*,[8] the tiny elite who thinks it owns our planet.

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The COVID-19 pandemic section of "Marketocracy and the Capture of People and Planet" covers in detail the emergence of the pandemic. The current pandemic and climate change are the direct results of the damage that humanity continues to inflict on the ecosystems of our home, Mother Earth because we are literally depredating the Earth's resources. This has placed our planet, by the vast majority of scientists, into the new geological era of the Anthropocene. Our epoch has put the planet on the brink of crossing a tipping point with dramatic transformations that can become cataclysmic and that threaten the future of all living things.

This excerpt assesses the criteria that governments around the world have applied to manage COVID-19 infections, the development of vaccinations and the programs for vaccinating the population, always in the context of a market-driven paradigm, where shareholder value of global corporations supersedes the protection and welfare of the Demos (the citizenry). It also covers the many questions that scientific communities across the world have raised on the criteria applied on the diagnosis and treatment of the illness and vaccine development, as well as the systematic repudiation and ostracism that governments are applying to questions coming not from so-called conspiracy theorists but from medical scientists specialised in a diversity of fields that directly deal with epidemiological events.

There is currently a global debate on the need to ask the citizenry to get a third dose of a vaccine as a booster shot, given the steep increase in contagions and hospitalisations caused by the Delta mutation SARS-CoV-2. While the U.S. government and rich countries are pushing for a third dose, many in the medical practice feel the best strategy is to put more pressure on people to get vaccinated in the U.S. and everywhere, and, to accomplish this, to support poor countries with massive supplies of vaccines instead of giving a third dose to those who have been vaccinated. This, coupled with the systematic use of masks and restrictions for circulation, work, travel, and daily activities against those who reject vaccinations, appears to be the most sensible and effective strategy to defeat the virus and all its mutations.[9]

Lastly, given the fluid state of the pandemic, this excerpt updates the latest VAERS data available for adverse reactions, two recent vaccine adverse reactions recently identified for the mRNA vaccines and the Janssen vaccine, as well as a new vaccine (Coronavax), developed using traditional methods, that is currently in its process of approval, again in a market-driven context.

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[8] ↩ Paul Burkett: An Eco-Revolutionary Tipping Point? — Global Warming, the Two Climate Denials, and the Environmental Proletariat, The Jus Semper Global Alliance, April 2020, p. 10..

[9] Eli Stokols and Del Quentin Wilber: Biden outlines new anti-COVID plans — Los Angeles Times, 19 August 2021.

The COVID-19 Pandemic

In the waning days of 2019, reports from China began to populate the press around the world, with news about a new virus that was beginning to spread. The conventional narrative is that the COVID-19 virus was first identified in Wuhan, China, in December, but now there are indications that the first person infected is from Hubei province in November 2019.[10]

Consistent with all the previous sections of this work, we will discuss this important event in human history by following a matter-of-fact process, clearly describing the critical social, economic, political and medical factors that have come together to play a role in the way the nations of the world, multilateral institutions and the Demos have addressed this pandemic.

What is a pandemic? It is an infectious disease that spreads across a large portion of the world or the entire planet affecting many people. If a disease only affects a specific region or is active worldwide but affects a stable number of people, or only happens seasonally, such as influenza, then it is not a pandemic but an epidemic instead.

What is the COVID-19 disease? This is the illness resulting from the infection of the virus denominated Coronavirus — SARS-CoV-2. The virus belongs to the Coronavirus family of RNA viruses that typically affect birds and mammals. The illness is considered a "severe respiratory syndrome" closely related to a bat coronavirus.[11]-[12] As we write, the last available count of cases is 154,4 million and 3,2 million deaths.[13] Thus the infectious fatality ratio is currently 2,1%. Based on the number of deaths, this pandemic currently ranks as the ninth with the most deaths.[14] Of course, this is only a very distant approximation to the proper metrics, given that many countries do not test for infections and, among those that test, many use different testing devices. By the same token, some countries use different strategies, such as PCR test sampling instead of a systematic count. Similarly, many deaths are not recorded as COVID, and while some countries do autopsies to confirm causes of death, many do not. It follows that the metrics reported by John Hopkins University or the World Health Organisation (WHO) only represent a relative dimension of the importance of the pandemic but not a true count of infections and deaths. There is also substantial controversy on the correct type of diagnosis of the illness. Many thousands of cases have shown that the virus causes severe immunological reactions that can spread to any organs, such as in the occurrence of cytokine storms. This may explain why while many people show no symptoms while, others get very sick and require ventilation due to a severe immune response. This is why many scientists suspect that our immune system is to blame for the intense illness and diversity of symptoms caused by COVID-19 and not properly due to a respiratory illness.[15] Lastly, PCR tests are not very reliable and tend to inflate the rate of infections with false positives and vice versa. We will cover this specific issue further ahead in this section.

What is the origin of the SARS-CoV-2? Although the zoonotic source of SARS-CoV-2 is currently unknown, there is ample agreement that infections started in China. However, and this is extremely important, the underlying cause of the

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[10] ↩ Josephine Ma: Exclusive | Coronavirus: China's first confirmed Covid-19 case traced back to November 17 — South China Morning Post, 13 March 2020.

[11] ↩ Stanley Perlman: Another Decade, Another Coronavirus — New England Journal of Medicine, 20 February 2020.

[12] ↩ WHO recommendations to reduce risk of transmission of emerging pathogens from animals to humans in live animal markets or animal product markets, 26 March 2020.

[13] ↩ Our World in Data Access on 5 May 2021.

[14] ↩ From Wikipedia, the free encyclopedia

[15] ↩ Sarah Bradley: What Is a Cytokine Storm? Doctors Explain How Some COVID-19 Patients' Immune Systems Turn Deadly — Health, 1 May 2020.

virus has seldom been addressed.[16]-[17]-[18] It follows that the important question is why we have an increasing number of viruses threatening human populations in large swaths of the planet. And the answer is because of the expansive nature of capitalism that has brought us the Anthropocene. This is the underlying cause at its deepest level. Indeed, unless we address, in a determined manner, the anthropogenic pressures on our planet and their direct underlying cause that capitalism clearly embodies, an ecological crisis will unfold to the point of no return, and it is already overshadowing all other issues. A groundbreaking study from the US National Academy of Sciences[19] found that humankind accounts for only 0,01% of all living things since the dawn of civilisation. However, it has destroyed 83% of all wild mammals and half of all plants, but livestock husbanded for human consumption abounds. We have invaded and destroyed a great portion of the Earth's ecosystems that, otherwise, would have remained pristine.[20] Although the COVID-19 pandemic is the emblematic example of what is to come as the direct result of the Anthropocene driven by our autocratic capitalistic system, the study unequivocally shows that we are a plague to the planet, a true pandemic, a pest much worse than COVID-19 or anything else, unless we change to take good care of the home that feeds our species.

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Hence, the COVID-19 pandemic is the direct result of capitalism's encroaching of previously pristine habitats. An ad hoc essay points at the structural trade and land-owning relations and calls for giving them central focus in the quest for the causes of these increasingly recurring pandemics.

COVID-19 — a direct by-product of the Capitalist mode or production

Modelling emergencies, however necessary, miss when and where to begin. Structural causes are as much a part of the emergency. Including them helps us figure out how best to respond moving forward beyond just restarting the economy that produced the damage.[21] The authors point out that the failures to deal with the pandemic were actually planned decades ago by systematically dismantling and monetising / financialising the shared commons of public health. As a result, *a country captured by a regimen of individualised, just-in-time epidemiology—an utter contradiction—with barely enough hospital beds and equipment for normal operations, is by definition unable to marshal the resources necessary to pursue a China brand of suppression.*[22]

The virus emerged at a regional supply line of exotic foods in a wild food market in Wuhan, China. The virus, subsequently, through the networks of the global economy, diffused exponentially worldwide. By the same token, globalised commodity agriculture that expanded production to remote reservoirs previously pristine, with little or no human activity, served as the propulsion engines that allowed disseminating a myriad of pathogens from the most remote areas to the largest urban conglomerates both North and South. *The lengthier the associated supply chains and the greater the extent of adjunct deforestation, the more diverse (and exotic) the zoonotic pathogens that enter the food chain. Among recent emergent and reemergent farm and foodborne pathogens, originating from*

[16] ↩ World Health Organization: Origin of SARS-CoV-2 26 March 2020

[17] ↩ WHO calls for further studies, data on origin of SARS-CoV-2 virus, reiterates that all hypotheses remain open, 30 March 2021.

[18] ↩ World Health Organisation: How WHO is working to track down the animal reservoir of the SARS-CoV-2 virus, 6 November 2020.

[19] Yinon M. Bar-Ona, Rob Phillips, and Ron Milo: The biomass distribution on Earth, 6506–6511 | PNAS | June 19, 2018 | vol. 115 | no. 25

[20] ↩ Damian Carrington: Humans just 0.01% of all life but have destroyed 83% of wild mammals – study, The Guardian, 21 May 2018.

[21] ↩ Rob Wallace, Alex Liebman, Luis Fernando Chaves and Rodrick Wallace: COVID-19 and Circuits of Capital, The Jus Semper Global Alliance, August 2020.

[22] ↩ ibidem for all italics in this box

across the anthropogenic domain, are African swine fever, Campylobacter, Cryptosporidium, Cyclospora, Ebola Reston, E. coli O157:H7, foot-and-mouth disease, hepatitis E, Listeria, Nipah virus, Q fever, Salmonella, Vibrio, Yersinia, and a variety of novel influenza variants. The production networks and the markets that demand these exotic foods and the large globalised agribusiness of certain commodities have practices that accelerate the transmission and evolution of pathogen virulence. *Growing genetic monocultures—food animals and plants with nearly identical genomes —remove immune firebreaks that in more diverse populations slow down transmission.*

A series of multinational-based "Soybean Republics," for instance, now range across Bolivia, Paraguay, Argentina, and Brazil. The new geography is embodied by changes in company management structure, capitalisation, subcontracting, supply chain substitutions, leasing, and transnational land pooling. In straddling national borders, these "commodity countries," flexibly embedded across ecologies and political borders, are producing new epidemiologies along the way.

These new exotic food and agribusiness networks produce virulent outbreaks that contaminate and ravage *livestock, crops, wildlife, workers, local and national governments, public health systems and alternate agrosystems to produce pandemics, such as the present one, as the direct result of the capitalist mode of production.*

Indeed, the authors state that *the underlying cause of COVID-19 and other* pathogens is not found just in the object of any one infectious agent, but also in the field of the ecosystemic relations of capitalism.

And here is their recommendation for the citizenry and not the market agents. *To avoid the worst outcomes here on out, disalienation offers the next great human transition: abandoning settler ideologies, reintroducing humanity back into Earth's cycles of regeneration, and rediscovering our sense of individuation in multitudes beyond the capital state. However, economism, the belief that all causes are economic alone, will not be liberation enough. Global capitalism is a many-headed hydra, appropriating, internalising, and ordering multiple layers of social relation.*

In a nutshell, if we want to prevent the killing of vast sectors of the world's population, with the precariat in the Global North and the vast majority of the Global South bearing the most peril, we must directly confront the owners of the capitalist system and their agents in the structures of political power. The authors warn us that *agribusiness is at war with public health. And public health is losing.* The same thing can be said of capitalism in general vis-à-vis human rights.

In the same line of thought, physicists explain how the inherent nature of capitalism demanding unrelenting growth causes:

ecological instabilities associated with excessive levels of economic growth. These instabilities can combine to pump and amplify existing natural phenomena. The amplifier effect works as follows. Economies absorb energy from the natural world and then exploit that energy for cycles of production and consumption. For highly energy-intensive economies, these cycles necessarily yield extensive levels of waste and dissipation, or energy losses that are dumped back out to the environment. These energy losses are not "useless" from the standpoint of physics or ecology. Under the right circumstances, they can power the formation of other natural dynamical systems, including everything from viruses and bacteria to wildfires and hurricanes.[23] *These highly chaotic effects associated with energy-intensive economies are largely ignored and dismissed by neoclassical theory, even though they have often played a central role in the evolution of human history.*[24] *As a highly dissipative system, capitalism regularly produces very powerful amplifier effects. Collectively, these amplifiers are now creating what Marx called*

[23] ↩ For a comprehensive guide to recent research on hurricanes and climate change, see Jennifer M. Collins and Kevin Walsh, eds., *Hurricanes and Climate Change*, vol. 3 (New York: Springer, 2017). For a review of the role climate change plays in the spread of infectious diseases, see Xiaoxu Wu et al., "Impact of Climate Change on Human Infectious Diseases: Empirical Evidence and Human Adaption," *Environment International* 86 (2016): 14–23.

