Joardan,

I have several documents that I will be emailing to you. I am not able to attach them all in one file. This is the first round.

Before the legislatures move forward with this criminal decision regarding forced "vaccines" onto state employees, UNR staff and students as well as others, you better read everything I am sending you. This is a global conspiracy that was brought to us and Dr. David Martin has laid the proof out as well as others. Dr. David Martin has followed the US Patents and this Plandemic has been planned for a long time and he proves it with the Patents he has discovered.

Dr. Reiner Fuellmich is the front person for the Corona Committee out of Germany and he has already presented his evidence that his committee has collected from hundreds if not thousands of people from all over the world and he went before the Warsaw Poland Parliament and after they heard his evidence they have decided to move forward with kicking off Nuremberg 2.0 because this whole Corona Plandemic is Crimes Against Humanity and people must be held accountable.

You can watch the video here to hear the evidence he spoke about.

https://notaakhirzaman.com/8171/

This is their Corona Committee Website

https://corona-ausschuss.de/en/

This PDF File is Dr. David Martin and the Fauci Conspiracy

Karen Kingston is a Pfizer whistleblower and all information she presents is always backed up by official documents. I suggest you watch her video with Stew Peters. Karen also covers how most officials have been told that they have immunity under the Prep Act and can push forward with this global genocide agenda but she also shows you through the Prep Act that those involved have zero immunity when there is death or injuries and they can then be held liable and accountable if there is death or injury.

https://www.redvoicemedia.com/2021/12/time-to-arrest-covid-tyrants-notice-public-officials-are-committing-felony-crimes/

#### https://renz-law.com/

Thomas Renz is an Attorney and he has posted lots of evidence and he even spoke recently at a convention about there being USA Nuremberg 2.0 trials. Our AG might not be doing anything but there are plenty around the nation that are banding together.

#### https://openvaers.com/covid-data

Open VAERS shows that over 20,000 people have died and thousands more have had adverse reactions to these bioweapon injections. They are not vaccine's because they do not deliver medicine. They deliver gene therapy. Only 1%-3% of deaths and injuries get reported into the VAERS system so you know these numbers are much higher than what they are showing here. Obama used this same system to stop the Swine Flu when 20 people died from that.

Our Legislatures should be working to rein in our Corrupt Governors "Emergency Power" instead of adding fuel to the fire and becoming part of The Crimes Against Humanity which still carries up to the death penalty for those that violate the Nuremberg Code. Our Legislatures should be talking to our Attorney General and having him open an investigation and seek grand juries and prosecution for Crimes that are and have been committed during this whole scam.

You can read the Nuremberg Code here:

http://www.cirp.org/library/ethics/nuremberg/

#### https://truth11.files.wordpress.com/2021/12/athletes-after-vaccination-.pdf

Athletes around the World are dropping dead and they all took the shot. There are videos of them dropping on the field. Others have spoken out that their careers are over because they now suffer from inflamed hearts because of the injections.

#### https://www.bitchute.com/video/FivK5lzEMNTR/

Senator Ron Johnson held a Committee and spoke to healthcare professionals and those that have been injured by these injections.

If you all move forward with this agenda and pass this into law then you all will be guilty of Crimes against humanity and can therefore be held liable and accountable.

Looks around this whole Global "Pandemic" is falling apart. The American People are awake and will not stand by while our own Government turns against us and weaponizes the Legislation against us by trying to force this bioweapon injection on Nevada citizens.

#### https://www.leg.state.nv.us/NRS/NRS-282.html

You all took an Oath to support and defend the Constitution. Have you forgotten?

#### https://www.bartleylawoffice.com/useful/what-is-the-supreme-law-of-land.html

The Constitution is the Supreme Law of the Land and any State that passes laws that are Unconstitutional are null and void because The Constitution is the Supreme Law of the Land.

I really hope you consider and weigh everything I have presented to you and that you make the right decision and do not weaponize the Legislatures against We The People.

Michelle

# The Fauci/COVID-19 Dossier

This document is prepared for humanity by Dr. David E. Martin.



# The Fauci/COVID-19 Dossier

This document is prepared for humanity by Dr. David E. Martin.