[24] ↩ See, for example, Jerry H. Bentley, "Environmental Crises in World History," *Procedia—Social and Behavioral Sciences* 77 (2013): 108–15.

a "metabolic rift" between nature and society, which means that the ecological basis of civilisation is steadily eroding under profit-seeking and energy-intensive development that does not care about replacing what it extracts.[25] *The natural world has major tipping points that we should not cross, but indefinite economic growth through substitution virtually guarantees that some of those critical thresholds will be breached, threatening the broader ecosphere that supports human civilisation.*[26]

➡ Management of COVID-19

The manner in which the COVID-19 pandemic has been confronted has been diverse with extremes ranging from genocidal, irresponsible, negligent and ineffective, such as in the case of Brazil[27] and to some degree Mexico[28] to autocratic, such as in Hungary[29] and China[30] to semi-transparent and closed to open dialogue on the ways to manage the pandemic, such as in the U.S., the European Union and other major economies.

There is intense criticism on the specific ways in which lockdowns were implemented, sometimes through drastic enforcement and repression against peaceful demonstrations, such as recently in London.[31] Equally important, there is strong criticism from both scientists and the general public about some of the public health strategies that have been used to confront the pandemic, with the most relevant being: 1) the faulty PCR testing, 2) diagnosis of COVID-19 as a respiratory disease, and 3) the therapies applied to cure or mitigate the illness.

• The PCR test. The world has bet on the Polymerase chain reaction, commonly known as the PCR test, which has been widely deployed since the beginning of the pandemic in January 2020, in a specific reverse-transcriptase PCR (RT-PCR) format developed for COVID-19 and has remained the primary device to test for infection.[32] In January 2020, a group of researchers specialised in infectious diseases, medical microbiology, medical virology and molecular virology submitted a research paper to Eurosurveillance[33] (Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR) in which they claim that the Real-time RT-PCR is a robust technology for use in public-health laboratory settings for COVID-19 testing.[34] This paper provided much validation worldwide to the use of RT-PCR testing as the standard method to test for COVID-19 infections and has a powerful influence in public policy strategies to track and confront COVID-19 infections.

However, in November 2020, a paper curated by an International Consortium of 22 Scientists in Life Sciences from a diversity of countries contested the aforementioned paper in the paper: *Corman-Drosten Review Report et al. — External*

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25 ↩ For more on Marx and his theory of the metabolic rift, see John Bellamy Foster, *Marx's Ecology* (New York: Monthly Review Press, 2000).

26 ↩ See Johan Rockström et al., "A Safe Operating Space for Humanity," *Nature* 461 (2009): 472–75.

27 ↩ Octávio Luiz Motta Ferraz: Between Gross Negligence and Genocide: Brazil's Failed Response to COVID-19 — Bill of Health, Petrie-Flom Center at Harvard Law School, 14 September 2020.

28 ↩ Patrick J. McDonnel: In Mexico, study of 'excess deaths' shows at least 60% more COVID-19 victims than reported — Los Angeles Times, 28 March 2021.

29 ↩ Shaun Walker: Authoritarian leaders may use Covid-19 crisis to tighten their grip — The Guardian, 31 March 2020

30 ↩ Harvard International Review: Authoritarianism in the Time of COVID, 23 May 2020.

31 ↩ Mattha Busby: Dozens of arrests as thousands march in London against Covid lockdown — The Guardian, 20 March 2021

32 ↩ COVID-19 Real-Time Learning Network: RT-PCR Testing — COVID-19, Real time learning network (CDC and IDSA), latest update: 20 November 2020.

33 ↩ *Eurosurveillance* is a European peer-reviewed scientific journal devoted to the epidemiology, surveillance, prevention and control of communicable diseases, with a focus on such topics that are of relevance to Europe.

34 ↩ Corman Victor M et al: Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR — Eurosurveillance, Article submitted on 21 Jan 2020 / accepted on 22 Jan 2020 / published on 23 Jan 2020

peer review of the RTPCR test to detect SARS-CoV-2 reveals ten major scientific flaws at the molecular and methodological level: consequences for false-positive results to Eurosurveillance. Thus, they contest the paper above and assert that the PCR tests are useless. *In light of all the consequences resulting from this very publication for societies worldwide, a group of independent researchers performed a point-by-point review of the aforesaid publication in which 1) all components of the presented test design were cross-checked, 2) the RT-qPCR protocol-recommendations were assessed w.r.t. good laboratory practice and 3) parameters examined against relevant scientific literature covering the field.*[35] They point to ten scientific flaws at the molecular and methodological levels. They also point at *serious conflicts of interest of the authors* that are not mentioned, and question the fact that *the very short timescale between submission and acceptance of the publication (24 hours) signifies that a systematic peer review process was either not performed here, or of problematic poor quality*.[36] As a result, because of the major flaws that they explain in detail in their paper, they render the PCR test useless: *In light of our re-examination of the test protocol to identify SARS-CoV-2 described in the Corman-Drosten paper we have identified concerning errors and inherent fallacies which render the SARS-CoV-2 PCR test useless.*[37] Lastly, they also submitted a Retraction request letter to the Eurosurveillance editorial board.[38] So far, Eurosurveillance examined the paper submitted by the consortium but concluded that the criteria for a retraction of the article had not been fulfilled.[39] This was to be expected, given that it would be a big blow to the journal's reputation. Nonetheless, the reputation of the scientists that contend the validation of the PCR test and the detailed analysis that they provided has many merits.

> *A paper curated by an International Consortium of 22 Scientists found major flaws in the PCR test and rendered it useless... The implication is that additional testing is necessary to confirm the infection prevalence.... The principal consequence of this issue is that most governments have been using PCR testing to justify how public policy is designed to confront the pandemic... These policies include blanket lockdowns that may cause a) impacts on mental health, b) cancelled or delayed essential hospital treatment, c) deaths among the elderly due to separation from loved ones, and d) inhumane confinement and isolation of the elderly.*

Among the ten flaws identified by these scientists, one that stands out is the well-known case of "False Positives". In their paper, the scientists argue that *The RT-PCR test described in the Corman-Drosten paper contains so many molecular biological design errors (see 1-5) that it is not possible to obtain unambiguous results. It is inevitable that this test will generate a tremendous number of so-called "false positives". The definition of false positives is a negative sample, which initially scores positive, but which is negative after retesting with the same test.*[40] As they point out, the consequences of false-positives—using the results of the Corman-Drosten paper that drew a 1,2% of false-positive—to the 178,1 million PCR test applied in the U.S. as of 21 November 2020, means that at least 2,3 million people were falsely infected with Covid-19. However, they explain that *in light of the errors presented in the previous section, the actual false positive rate is unknown and therefore 2,3 million must be considered a minimum estimate; so the distressing reality is likely to be much greater.*[41] If the same ratio were to be applied worldwide, we would be talking of tens of millions of false positives.

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35 ↩ Peter Borger et al: Corman-Drosten Review Report — External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results., 27 November 2020.

36 ↩ ibidem.

37 ↩ ibidem.

38 ↩ Peter Borger et al: Retraction request letter to Eurosurveillance editorial board regarding the Corman Victor M et al report. 28 November 2020.

39 ↩ Corman-Dorster Review Report: Official Public Announcement by Eurosurveillance, Last Updated 06.02.2021

40 ↩ Peter Borger et al: Corman-Drosten Review Report — External peer review of the RTPCR test to detect SARS-CoV-2 reveals 10 major scientific flaws at the molecular and methodological level: consequences for false positive results., 27 November 2020.

41 ↩ Howard Steen & Saji Hameed: Corman-Dorster Review Report: The consequences of false positives, November 2020.

It follows as they envisage that the rate of false positives could very well be much higher. Indeed, this is the case of three sets of PCR testing compiled in Massachusetts, New York and Nevada, where up to 90 per cent of people testing positive carried barely any virus. In one day, the rate of new COVID-19 positives in those three states was 45.604. It follows that perhaps only about 4.500 were actually infected and needed to isolate themselves, according to a database maintained by the New York Times.[42] This is why the U.S. Centre for Disease Control (CDC) eventually, at the end of last year, had no choice but to admit the risk of false-positives, as well as false-negatives, with PCR testing. *The CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel has been designed to minimise the likelihood of false positive test results. However, it is still possible that this test can give a false positive result, even when used in locations where the prevalence is below 5%.*[43]

The implication is that additional testing is necessary to confirm the infection prevalence. Indeed, the recommendation of the authors of the Corman-Drosten review report is that *In the literature of PCR testing, it is known that there are many dangers, such as operational false positives that can lead to misinterpretation of the test results. For this reason it is recommended by Kurkela et al. [1] that PCR should only ever be used in tandem with a clinical diagnosis of infection based on symptoms.*[44] To be sure, this will increase the cost of the associated healthcare services, which in the case of the U.S., where healthcare is only a market commodity, is a major problem.

The principal consequence of this issue is that most governments have been using PCR testing to justify how public policy is designed to confront the pandemic. *Misdiagnosis of PCR positives as infections has a history of causing 'Casedemics' which are typically characterised by an incongruity between positive PCR test results and deaths.* These policies include blanket lockdowns that may cause a) impacts on mental health, b) cancelled or delayed essential hospital treatment, c) deaths among the elderly due to separation from loved ones, and d) inhumane confinement and isolation of the elderly among the most important. Additionally, the economic impact has been devastating.[45] There have also been many violations of fundamental human rights in many parts of the world to enforce lockdowns using aggressive police and military power—based on the infection rates reported using PCR testing. In summary, overwhelmingly relying on one diagnostic methodology to drive pubic policy should be regarded as a major flaw in public health policy. Governments must learn from this experience in managing the ongoing pandemic and potential pandemics or epidemics that will most likely emerge in the coming years.

In summary, overwhelmingly relying on one diagnostic methodology to drive pubic policy should be regarded as a major flaw in public health policy. Governments must learn from this experience in managing the ongoing pandemic and potential pandemics or epidemics that will most likely emerge in the coming years.

• Faulty comparison between countries. Every day, we get a global report, courtesy of Johns Hopkins University, that lists confirmed cases and deaths, fatality rates, test, vaccine doses, people fully vaccinated and other related metrics. However, the exercise is meaningless for several of the metrics. Many countries have done minimal testing and drive their public policies in a rather reactive manner instead of proactively. For instance, the Mexican government declared, from the start of the pandemic, that it could manage it using its version of the Sentinel Surveillance Model.[46] Instead of

42 ↩ Apoorva Mandavilli: Your Coronavirus Test Is Positive. Maybe It Shouldn't Be — New York Times, 29 August 2020.

43 ↩ CDC: Fact sheet for Healthcare providers: CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel, 1 December 2020.

44 ↩ Howard Steen & Saji Hameed: Corman-Dorster Review Report: The consequences of false positives, November 2020.

45 ↩ Howard Steen & Saji Hameed: Corman-Dorster Review Report: The consequences of false positives, November 2020.

46 ↩ National Center for Biotechnology Information: Sentinel Surveillance

systematic testing of as many people as possible, as in the UK and U.S., this model is based on sampling using a network of doctors, laboratories, clinics, or hospitals. Thus, comparing cases using this model versus other strategies is irrelevant in assessing the infection prevalence of a disease. It is the same as comparing apples with pineapples. The same goes in the case of deaths. There is no agreed criteria to diagnose the cause of death during the pandemic. People may die because of a heart attack, blood clot, sepsis, kidney failure, or a massive immune reaction. The virus triggered it in all cases, but while in one country a person may be diagnosed as a COVID-19 victim, in another, the death certificate would record another cause of death because the person had not been tested and no autopsy was performed. Even in countries where PCR tests have been applied systematically, autopsies have not been carried out at the same systemic level and have not been performed on the whole body. This creates problems in reporting the cause of death and also the diagnosis of the COVID-19 illness, which we will address further ahead in this paper.

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This is why a group of Italian physicians alerted governments about the need to perform whole-body autopsies of COVID-19 patients to define further the pathologies caused by SARS-CoV-2. They consider that autopsies across all body organs have been sparse.[47] The physicians state that COVID-19 has caused multi-system pathologies. Thus, while pulmonary and cardiovascular involvement were dominant pathological features, extra-pulmonary manifestations included hepatic, kidney, splenic, bone marrow involvement, and microvascular injury and thrombosis were also detected. These findings were similar in patients regardless of whether preexisting medical comorbidities were found or not. Hence, they conclude that *SARS-CoV-2 infection causes multi-system disease and significant pathology in most organs in patients with and without comorbidities*. In other words, patients with COVID-19 who do not have comorbidities appear to have similar pathological manifestations as those with comorbidities. Thus, there is a need for a more detailed and more extensive autopsy case series to define the pathological manifestations of COVID-19 further and determine the full extent of organ involvement.[48] This also directly affects COVID-19 infections since, in many cases, the symptoms are not respiratory. The virus may be attacking another organ, and no COVID-19 infection test is conducted. If the person dies, the death certificate may not be the virus unless an autopsy is performed. All of these methodological issues directly influencing the assessment of COVID-19 management—in terms of infection and death —compounds the management of COVID-19 at the public health level.

Needless to say that there is also a wide spectrum in how governments address the socio-economic impact of the pandemic, which depends both on the economic capacity of a country to support the economic losses to workers and businesses and the personality of the government's leader.

The cases of Trump, Brazil's Bolsonaro, Mexico's López Obrador, and India's Narendra Modi stand out for their irresponsible demeaning of the pandemic. Unsurprisingly, Trump consistently downplayed its importance and battled the opinions of his health experts on how to confront the pandemic. He declared that the virus affects *virtually nobody,* after the U.S. had surpassed more than 200 thousand deaths.[49] Bolsonaro regarded COVID-19 from the onset as "little more

47 ↩ Laura Falasca: Postmortem Findings in Italian Patients With COVID-19: A Descriptive Full Autopsy Study of Cases With and Without Comorbidities — The Journal of Infectious Diseases, 1 December 2020, p. 1807.

48 ↩ Ibidem.

49 ↩ Quint Forgey: 'It affects virtually nobody': Trump downplays virus threat to young people, Politico, 22 September 2020.

than a cold",[50] and, given that his response remains pathetic and extremely irresponsible, he has been accused in the International Criminal Court in The Hague of committing "crimes against humanity".[51] The Brazilian Senate has now launched an investigation on the issue.[52]

López Obrador response in the early stage of COVID-19 was unconcerned, asking people to "live life as usual", never missing an opportunity to contradict the advice of his public health officials or paint the pandemic as a plot to derail his presidency.[53] Then, instead of supporting the working class with a programme to reduce the impact of the pandemic, he used the opportunity to slash federal programmes as much as possible, offering loans to workers and businesses instead.[54] Then he named López Gatell, Deputy Minister of Health, as Mexico's pandemic zar, who constantly criticised the strategies followed by countries that implemented systemic testing as the way to track and battle the pandemic. As a result, the number provided by the government for cases and confirmed deaths are only a fraction of what has happened. Then the true number of the pandemic was no longer avoidable, and the Mexican government was forced to acknowledge that *the country's true death toll from the coronavirus pandemic now stands above 321,000, almost 60% more than the official test-confirmed number of 201,429.*[55]

In India, Narendra Modi also downplayed the pandemic and declared *Friends, it would not be advisable to judge India's success with that of another country. In a country which is home to 18% of the world population, that country has saved humanity from a big disaster by containing corona effectively.*[56] Now India is in dire straits—with nearly 400 thousand daily cases and nearly 3.900 daily deaths—,[57] struggling to get oxygen and beds for the thousands that need emergency care and cannot get it.[58]

However, little more than a month later, a new study from The Institute for Health Metrics and Evaluation (IHME) of the University of Washington, exposed the true toll of the pandemic —as of 3 May 2021—and found, for instance, that the death toll in the U.S. was 905.289 instead of the government's 574.043 reported; in Brazil was 595.903 instead of the government's 408.680 reported; in Mexico was 617.127 instead of the government's 217.694 reported; and in India 654.395 instead of the government's 221.181 reported. The study covered 20 countries and found that the true count is much higher in all cases, and in most cases, several times higher than what was reported, regardless of systematic PCR testing or Sentinel Surveillance Model or some other strategy or lack of it. This is true in countries such as Germany, France, Japan, Italy, U.S., UK, Russia, Indonesia and Peru, among others. Essentially, the number of COVID-19 death is, so far, more than double the numbers reported by all countries.[59]

Essentially, the number of COVID-19 death is, so far, more than double the numbers reported by all countries... All we can take for granted is that the dimension of the pandemic in terms of cases and mortality is much greater than what the numbers indicate.

50 ↩ Terrence McCoy and Heloísa Traiano: Brazil's Bolsonaro, channeling Trump, dismisses coronavirus measures — it's just 'a little cold', The Washington Post, 25 March 2020.

51 ↩ Andrew Fishman: Brazil Seeks to Hold Bolsonaro Accountable for More Than 400,000 Covid-19 Deaths — The Intercept, 1 May 2021.

52 ↩ Sam Cowie: Brazil Senate investigating Bolsonaro's handling of COVID-19 — Al Jazeera, 14 April 2021.

53 ↩ David Agren: Coronavirus advice from Mexico's president: 'Live life as usual' — The Guardian, 25 March 2020.

54 ↩ David Agren: 'He's Mr Scrooge': Mexican president unveils severe cuts amid coronavirus — The Guardian, 24 April 2020.

55 ↩ Associated Press: Mexico Covid death toll leaps 60% to reach 321,000 — The Guardian, 28 March 2021.

56 ↩ Arundhati Roy: 'We are witnessing a crime against humanity': Arundhati Roy on India's Covid catastrophe — The Guardian, 28 April 2021.

57 ↩ World In data: India: Coronavirus Pandemic Country Profile, as of 9 May 2021.

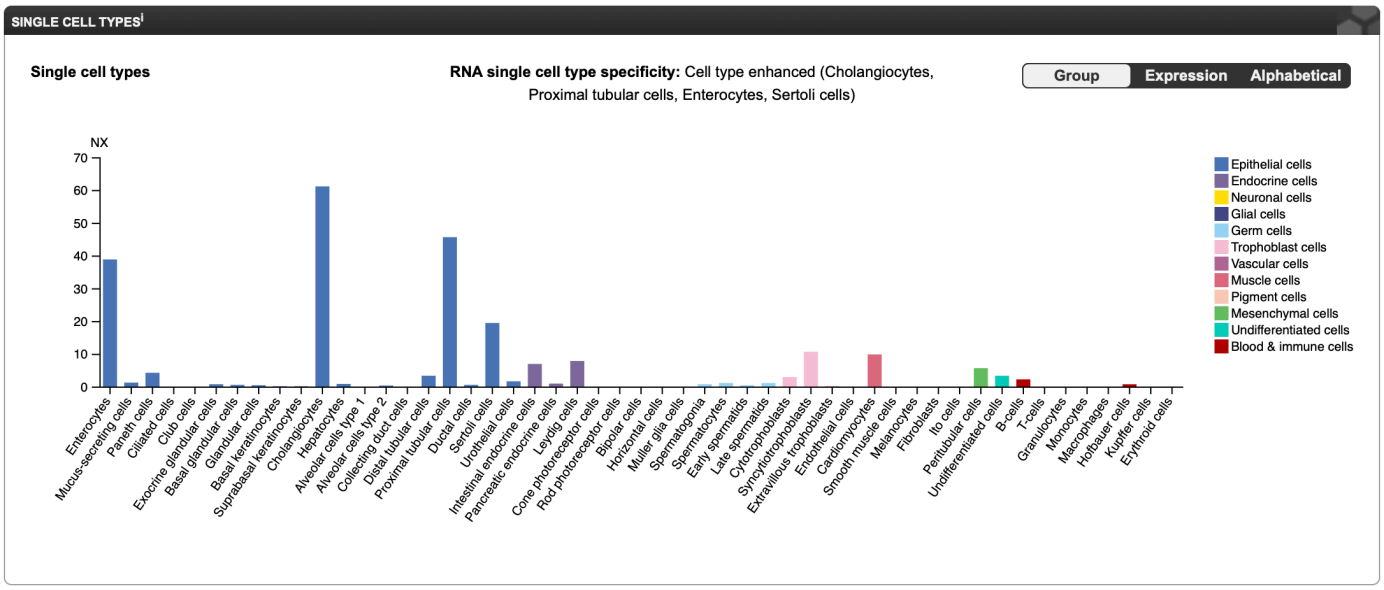
58 ↩ Hannah Ellis-Petersen: 'The system has collapsed': India's descent into Covid hell — The Guardian, 21 April 2021.

59 ↩ IHME-Measuring What Matters: COVID-19 has caused 6.9 million deaths globally, more than double what official reports show, 6 May 2021.

Hence, the daily reported metrics are nothing more than a sample, a trajectory and a trend that the pandemic is following, in the best case, and are not a realistic indicator of the true picture of the pandemic in the world. All we can take for granted is that the dimension of the pandemic in terms of cases and mortality is much greater than what the numbers indicate.

•Diagnosis of COVID-19. As previously noted, COVID-19 has been clinically determined as a respiratory disease. Nonetheless, there is considerable contention from epidemiologist and other experts that the correct diagnosis of COVID-19 should be an immune reaction. One analysis by Acevedo Whitehouse[60] asserts that the illness should be determined as an acute systemic immune reaction. The reason is that even though the virus attacks the respiratory tract—which justifies the need to cover mouths and noses and keep a distance—there is reason to believe that the virus is much more than a respiratory disease. The analysis points at the Human Protein Atlas portal,[61] to look for where in the body the virus is expressed by searching for the angiotensin-converting enzyme 2 (ACE2), which is the receptor for COVID-12. The search shows that the ACE2 is expressed far more in RNA single cell types in digestive, gallbladder, kidneys, testicles, and other organs but none or very little in RNA single cell types for the alveolar cells of the lungs as shown in illustration 1:

Illustration 1: Where does enzyme angiotensin-converting enzyme 2 (ACE2) is expressed in RNA singles cells, which is the receptor for SARS-CoV-2 (taken from the Human Protein Atlas)



If we also look at proteins instead of RNA, we find that it is not present in the lungs as well, as shown in illustration 2, nor in the nasopharynx and bronchus. In contrast, the virus is expressed much more in the ACE2 receptor enzyme in the duodenum, small intestine, gallbladder, kidney, testicles, and placenta than in the nasopharynx and bronchus nor in the lungs. For this reason, when testing, according to Acevedo Whitehouse, the virus should be looked for in the organs where the virus is expressed in the ACE2 receptor enzyme (illustration 3).[62] This is confirmed in a series of published scientific studies: *We have reviewed previously published studies on SARS and recent studies on SARS-CoV-2 infection,*

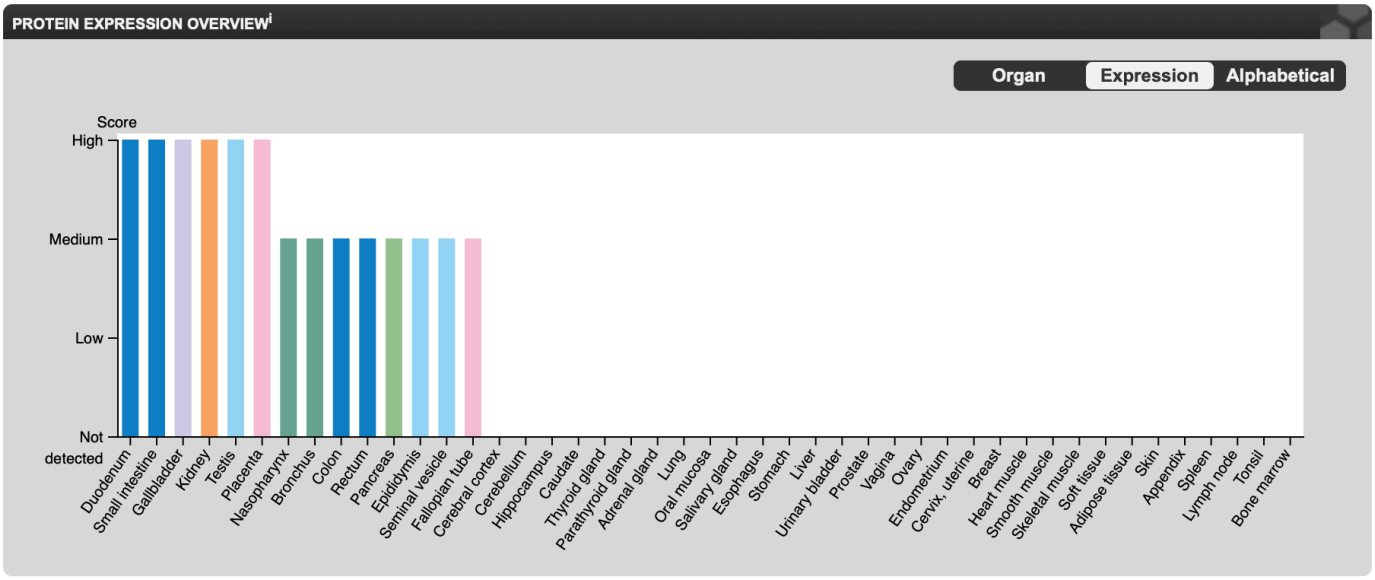
60 ↩ Karina Acevedo Whitehouse: LA OTRA CARA DE LA MONEDA Charla UM. Dra. Karina Acevedo Whitehouse. 2021. Available as of 10 May 2021.

61 ↩ Human Protein Atlas: ACE2 in RNA and in Tissue cells

62 ↩ Karina Acevedo Whitehouse: LA OTRA CARA DE LA MONEDA Charla UM. Dra. Karina Acevedo Whitehouse. 2021. Available as of 10 May 2021.

named coronavirus disease 2019 (COVID-19) by the World Health Organization (WHO), confirming that many other organs besides the lungs are vulnerable to the virus.[63]

Illustration 2: Where does enzyme angiotensin-converting enzyme 2 (ACE2) is expressed in proteins, which is the receptor for SARS-CoV-2 (taken from the Human Protein Atlas)



Acevedo Whithouse asserts that the issue is that the virus is showing an exacerbated immune response. Thus, while the virus is certainly present in the respiratory tract, it is far more prevalent in other organs, as shown in illustration 4 (Melenotte et al. quoted by Acevedo Whitehouse).[64] Hence, it is not truly a respiratory disease. Yet, it is a systemic type due to its immune effect, whilst its cytopathic effects are far more present in the digestive and renal organs.[65] It does not mean that it does not penetrate lung cells, but only alveolar cells type II and at a minimum. Why does it have effects anywhere in the body? Because it attacks endothelial cells, which may cause thrombus and cytokine storms. While it may damage the respiratory tract, the prophylaxis/treatment is with anti-coagulants because it is causing a problem of blood alteration closely linked to the immune system. Essentially, it is an "acute systemic immune dysregulation".[66] The virus can penetrate any part of our body, but then the immune reaction will cause problems in all other systems. Furthermore, if cells produce dysregulated type interferon (Kindler and Thiel quoted by Acevedo Whitehouse),[67] which produces a thick layer of cells in the epithelial membrane, oxygen cannot go through. In these cases, intubation does not work, causing 80-90% mortality rates in such cases.[68]

The other major issue is the risk of a pathological immune reaction; when immune complex formation produces cytokine storms, thrombus can be triggered anywhere in the circulatory system, including in the capillary endothelium

63 ↩ Wentao Ni et al: Role of angiotensin-converting enzyme 2 (ACE2) in COVID-19 — Critical Care. July 2020.

64 ↩ Cléa Melenotte et al (2020) Immune responses during COVID-19 infection, OncoImmunology, 9:1, 1807836, DOI: 10.1080/2162402X.2020.1807836

65 ↩ Karina Acevedo Whitehouse: LA OTRA CARA DE LA MONEDA Charla UM. Dra. Karina Acevedo Whitehouse. 2021. Available as of 10 May 2021.

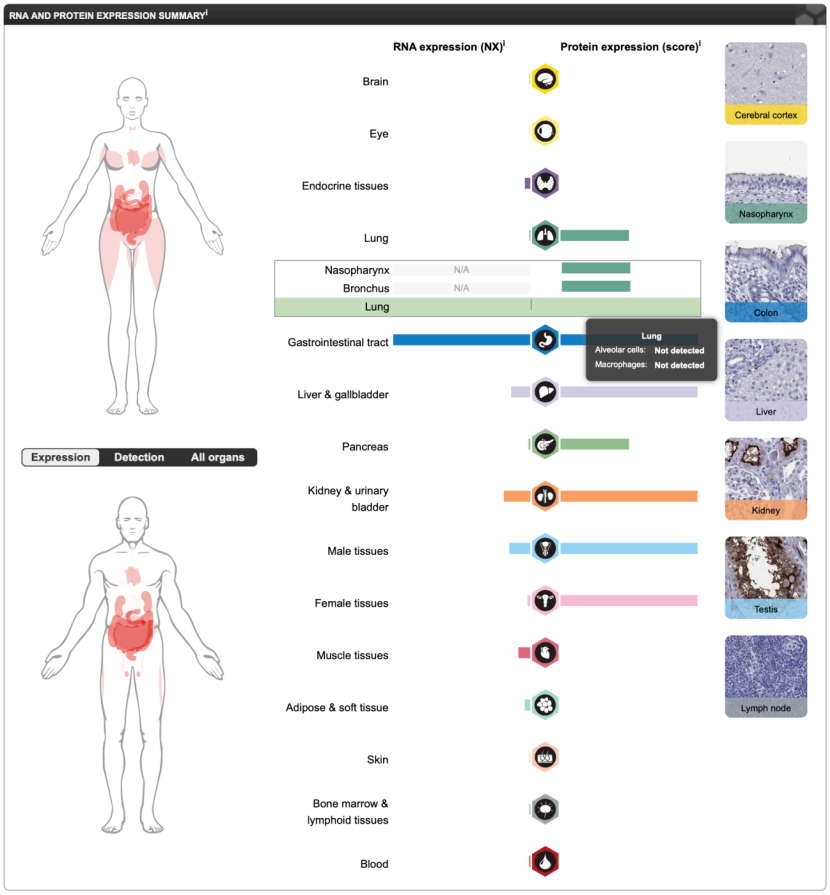
66 ↩ Ibidem.

67 ↩ Evelyn Kindler and Volker Thiel: SARS-CoV and IFN: Too Little, Too Late — Cell Host & Microbe 19, 10 February 2016 a2016 Elsevier Inc.

68 ↩ Karina Acevedo Whitehouse: LA OTRA CARA DE LA MONEDA Charla UM. Dra. Karina Acevedo Whitehouse. 2021. Available as of 10 May 2021.

of the lung alveoli (Manjilli et al. quoted by Acevedo Whitehouse).[69] In this case, the appropriate therapy is with anti-coagulants. In fact, a critical literature review suggests that the severity of SARS-CoV-2 infection is associated with dysregulation of inflammatory immune responses, which in turn inhibits the development of protective immunity to the infection. Therefore, therapeutics that modulate inflammation without compromising the adaptive immune response could be the most effective therapeutic strategy. Moreover, scientists (as quoted by Acevedo Whithouse) have found in recent research that COVID-19 is associated with a high incidence of venous thromboembolism (VTE) and PE/thrombosis, with a high incidence of VTE of 25% in critically ill COVID-19 patients, with mortality in these patients of 40%. In these cases, pulmonary embolism was the most frequent thrombotic complication with 81% incidence. Llitjos et al. reported that VTE was even detected in 100% (8/8) of severe COVID-19 patients treated with prophylactic and in 56% (10/18) in patients with therapeutic anticoagulation.[70]

Illustration 3: RNA and Protein expression summary for enzyme angiotensin-converting enzyme 2 (ACE2), which is the receptor for SARS-CoV-2 (taken from the Human Protein Atlas)



In summary, COVID-19, the illness produced by SARS-CoV-2, should not be regarded strictly as a respiratory disease but rather as an acute systemic immune reaction,[71] and much work must be done to find the appropriate therapies to be used to effectively address the inflammatory responses of the immune system when faced with this kind of infection. In fact, scientists point out that *therapeutic options are actually limited to unspecific supportive therapy. Whether viscoelastic testing can provide additional value in predicting clinical course, need for hospital resources and patient's outcome or in guiding anticoagulation in COVID-19–associated coagulopathy is still incompletely understood and currently under investigation.*[72] This is why Italian physicians have insisted on the need to do whole body postmortem studies to improve detection and therapies for this illness.[73]

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69 ↩ Rose H. Manjili, Melika Zarei, Mehran Habibi and Masoud H. Manjili: COVID-19 as an Acute Inflammatory Disease — The Journal of Immunology, current as of 4 May,2021.

70 ↩ Klaus Görlinger Daniel Dirkmann, Ajay Gandhi, MD, and Paolo Simioni: COVID-19–Associated Coagulopathy and Inflammatory Response: What Do We Know Already and What Are the Knowledge Gaps? — International Anesthesia Research Society, November 2020 • Volume 131 • Number 5.

71 ↩ Virginia Commonwealth University: COVID-19 should be treated as an acute inflammatory disease, scientist suggests — Science Daily, 5 August 2020.

72 ↩ Klaus Görlinger Daniel Dirkmann, Ajay Gandhi, MD, and Paolo Simioni: COVID-19–Associated Coagulopathy and Inflammatory Response: What Do We Know Already and What Are the Knowledge Gaps? — International Anesthesia Research Society, November 2020 • Volume 131 • Number 5.

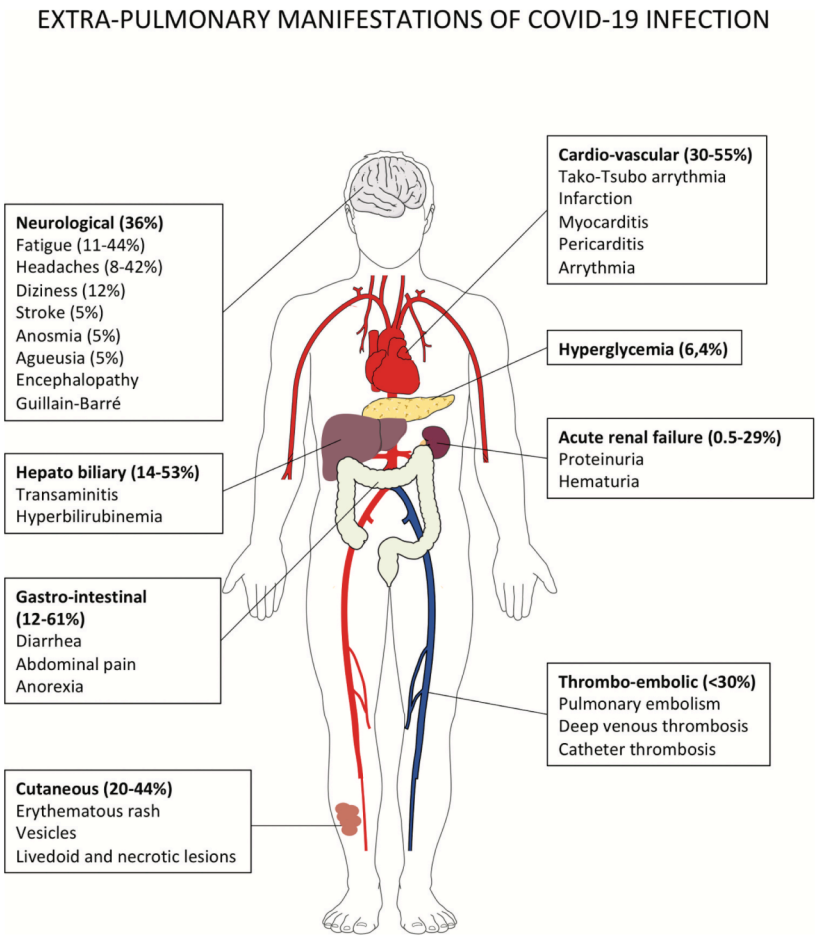
73 ↩ Laura Falasca: Postmortem Findings in Italian Patients With COVID-19: A Descriptive Full Autopsy Study of Cases With and Without Comorbidities — The Journal of Infectious Diseases, 1 December 2020, p. 1807.

➡ Vaccines

To treat any infection, there are a number of vaccines types, including : 1) Inactivated vaccines, 2) Live-attenuated vaccines, 3) Toxoid (inactivated toxin) 4) Subunit, recombinant, polysaccharide, and conjugate vaccines, 5) mRNA (messenger) vaccines, 6) Viral vector with defective replication, and 7) Viral vector with replication.[74]

For COVID-19, there are many vaccines under development, with a current count of 90 in process, with 27 reaching the final stages of testing. The leading COVID-19 vaccines currently are: Pfizer-BioNTech (mRNA), Moderna (mRNA), Sputkin V-Gamaleya (DNA inside an adenovirus), AstraZeneca (DNA inside an Adenovirus), Cansino (Viral Vector with defective replication - Adenovirus 5), Johnson & Johnson (DNA inside an adenovirus), Sinovac (Inactivated Coronavirus), Sinopharm (Inactivated Coronavirus), EpiVacCorona (Viral proteins) and Covaxin (Inactivated chimpanzee adenovirus).[75]

Illustration 4: Immune responses during COVID-19 infection (taken from Cléa Melenotte et al (2020) OncoImmunology, 9:1,)



The purpose of all vaccines is to trick the immune system to make it think that it has already faced a specific virus and to stimulate the immune response (immunogeneses) to produce antibodies. If this takes place, the body has developed immunity to a specific virus or bacteria.

• Level of confidence and public trust. To assess the value of a vaccine, one has to weigh the benefits and risks, the probability of protection versus the potential side effects, such as adverse reactions, which can range from minor to life-threatening. The vaccines that have been developed and approved to confront the COVID-19 pandemic have received an emergency approval. This means that while developers may already know most of the immediate risks and potential side effects, there is no way to assess the long-term risks without the proper length of time usually provided for the approval of any vaccines under normal circumstances. In the U.S., developing and approving a typical vaccine usually takes 5-10 years[76] and sometimes as long as 15 years.[77] Just the first steps, including laboratory and animal studies, take 2 - 4 years. Then the clinical studies involving testing with human subjects during three phases may take about ten years.

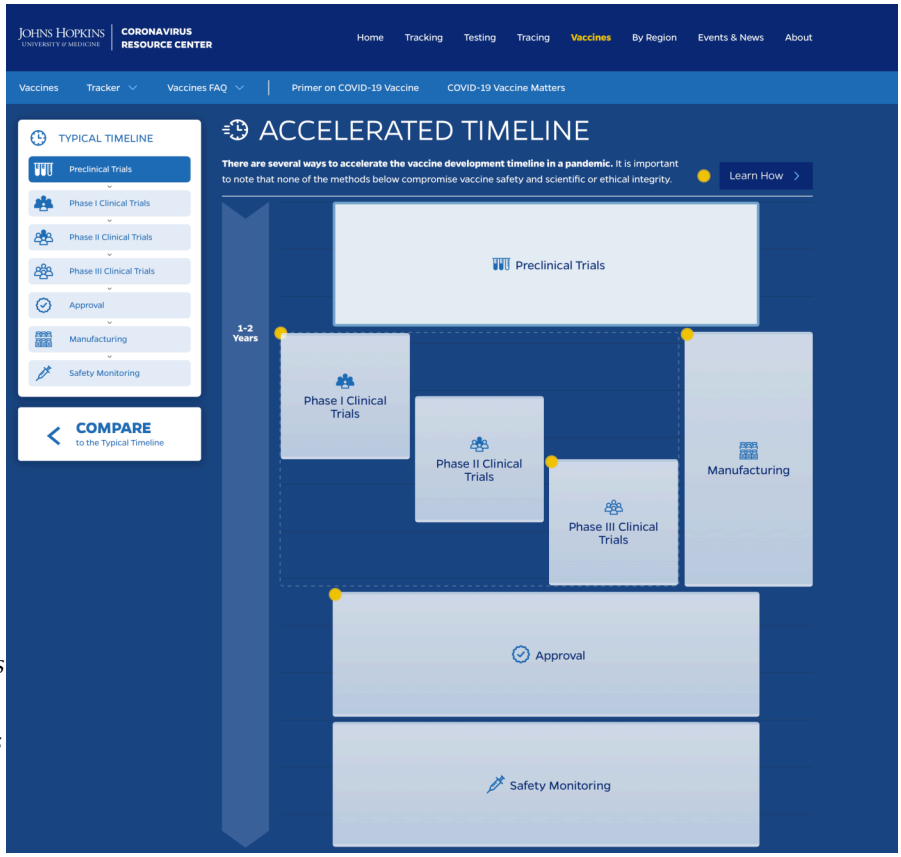
74 ↩ U.S. Department of Health and Human Services: Vaccine Types. As of 11 May 2021.

75 ↩ Carl Zimmer, Jonathan Corum and Sui-Lee Wee: Coronavirus Vaccine Tracker — New York Times, 10 May 2021

76 ↩ Johns Hopkins University: Vaccine Research and Development, as of May 2021.

77 ↩ The College of Physicians of Philadelphia: The History of Vaccines, as of May 2021.

Illustration 5: Accelerated timeline for COVID-19 vaccines (taken from Vaccine Research and Development —Johns Hopkins U.)



In the case of COVID-19, the pre-clinical trials (animal testing) were performed either concurrent with the clinical trials (human testing),[78] after one or various stages of the clinical trials were completed or skipped entirely. The Johns Hopkins portal for COVID-19 explains in detail the difference between the typical timeline for development (5-10 years) and the "accelerated timeline" (1-2 years). In the accelerated timeline shown in illustration 5, the pre-clinical trials do not appear to play a role (lack a yellow dot). The portal explains that to accelerate the process the vaccine developers may combine phases I and II or II and III of the clinical trials. No mention is made of pre-clinical trials. In line with this approach, Harvard Medical School asserts that pre-clinical trials are required for vaccine development: *Animals are infected with the virus. Scientists study their immune response to see what aspects of the immune response might be critical for protection. Normally, a vaccine is first tested in animals. However, in the setting of a pandemic such as this one, the animal testing stage can be skipped.*[79] Tal Zaks, Chief Medical Officer at Moderna, indicates that he *does not think proving this in an animal model is on the critical path to getting this to a clinical trial, and that scientists at the National Institutes of Health are "working on nonclinical research in parallel.*[80] Some scientists in this article seem to think that given the emergency, there is no way to develop new vaccines in an extremely short timeline unless new approaches are taken.

Yet other scientists interviewed considered the ethical factor and the more significant risks convoluted in the rushing of the process. *Outbreaks and national emergencies often create pressure to suspend rights, standards and/or normal rules of ethical conduct. Often our decision to do so seems unwise in retrospect,* wrote Jonathan Kimmelman, Director of McGill University's Biomedical Ethics Unit.[81] The position of governments and media is that the benefits outweigh the risks. However, there are more significant risks associated with using new technologies

Other scientists considered the ethical factor and the more significant risks convoluted in the rushing of the process. Outbreaks and national emergencies often create pressure to suspend rights, standards and/or normal rules of ethical conduct.

78 ↩ Arthur Villasanta: Coronavirus Update: Vaccine Skips Important Animal Testing Phase, Straight To Human Trials, International Business Times, 16 March 2020.

79 ↩ Harvard Health Publishing: COVID-19 vaccines – What you need to know about vaccination, as of May 2021.

80 ↩ Eric Boodman: Researchers rush to test coronavirus vaccine in people without knowing how well it works in animals, STAT, 11 March 2020.

81 ↩ ibidem.

and thus greater ethical questions. The question is complicated by the newness of the science at play with the mRNA messenger vaccines of Moderna and Pfizer. To Holly Fernandez Lynch, Assistant Professor of Medical Ethics at the University of Pennsylvania, rushing the process without properly testing with animals raises a major ethical question: *We may not be able to minimise the risks as much as we would hope to, because we have the time pressure of the outbreak*, thus, *are the remaining risks acceptable in relation to the benefits of the research?*[82] The fact is that no one can assert that the risks will not be more significant than usual due to the emergency of the pandemic. Also, not just the rush to protect people is at play in the acceleration of the process, but the vying of the big-pharma companies for a huge opportunity to maximise their unrelenting quest for profit and shareholder value. It is a carpe diem opportunity.

The fact is that no one can assert that the risks will not be more significant than usual due to the emergency of the pandemic. Also, not just the rush to protect people is at play in the acceleration of the process, but the vying of the big-pharma companies for a huge opportunity to maximise their unrelenting quest for profit and shareholder value.

• Unknown Risks. The above notwithstanding, the far greater issue is the unknown risk of mid and long-term effects that may come from these vaccines. If, instead of a 10-15 year timeline, vaccines have been approved for widespread use in less than a year, the only way of knowing if there are any meaningful risks (adverse side effects) directly associated with any of the vaccines is to wait and see. Governments insist that the benefits outweigh the risks, but how can they know if time has not passed to observe potential risks that can only be identified after years of observation? The Center for Disease Control (CDC) of the U.S. government reports the typical side effect of these vaccines, such as pain, redness, swelling, tiredness, headache, muscle pain, chills, fever and nausea, which are expected. The CDC also acknowledges the rare case of anaphylaxis with the Pfizer vaccine.[83] Harvard Medical School acknowledges the same reaction at 11 per million and the case of 23 unexplained deaths among elderly vaccine recipients in Norway.[84]

The far greater issue is the unknown risk of mid and long-term effects that may come from these vaccines. If, instead of a 10-15 year timeline, vaccines have been approved for widespread use in less than a year, the only way of knowing if there are any meaningful risks (adverse side effects) directly associated with any of the vaccines is to wait and see. Governments insist that the benefits outweigh the risks, but how can they know if time has not passed to observe potential risks that can only be identified after years of observation?

But the issue is not that simple. In the small sample of anaphylaxis cases, the underlying reasons identified behind them were quite diverse, from allergies to tropical fruit, sulpha drugs, walnuts, cats, eggs, milk, penicillin, influenza vaccine and jellyfish, among others.[85] All cases had a history of some kind of allergy. It follows that for people allergic to anything, there is no way of knowing if anyone can get an allergic reaction of the dimension of the anaphylaxis because there is not one specific reason behind it. In another study of 64.900 Mass General Brigham employees receiving the Pfizer vaccine (40%) and the Moderna vaccine (60%), 2,1% experienced an allergic reaction, and 16 experienced an anaphylaxis shock.[86] This means that instead of 11 per million, the rate is 247 per million. The odds are still minimal,

[82] ↩ ibidem.

[83] ↩ Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine — United States, December 14–23, 2020. MMWR Morb Mortal Wkly Rep 2021;70:46–51. DOI: http://dx.doi.org/10.15585/mmwr.mm7002e1

[84] ↩ Robert H. Shmerling: COVID-19 vaccines: Safety, side effects — and coincidence — Harvard Health Publishing, 8 February 2021.

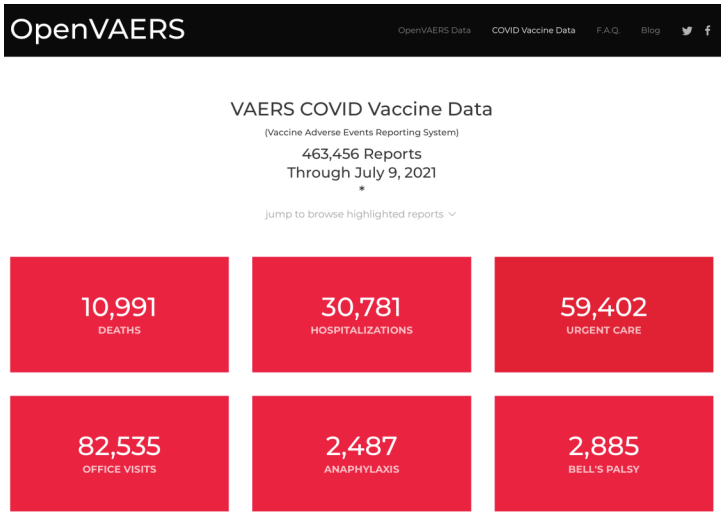
[85] ↩ Tom Shimabukuro and Narayan Nair: Allergic Reactions Including Anaphylaxis After Receipt of the First Dose of Pfizer-BioNTech COVID-19 Vaccine— JAMA Insights |CLINICAL UPDATE, 23 February 2021.

[86] ↩ Blumenthal KG, Robinson LB, Camargo CA, et al. Acute Allergic Reactions to mRNA COVID-19 Vaccines — JAMA April 20, 2021 Volume 325, Number 1

about 0,02% incidence. Yet, it is genuinely a roulette game because virtually anyone with an allergy can have the winning number. Then came the reports of thrombosis in the AstraZeneca vaccine in the European Union and the UK,[87] France[88] and Denmark[89] and 11 cases in the Janssen (Johnson & Johnson) vaccine in the U.S— with three deaths. In both cases, authorities ordered a pause to investigate and a few weeks later resumed vaccination.[90]-[91] In fact, as we write, the U.S. CDC *found more cases of potentially life-threatening blood-clotting among people who received the Johnson & Johnson Covid-19 vaccine and sees a "plausible causal association"*.[92] These are serious events. Unfortunately, the conclusion so far remains that the benefits still outweigh the risks —as long as one is willing to take the risk.[93]

However, what happens as time passes by? If we check the open portal for "Vaccine Adverse Events Reporting System, USA" (illustration 6), we see that through 9 July 2021, there have been 10991 deaths, 30781 hospitalisations and 59402 urgent care cases, among others.[94] VAERS is a national early warning system to detect possible safety problems in U.S.-licensed vaccines.[95] Open VAERS provides access to the general public to the data recorded by VAERS. The numbers may not seem significant given that over 300 million doses of the vaccines approved in the U.S for COVID-19 have been applied. Yet VAERS is a passive reporting system and only records what people or physicians want to report. Thus, it should be considered that VAERS cannot determine if the vaccine caused the reported adverse event and that very few people are aware of VAERS. It follows that the number of unreported adverse effects is likely to be significantly greater.

Illustration 6: VAERS COVID reports (taken from Open VAERS)



Of the 10991 deaths reported, the vast majority were attributed to the mRNA vaccines developed by Pfizer and Moderna for the simple reason that these are the vaccines that have been the most administered in the U.S., by far, as shown in illustration 7. The case of so many adverse effects has prompted physicians such as Eric Caumes of the epidemiology unit of La Pitié-Salpetrière Hospital in Paris to say, despite stating that he is convinced that vaccination is the only way that we can get out of this pandemic, that he is amazed because he has never seen such a high rate of adverse effects in a vaccine, such as in the case of the Pfizer vaccine.[96]

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87 ↩ James Gallagher: Covid-19: Seven UK blood clot deaths after AstraZeneca vaccine, BBC, 3 April 2021.

88 ↩ Hannah Thompson: France AstraZeneca Covid jab: Nine new cases of thrombosis reported — The Conexion, 18 April 2021

89 ↩ Denmark prolongs suspension of AstraZeneca COVID-19 vaccine — CTV News, 25 March 2021.

90 ↩ See I, Su JR, Lale A, et al.: US Case Reports of Cerebral Venous Sinus Thrombosis With Thrombocytopenia After Ad26.COV2.S Vaccination, March 2 to April 21, 2021. JAMA. Published online 30 April 2021.

91 ↩ European Medicine Agency: COVID-19 Vaccine AstraZeneca: PRAC investigating cases of thromboembolic events - vaccine's benefits currently still outweigh risks - Update, 11 March 2021.

92 ↩ Nadeem Badshah (now); Mattha Busby , Tobi Thomas, Martin Belam , Martin Farrer (earlier): 'Plausible causal association' between J&J jab and potentially life-threatening blood clotting — The Guardian, 12 May 2021.

93 ↩ William Petri: Restart of the Johnson & Johnson COVID-19 vaccine: A doctor explains why benefits far outweigh risks — AP News, 26 April 2021.

94 ↩ Open VAERS

95 ↩ VAERS U.S.

96 ↩ PFIZER VACCINE: A WORRYING LEVEL OF ADVERSE EFFECTS, PROFESSOR CAUMES SAYS — Solidaires Sortir Paris, 10 December 2020.

The question is, why is this happening? In the opinion of Acevedo Whitehouse, this is due to some of the adjuvants, the ingredients used in some of the vaccines. In the Pfizer case, she thinks that the reason may be the use of nanolipids that have never been used in a vaccine before (ALC-035 and 0159), as shown in illustration 8, which are used to stabilise the RNA to prevent degradation and facilitate penetrating the cell. By wrapping the RNA in nanolipids, it lasts a lot longer in the cell. Both the Pfizer and Moderna vaccines have PEG 2000 (polyethene glycol), which has not been used before in any vaccines. The AstraZeneca and Sanofi vaccines use polysorbate 80 (illustrations 8 and 9), which has been used in many vaccines before. However, PEG 2000 has not been used before, until the Moderna and Pfizer mRNA vaccines, as shown in Illustration 9 in the table below. It should be known that a large portion of the population (as much as 50% in her opinion) has anti-PEG antibodies because it is used in many consumer products, such as dental paste, shampoos and sweeteners.[97] One relatively recent study reports anti-PEG prevalence ranging from as low as 5% to over 40%.[98] In Acevedo Whitehouse's opinion, this may explain some of the adverse reactions in these vaccines—such as anaphylaxis—that occur at a greater rate than in other vaccines. Moreover, polysorbate is similar to PEG and is used in many medical preparations. This is the underlying reason why both, but especially PEG, may be the cause of anaphylaxis cases with mRNA vaccines. Her opinion is supported by new studies, such as one that states that: *In the context of evolving literature demonstrating PEG as an allergen, many allergists have hypothesised that any cases of anaphylaxis during the rollout of the Pfizer/BioNTech and Moderna severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccines, which use different liposomal delivery vehicles but contain PEG2000 (illustration 9), could potentially be due to preexisting PEG.*[99] This is why the authors reflect in a more recent study that,

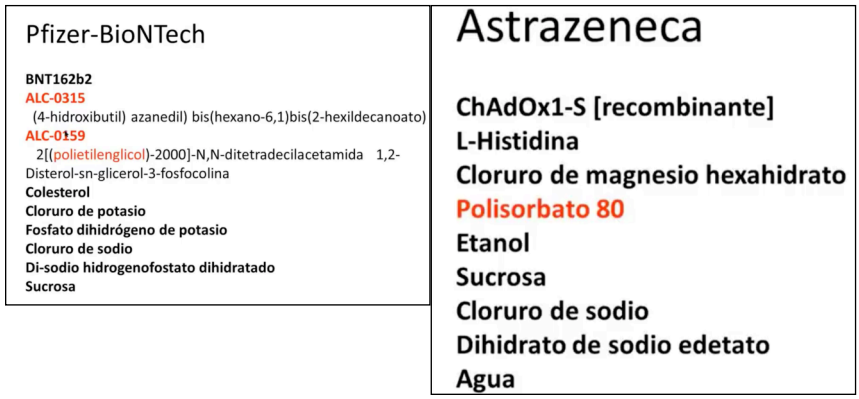
Illustration 7: Deaths reported from COVID-19 vaccines in the U.S. (taken from Open VAERS)

COVID Vaccine Data

Through July 9, 2021

MANUFACTURER	DEATHS
GLAXOSMITHKLINE BIOLOGICALS, MERCK & CO. INC., MODERNA, SANOFI PASTEUR	1
GLAXOSMITHKLINE BIOLOGICALS, MODERNA	1
GLAXOSMITHKLINE BIOLOGICALS, PFIZER\BIONTECH	1
JANSSEN	568
JANSSEN, MODERNA, PFIZER\BIONTECH	1
JANSSEN, UNKNOWN MANUFACTURER	3
MODERNA	2939
MODERNA, PFIZER\BIONTECH	2
MODERNA, UNKNOWN MANUFACTURER	9
PFIZER\BIONTECH	7366
PFIZER\BIONTECH, UNKNOWN MANUFACTURER	71
UNKNOWN MANUFACTURER	29

Illustration 8: Adjuvants in Pfizer BioNTech and AstraZeneca COVID-19 vaccines (taken from Acevedo Whitehouse video presentation)



97 ↩ Karina Acevedo Whitehouse: LA OTRA CARA DE LA MONEDA Charla UM. Dra. Karina Acevedo Whitehouse. 2021. Available as of 10 May 2021.

98 ↩ Qi Yang and Samuel K. La: Anti-PEG immunity: emergence, characteristics, and unaddressed questions — Wiley Interdiscip Rev Nanomed Nanobiotechnol. 2015 September

99 ↩ Aleena Banerji et al: mRNA Vaccines to Prevent COVID-19 Disease and Reported Allergic Reactions: Current Evidence and Suggested Approach — The Journal of Allergy and Clinical Immunology: In Practice, Volume 9, Issue 4, April 2021, Pages 1423-1437.

Despite increasing knowledge, the mechanism of allergic reactions to any of the COVID-19 vaccines remains unclear but the excipients within these vaccines remain a possibility. Polyethylene glycol (PEG) is the common excipient in both mRNA COVID-19 vaccines, whereas polysorbate 80 is the excipient in the Janssen COVID-19 vaccine. PEG and polysorbate are structurally related, and skin testing has shown cross-reactive hypersensitivity in rare cases when evaluation to both excipients has been pursued… At the time of publication, updated CDC guidance states ***(1) if you are allergic to PEG, you should not receive an mRNA COVID-19 vaccine and instead speak to your physician about receiving the Janssen COVID-19 vaccine; (2) if you are allergic to polysorbate 80, you should not receive the Janssen COVID-19 vaccine and instead speak to your physician about receiving the mRNA COVID-19 vaccines; (3) a history of polysorbate allergy is a precaution rather than a contraindication to mRNA vaccination; and (4) vaccination of these individuals (ie, those with PEG or polysorbate allergy histories) should be undertaken only under the supervision of a health care provider experienced in the management of severe allergic reactions.*** *Therefore, the CDC suggests that individuals with a contraindication to the mRNA COVID-19 vaccines (due to a history of possible PEG allergy) may be considered for the Janssen COVID-19 vaccine and similarly, individuals with a contraindication to the Janssen COVID-19 vaccine (due to a history of possible polysorbate allergy) may be considered for the mRNA COVID-19 vaccines. The CDC also provides guidance around use of Janssen COVID-19 vaccine if the recipient develops a severe allergic reaction to dose 1 of an mRNA COVID vaccine, allowing for Janssen vaccination provided a delay between mRNA and Janssen vaccination of at least 28 days.There are currently no efficacy data on this"mix and match"approach, and we do not know the long-term durability of protection from any of the current COVID-19 vaccines. Additionally, on April 13, 2021, the CDC placed the Janssen vaccine on"pause"while investigating adverse events of thrombocytopenia and central venous thrombosis.*[100]

Illustration 9: Polysorbate and PEG excipients in selected vaccines — Institute for Vaccine Safety Excipients in vaccines per 0.5 mL dose. (taken from Aleena Banerji et al: mRNA Vaccines to Prevent COVID-19 Disease and Reported Allergic Reactions)

Table II

Polysorbate and PEG excipients in select vaccines[12]

Excipient	Vaccine type	Vaccine	Amount per dose
Polysorbate 20	Influenza	Flublok&Flublock quad	≤27.5 µg (Tween20)
Polysorbate 20	Hepatitis A	Havrix	0.05 mg/mL
Polysorbate 20	Hepatitis A&B	Twinrix	Unknown
Polysorbate 20*	SARS-CoV-2 (Sanofi)		
Polysorbate 80	Tdap	Boostrix	≤100 µg (Tween 80)
Polysorbate 80	Influenza	Fluad	1.175 mg
Polysorbate 80	Influenza	Fluarix quad	≤0.055 mg (Tween 80)
Polysorbate 80	Influenza	Flucelvax quad	≤1500 µg (Tween 80)
Polysorbate 80	Influenza	Flulaval Quad	≤887 µg
Polysorbate 80	HPV	Gardasil and Gardasil -9	50 µg
Polysorbate 80	Hepatitis B	Heplisav-B	0.1 mg/mL
Polysorbate 80	DTaP	Infanrix	≤100 µg (Tween 80)
Polysorbate 80	Japanese encephalitis	JE-Vax	<0.0007%
Polysorbate 80	DTaP + IPV	Kinrix	≤100 µg (Tween 80)
Polysorbate 80	DTaP + HepB + IPV	Pediarix	≤100 µg (Tween 80)
Polysorbate 80	Pneumococcal 13-valent	Prevnar 13	100 µg
Polysorbate 80	DTaP + IPV	Quadracel	10 ppm
Polysorbate 80	Rotavirus	RotaTeq	?
Polysorbate 80	Zoster	Shingrix	0.08 mg
Polysorbate 80	Meningococcal group B	Trumenba	0.018 mg
Polysorbate 80	DTaP + IPV + HepB + Hib	Vaxelis	<0.0056%
Polysorbate 80*	SARS-CoV-2 (AstraZeneca) SARS-CoV-2 (Johnson & Johnson)		
PEG2000	SARS-CoV-2 (Moderna) SARS-CoV-2 (Pfizer)		

*Not approved at the time of publication.

It is evident from the above analysis that "one size does not fit all" for COVID-19 vaccines. The risks will be lower or higher depending, particularly, on the allergic history of the individual. There is another major issue in the management of vaccines concerning the autoimmune/inflammatory syndrome induced by adjuvants (ASIA) that must be considered. The syndrome can cause systemic sclerosis, Systemic lupus erythematosus, rheumatoid arthritis and autoimmune thyroid, among others.[101]-[102] ASIA has a substantial genetic component with the name DRB1*01, which produces a greater risk among people of having a problem with any vaccine

It is evident from the above analysis that "one size does not fit all" for COVID-19 vaccines.

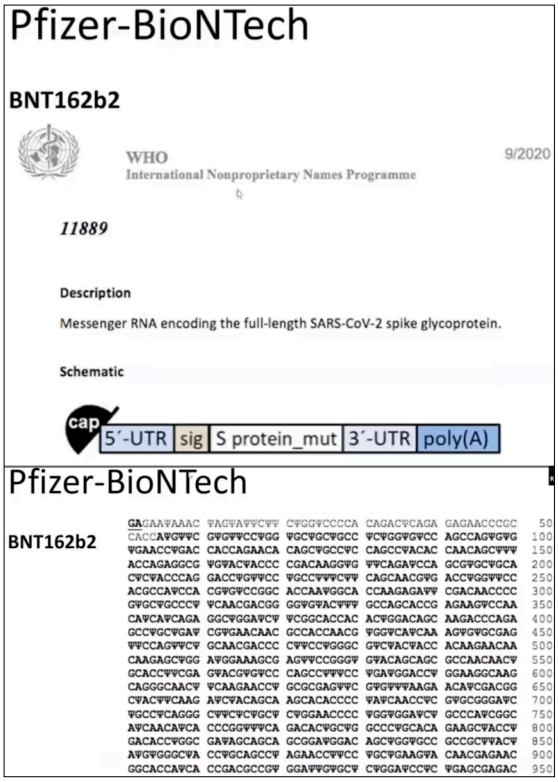
[100] ↩ Aleena Banerji et al: COVID-19 Vaccination in Patients with Reported Allergic Reactions: Updated Evidence and Suggested Approach — The Journal of Allergy and Clinical Immunology: In Practice, Available online 15 April 2021

[101] ↩ Karina Acevedo Whitehouse: LA OTRA CARA DE LA MONEDA Charla UM. Dra. Karina Acevedo Whitehouse. 2021. Available as of 10 May 2021.

[102] ↩ Abdulla Watad et al: The autoimmune/inflammatory syndrome induced by adjuvants (ASIA)/Shoenfeld's syndrome: descriptive analysis of 300 patients from the international ASIA syndrome registry — Clin Rheumatol. 2018 Feb. Epub 2017 Jul 25. PMID: 28741088.

adjuvants. Normally, no one knows their genetic make-up unless a specific test is performed for some medical need. Acevedo Whitehouse asserts that this is a severe problem because, in the absence of knowledge about this genetic component in the general population, it is impossible to carry out preventive measures when administering vaccines to reduce the chance of anaphylaxis or other severe adverse reactions. The fact that the mRNA uses the nanolipids above makes it far more difficult to break down. The sequencing of the messenger RNA encoding the entire length of SARS-CoV-2 spike glycoprotein shows (illustration 10) that it has a methylated base, and this is what makes it far more difficult to break it down. Hence the mRNA messenger will remain for a long time in the cell generating the spike protein. Moreover, the mRNA molecule does not remain in the tissue of inoculation but goes to tissues everywhere in the body, to the brain, heart, lung, rectum, testicles, among others. Acevedo Whitehouse supports her argumentation on a study prepared by researchers at Moderna in 2017 with mice for a messenger RNA influenza vaccine.[103] The mRNA messenger vaccine was distributed into the tissues of many organs.[104] The risk at hand is that the ASIA immune pathology, previously mentioned, may be exacerbated by these clinical manifestations regardless of whether the vaccine is mRNA or another kind. If a vaccine produces antibodies and then they confront a virus, it will produce immune complexes that, in the case of COVID-19, will produce a COVID complex. In other words, the vaccine may produce the same clinical manifestations/symptoms as COVID.

Illustration 10: Pfizer-BioNTech RNA encoding sequencing ((taken from Acevedo Whitehouse video presentation)



There is another risk that has been researched for all the COVID vaccines: the antibodies that we produce end with a lesser affinity—if there are changes in the spike protein—to the new virus mutations, which would help the virus to penetrate the cells. This is known as antibody-dependent enhancement (ADE). Both risks are illustrated and explained in illustration 11. The researchers conclude that *ADE has been observed in SARS, MERS and other human respiratory virus infections*, including RSV and measles, suggesting a real risk of ADE for SARS-CoV-2 vaccines and antibody-based interventions. Going forwards, it will be crucial to evaluate the animal and clinical datasets for signs of ADE and to balance ADE-related safety risks *against intervention efficacy if clinical ADE is observed.*[105] The ADE is well-known in the scientific community to be a risk with vaccines. They consider that a major challenge in rapid vaccine development is avoiding safety issues by both thoughtful vaccine design and a thorough evaluation. Given that the syndrome of "disease enhancement" (ADE) has been reported in the past for a few viral vaccines, the fact that SARS-CoV-1 vaccines have shown evidence of ADE in some animal models is of particular concern for SARS-CoV-2 vaccines. For this reason, the Coalition for Epidemic Preparedness Innovations (CEPI) and the Brighton Collaboration (BC) Safety Platform for Emergency Vaccines (SPEAC) convened a scientific working meeting on March 12 and 13, 2020, to address the

[103] ↩ No mRNA vaccines had been approved to be used in humans before COVID-19.

[104] ↩ Bahl K, Senn JJ, Yuzhakov O, et al. Preclinical and Clinical Demonstration of Immunogenicity by mRNA Vaccines against H10N8 and H7N9 Influenza Viruses. Mol Ther. 2017;25(6):1316-1327.

[105] ↩ Wen Shi Lee 1, Adam K. Wheatley 1,2, Stephen J. Kent 1,2,3 ✉ and Brandon J. DeKosky: Antibody-dependent enhancement and SARS-CoV-2 vaccines and therapies — Nature Microbiology - Perspective,

issue. *The group found that there is evidence for "disease enhancement" in vaccinated animals after challenge with live virus in multiple studies with SARS–CoV-1 vaccine candidates* as summarised in illustration 12.[106]

Illustration 11: Two main ADE mechanisms in viral disease (taken from Wen Shi Lee et al: Antibody-dependent enhancement and SARS-CoV-2 vaccines and therapies)

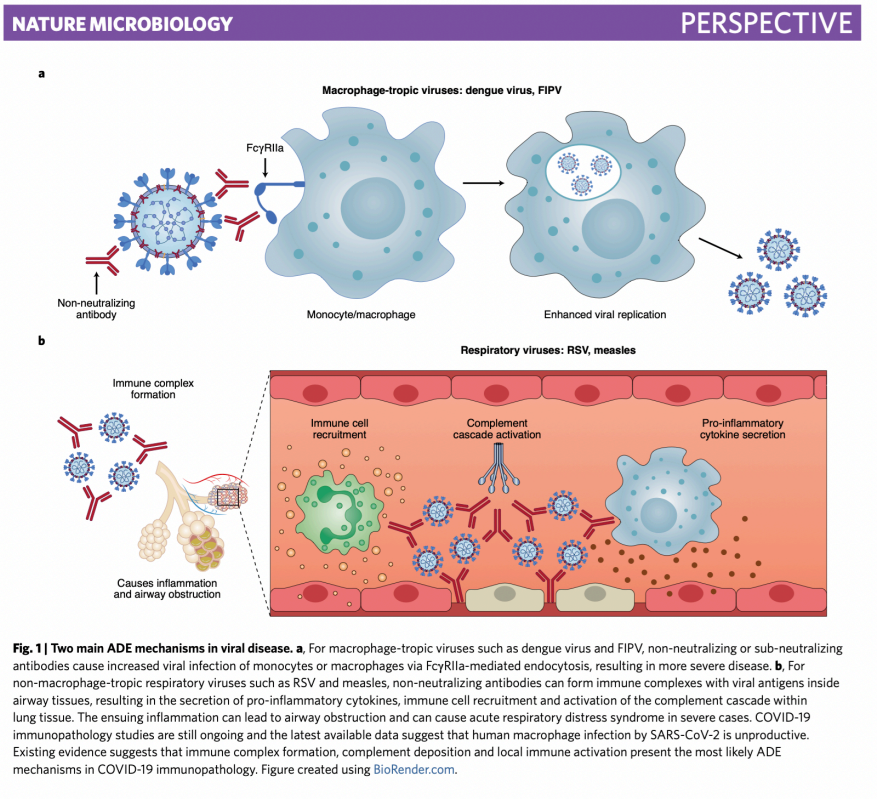


Fig. 1 | Two main ADE mechanisms in viral disease. a, For macrophage-tropic viruses such as dengue virus and FIPV, non-neutralizing or sub-neutralizing antibodies cause increased viral infection of monocytes or macrophages via FcγRIIa-mediated endocytosis, resulting in more severe disease. **b**, For non-macrophage-tropic respiratory viruses such as RSV and measles, non-neutralizing antibodies can form immune complexes with viral antigens inside airway tissues, resulting in the secretion of pro-inflammatory cytokines, immune cell recruitment and activation of the complement cascade within lung tissue. The ensuing inflammation can lead to airway obstruction and can cause acute respiratory distress syndrome in severe cases. COVID-19 immunopathology studies are still ongoing and the latest available data suggest that human macrophage infection by SARS-CoV-2 is unproductive. Existing evidence suggests that immune complex formation, complement deposition and local immune activation present the most likely ADE mechanisms in COVID-19 immunopathology. Figure created using BioRender.com.

There is an additional risk with viral vector adenovirus vaccines for SARS-CoV-2. Researchers expressed concern about using recombinant adenovirus type-5 (Ad5) vector in the development of COVID-19 vaccines. This is stressed in an article in the Lancet based on past experience in research studies—Step and Phambili phase 2b studies—carried out over a decade ago in developing HIV vaccines. The studies found that there is an increased risk of HIV-1 acquisition among vaccinated men. The studies found that men who were Ad5 seropositive and uncircumcised were at an elevated risk of HIV-1 acquisition, and that the hazard ratios were particularly high among uncircumcised men. Additional exploratory studies suggest that pre-existing Ad5 immunity might dampen desired vaccine-induced responses and that Ad5 immune complexes might enhance HIV-1 replication.[107] A 2014 article, signed by Dr Fauci and others, revisits this issue and considers that given the increased risk together with the lack of efficacy in trials using rAd5, further HIV vaccine studies testing rAd5 vectors are not appropriate.[108] Hence, the scientists who conducted the Step and Pambili studies, reflecting on the current pandemic, conclude that ***on the basis of these findings, the use of an Ad5 vector for immunisation against severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) could similarly increase the risk of HIV-1 acquisition among men who receive the vaccine.*** The problem is that already two adenovirus vaccines: Sputnik and Cansino, use AD5 and have been approved in at least one country.[109] Furthermore, in the opinion of Acevedo Whitehouse, no Adenovirus type-5 vectored vaccines should be developed

It is not proper nor ethical to give vaccines as if they fit all. It is necessary to know what side effects vaccines can cause at different ages, in different physiological conditions such as pregnancy, with different pathological conditions, and to identify risk groups for different COVID-19 vaccines. Vaccines should not be applied indiscriminately.

106 ↩ Paul-Henri Lambert: Consensus summary report for CEPI/BC March 12–13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines — Vaccine Volume 38, Issue 31, 26 June 2020, Pages 4783-4791

107 ↩ Susan P Buchbinder, M Juliana McElrath, Carl Dieffenbach, Lawrence Corey: Use of adenovirus type-5 vectored vaccines: a cautionary tale — The Lancet - CORRESPONDENCE| VOLUME 396, ISSUE 10260, E68-E69, OCTOBER 31, 2020.

108 ↩ Anthony S. Fauci1,*, Mary A. Marovich1, Carl W. Dieffenbach1, Eric Hunter2, and Susan P. Buchbinder: Immune Activation with HIV Vaccines: Implications of the Adenovirus Vector Experience — Science 04 Apr 2014: Vol. 344, Issue 6179, pp. 49-51

109 ↩ Wikipedia: Viral Vector Vaccines, as of 13 May 2021.

for any type of vaccine, not just for COVID-19, because of the increased risk in men of HIV infection. Her fundamental argument is that COVID-5 vaccines should not be given liberally or, worse, mixed vaccines. She believes that no effort is being made to identify risk groups for different vaccines in phase III studies that will not be completed until 2022. It is not proper nor ethical to give vaccines as if they fit all. It is necessary to know what side effects vaccines can cause at different ages, in different physiological conditions such as pregnancy, with different pathological conditions, and to identify risk groups for different COVID-19 vaccines. Vaccines should not be applied indiscriminately.[110]

The dominant position that the benefits outweigh the risks is irresponsible and unethical. Determining the genetic component of each person may be an insurmountable challenge. However, assessing the clinical profile of each individual with a proper interview should at least reduce the risk meaningfully.

Illustration 12: Evidence of enhanced disease in SARS-CoV-1 vaccine candidates (taken from Paul-Henri Lambert: Consensus summary report for CEPI/BC March 12–13, 2020 meeting: Assessment of risk of disease enhancement with COVID-19 vaccines)

Table 1

Evidence of enhanced disease in SARS-CoV-1 vaccine candidates.

Animal Model	Vaccine	Adjuvant	Immunopathology	Reference
Murine[1]	VEE Replicon Particles expressing N protein	–	YES	Deming 2006
Murine[2]	Recombinant Vaccinia virus expressing N protein	–	YES	Yasui 2008
Murine[3]	Inactivated Whole Virus	Alum	YES	Bolles 2011
		–	YES	
Murine[4]	Replicon Particles expressing S protein	–	YES	Sheahan 2011
Murine[5]	Inactivated Whole Virus and S protein vaccines	Alum	YES	Tseng 2012
		–	YES	
Ferret[6]	Recombinant Modified Vaccinia Virus Ankara (rMVA) expressing S protein	–	YES†	Weingartl 2004
NHP[7]	Modified Vaccinia Ankara (MVA) virus encoding full-length S protein	–	YES	Liu 2019
	Passive anti-S sera	N/A	YES	
NHP[7]	Inactivated Whole Virus	–	YES	Wang 2016/2020
	Passive Human SARS Antiserum	N/A	YES	

From the findings of different researchers previously mentioned, it is evident that the population has the right to be well-informed in detail before people decide to get vaccinated. Governments have the responsibility to provide such information by directing their medical communities to assess the physiological conditions of each person and then determine which vaccine is appropriate or if a person should not receive any of the vaccines currently under development. Governments are responsible for minimising at maximum the odds for the occurrence of any of the severe adverse reactions previously noted or new reactions that have not yet been identified. In our opinion, the dominant position that the benefits outweigh the risks is irresponsible and unethical. What if any of the government administrators of the vaccine experience dangerous severe adverse reactions because they did not know they were allergic to any of the vaccines' components or because their immune systems

Governments are obliged to fulfil people's right to be adequately informed and ensure that the type of experimental vaccine to be applied to an individual will not pose a danger to life. Instead they shield all the pharmaceutical companies developing the COVID experimental vaccines from any responsibility. If there is so much confidence about the safety of COVID-19 vaccines, why do they shield pharmaceutical companies from any liability for potential adverse effects.

[110] ↩ Karina Acevedo Whitehouse: LA OTRA CARA DE LA MONEDA Charla UM. Dra. Karina Acevedo Whitehouse. 2021. Available as of 10 May 2021.

are compromised in some way? Determining the genetic component of each person may be an insurmountable challenge. However, assessing the clinical profile of each individual with a proper interview should at least reduce the risk meaningfully.

Governments are obliged to fulfil people's right to be adequately informed and ensure that the type of experimental vaccine to be applied to an individual will not pose a danger to life. Doing this may increase the cost of carrying out the vaccination effort. Yet, lives are far more important than cost, and it is a public health responsibility to administer the vaccines with utmost care to preserve the lives and the health of the majority. However, instead of governments showing their total commitment to the public health of their Demos, they shield all the pharmaceutical companies developing the COVID experimental vaccines from any responsibility if they produce severe health problems or death to any of the recipients.[111] In the U.S., according to U.S. Code § 300aa–22 - Standards of responsibility *(1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.*[112] Furthermore, there is the National Vaccine Injury Compensation Program (VICP) administered by the U.S. Department of Health and Human Services (HHS). The programme may provide financial compensation to individuals who file a petition and are found to have been injured by a VICP-covered vaccine.[113] But none of the COVID-19 experimental vaccines are covered by such a programme.[114] If there is so much confidence about the safety of COVID-19 vaccines, why do they shield pharmaceutical companies from any liability for potential adverse effects and why are COVID-19 vaccines not covered by the VICP? No compensation scheme for COVID-19 has been developed in the world so far.[115]

• COVID-19 controversies. This is the proper time to state that it has been extremely notorious that any kind of questioning about the vaccine effort is automatically and sometimes harshly repressed by the system, including governments, medical authorities and the marketocratic media. Hence, it is likely that many who may read this paper will regard it as anti-vaccine for making constant references and quoting many papers from scientific researchers who have considerations about a diversity of aspects about COVID-19 or the vaccines that have been developed to confront it. It should be clear that none of the sources we have quoted are against vaccines, but many see valid caveats in the way they are being developed and administered that increase the risks to public health. However, some people have been able to get a response but remain concerned about the way vaccines have been administered. This is the case of several hundred doctors in Europe who have organised as “Doctors for COVID Ethics”, who sent letters of concern to the European Medicines Agency, the maximum authority in the European Union in charge of the evaluation and supervision of medicinal products. In their letters, they urgently warn of

> *short term and long term dangers from COVID-19 vaccines, including clotting, bleeding and platelet abnormalities*. They also demand *the immediate withdrawal of all experimental gene-based COVID-19 vaccines. We oppose vaccine passports, which threaten public health and violate Nuremberg and other protections. We are warning that 'health passes' place coercive pressure on citizens to submit to dangerous medical experimentation,*

111 ↩ Ludwig Burger, Pushkala Aripaka: AstraZeneca to be exempt from coronavirus vaccine liability claims in most countries — Reuters, 30 July 2020.

112 ↩ Cornell Law School - Legal Information Institute: 42 U.S. Code § 300aa–22 - Standards of responsibility

113 ↩ HRSA: National Vaccine Injury Compensation Program

114 ↩ HRSA: National Vaccine Injury Compensation Program - Covered Vaccines

115 ↩ Sam Halabi, Andrew Heinrich and Saad B. Omer: No-Fault Compensation for Vaccine Injury — The Other Side of Equitable Access to Covid-19 Vaccines — The New England Journal of Medicine, 3 December 2020.

> *in return for freedoms that once were human rights.*[116] In their first letter, they detail a series of concerns and state that *should all such evidence not be available, we demand that approval for use of the gene-based vaccines be withdrawn until all the above issues have been properly addressed by the exercise of due diligence by the EMA.*[117]

On 23 March, they received a response that dismisses their concerns.[118] Thus, they sent a rebuttal letter—point by point—in April in which they state that,

> *Regrettably, your reply of March 23 is unconvincing and unacceptable. We are dismayed that you choose to respond to our request for crucially important information in a dismissive and unscientific manner. Such a cavalier approach to vaccine safety creates the unwelcome impression that the EMA is serving the interests of the very pharmaceutical companies whose products it is your pledged duty to evaluate. The evidence is clear that there are some serious adverse event risks & that a number of people, not at risk from SARS-CoV-2, have died following vaccination* and accuse the EMA of persistently shrinking from open debate and the truth. They end by stating that, *You understand that coercive pressure is being placed on citizens to receive COVID-19 vaccines, which are experimental medical treatments. Your responsibility to those citizens includes ensuring that they are informed of the adverse event risks of every such treatment. To date you have failed to do so, and have instead misled the public on the reality of the "vaccines'" risk-benefit profile. If you continue to conceal the truth, efforts will be made to bring this to light and to see that justice is done. For the sake of the injured and the dead, and to protect further lives from similar fates.*[119]

There is a major and quite reasonable concern and frustration for the refusal to enter into an open dialogue on the part of the EMA. Needless to say that many of the concerns they express have to do with the adverse reactions addressed in this paper. They express frustration because their *concerns arise from multiple lines of evidence, including that the SARS-CoV-2 "spike protein" is not a passive docking protein, but its production is likely to initiate blood coagulation via multiple mechanisms,* and because they did not receive *reassurance that foreseeable risks of gene-based COVID-19 "vaccines" had been ruled out in animal trials prior to human use,* among others.[120]

Instead of a general agreement, there is an underground debate only because the authorities in most parts of the world have refused to sustain an open dialogue. One major issue in which we do not need to be scientists to be certain about is that the only way to know is to let time pass, and this represents a significant risk and a major unethical demeanour of unknown proportions that nobody can deny. Hence, the assertion that "the benefits outweigh the risks" is nothing more than a bet at the cost of the people that will have to die for being part of this experiment.

Clearly, there is much concern from many scientists and physicians about the development of these vaccines. Instead of a general agreement, there is an underground debate only because the authorities in most parts of the world have refused to sustain an open dialogue. Furthermore, one major issue in which we do not need to be scientists to be certain

116 ↩ Doctors for COVID ethics, about — as of 12 May 2021.

117 ↩ Doctors for COVID ethics: Urgent Open Letter from Doctors and Scientists to the European Medicines Agency regarding COVID-19 Vaccine Safety Concerns, 28 February 2021.

118 ↩ Doctors for COVID ethics: Reply from the European Medicines Agency to Doctors for Covid Ethics, March 23, 2021

119 ↩ Doctors for COVID ethics: Rebuttal letter to European Medicines Agency from Doctors for Covid Ethics, April 1, 2021

120 ↩ ibidem.

about is that because these vaccines have been approved without the customary 5-10 years length of time required to determine whether or not they may embody major risks to public health—affecting billions of people around the world—the only way to know is to let time pass, and this represents a significant risk and a major unethical demeanour of unknown proportions that nobody can deny. Since the original publication of this excerpt two new adverse reaction have been identified. The CDC reported that, *there have been more than a thousand reports to VAERS of cases of inflammation of the heart—called myocarditis and pericarditis—happening after mRNA COVID-19 vaccination (i.e., Pfizer-BioNTech, Moderna) in the U.S.*[121] As for the Janssen vaccines, the FDA *announced revisions to the vaccine recipient to include information pertaining to an observed increased risk of Guillain-Barré Syndrome (GBS) following vaccination. GBS is a neurological disorder in which the body's immune system damages nerve cells, causing muscle weakness, or in the most severe cases, paralysis.*[122] Hence, the assertion that "the benefits outweigh the risks" is nothing more than a bet at the cost of the people who will have to die for being part of this experiment. Only time will tell.

This is the main reason why vaccination efforts are beginning to stall as they face public resistance. In the U.S., for instance, polls show that about thirty per cent of the population is reluctant to be vaccinated. This defeats the purpose of achieving herd immunity, and so-called experts already acknowledge it.[123] The effort to convince people persists. Yet, unless specific policies are adopted to reduce risks, and the public is appropriately informed—which is our right and governments must fulfil it—such as assessing the physiological conditions of each potential vaccine candidate to determine which vaccine is suitable or none, herd immunity is unlikely to be achieved. At the very least, governments must prepare informative brochures in lay language to inform people about the current vaccines, that one size does not fit all, that there are pros and cons to each vaccine, depending on the clinical profile of each person, that depending on our profile, one vaccine will be the best suited for each specific case and that in some cases, there may be no vaccine suited for a person, and they will have to remain unvaccinated until other vaccines are developed.[124] This is not a suggestion. Governments' ethical responsibility is to properly inform the Demos so that we can freely choose after being adequately informed and not just told that we must get vaccinated by inducing fear—implicitly or explicit—that if we do not, we may die.

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However, parting from the fact that we are enduring a marketocratic ethos, where governments serve the market and not the Demos, it is unlikely that this will change for the better unless people organise to the level necessary to force governments to fulfil their duty.

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121 ↩ CDC: Myocarditis and Pericarditis Following mRNA COVID-19 Vaccination, 23 June 2021

122 ↩ FDA News Release: Coronavirus (COVID-19) Update: July 13, 2021

123 ↩ Apoorva Mandavilli: Reaching 'Herd Immunity' Is Unlikely in the U.S., Experts Now Believe — The New York Times, 3 May 2021.

124 ↩ Many COVID-19 vaccines are in development. One recent case is the Coronavax vaccine in the U.S. This vaccine uses a well-established protein-based traditional approach, unlike the mRNA vaccines, and other COVID-19 vaccines, with very similar efficacy and less risk according to their clinical trials and various initial assessments. See: Hilda Bastian: The mRNA Vaccines Are Extraordinary, but Novavax Is Even Better — The Atlantic, 24 June 2021. Also Trial Site staff: Breaking News Novavax' Traditional Vaccine Brings Imminent Competition to the Genetic-based Vaccines Currently Under EUA, Trial Site News, 14 June 2021.

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- **About the author:** Álvaro J. de Regil is the Project initiator and Executive Director of The Jus Semper Global Alliance since 2003. At a broader level, his work is currently centred on advancing a "people and planet" paradigm. As part of this transformative concept, he is active in the areas of labour rights, business and human rights, no-growth / degrowth / steady-state economics, basic income and the drastic reduction of humanity's environmental footprint on our planet as the only way to achieve real sustainability of life on our home: planet earth. Álvaro is also a founding member and facilitator of the International Living Wage Observatory at La Salle University (Mexico City campus), a contributor to the transformative vision and praxis of the Great Transition Initiative of the Tellus Institute in Boston, Massachusetts and consultant on the underlying causes of immigration with various community organisations in California.

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