This work was supported, in part, by a fund-raising effort in which approximately 330 persons contributed funds in support of the New Earth technology team and Urban Global Health Alliance. It is released under a Creative Commons license CC-BY-NC-SA. Any derivative use of this dossier must be made public for the benefit of others. All documents, references and disclosures contained herein are subject to an AS-IS representation. The author does not bear responsibility for errors in the public record or references therein. Throughout this document, uses of terms commonly accepted in medical and scientific literature do not imply acceptance or rejection of the dogma that they represent.

#### **Background:**

Over the past two decades, my company – M·CAM – has been monitoring possible violations of the 1925 Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or other Gases, and of Bacteriological Methods of Warfare (the Geneva Protocol) 1972 Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological and Toxin Weapons and Their Destruction (the BTWC). In our 2003-2004 *Global Technology Assessment: Vector Weaponization* M·CAM highlighted China's growing involvement in Polymerase Chain Reaction (PCR) technology with respect to joining the world stage in chimeric construction of viral vectors. Since that time, on a weekly basis, we have monitored the development of research and commercial efforts in this field, including, but not limited to, the research synergies forming between the United States Centers for Disease Control and Prevention (CDC), the National Institutes for Allergies and Infectious Diseases (NIAID), the University of North Carolina at Chapel Hill (UNC), Harvard University, Emory University, Vanderbilt University, Tsinghua University, University of Pennsylvania, many other research institutions, and their commercial affiliations.

The National Institute of Health's grant Al23946-08 issued to Dr. Ralph Baric at the University of North Carolina at Chapel Hill (officially classified as affiliated with Dr. Anthony Fauci's NIAID by at least 2003) began the work on synthetically altering the *Coronaviridae* (the coronavirus family) for the express purpose of general research, pathogenic enhancement, detection, manipulation, and potential therapeutic interventions targeting the same. As early as May 21, 2000, Dr. Baric and UNC sought to patent critical sections of the coronavirus family for their commercial benefit. In one of the several papers derived from work sponsored by this grant, Dr. Baric published what he reported to be the full length cDNA of SARS CoV in which it was clearly stated that SAR CoV was based on a composite of DNA segments.

"Using a panel of contiguous cDNAs that span the entire genome, we have assembled a fulllength cDNA of the SARS-CoV Urbani strain, and have rescued molecularly cloned SARS

<sup>&</sup>lt;sup>1</sup> U.S. Provisional Application No. 60/206,537, filed May 21, 2000

viruses (infectious clone SARS-CoV) that contained the expected marker mutations inserted into the component clones."<sup>2</sup>

On April 19, 2002 – the Spring before the first SARS outbreak in Asia – Christopher M. Curtis, Boyd Yount, and Ralph Baric filed an application for U.S. Patent 7,279,372 for a method of producing recombinant coronavirus. In the first public record of the claims, they sought to patent a means of producing, "an infectious, replication defective, coronavirus." This work was supported by the NIH grant referenced above and GM63228. In short, the U.S. Department of Health and Human Services was involved in the funding of amplifying the infectious nature of coronavirus between 1999 and 2002 **before SARS** was ever detected in humans.

Against this backdrop, we noted the unusual patent prosecution efforts of the CDC, when on April 25, 2003 they sought to patent the SARS coronavirus isolated from humans that had reportedly transferred to humans during the 2002-2003 SARS outbreak in Asia. 35 U.S.C. §101 prohibits patenting nature. This legality did not deter CDC in their efforts. Their application, updated in 2007, ultimately issued as U.S. Patent 7,220,852 and constrained anyone not licensed by their patent from manipulating SARS CoV, developing tests or kits to measure SARS coronavirus in humans or working with their patented virus for therapeutic use. Work associated with this virus by their select collaborators included considerable amounts of chimeric engineering, gain-of-function studies, viral characterization, detection, treatment (both vaccine and therapeutic intervention), and weaponization inquiries.

In short, with Baric's U.S. Patent 6,593,111 (Claims 1 and 5) and CDC's '852 patent (Claim 1), no research in the United States could be conducted without permission or infringement.

We noted that gain-of-function specialist, Dr. Ralph Baric, was both the recipient of millions of dollars of U.S. research grants from several federal agencies but also sat on the World Health Organization's International Committee on Taxonomy of Viruses (ICTV) and the *Coronaviridae* Study Group (CSG). In this capacity, he was both responsible for determining "novelty" of clades of virus species but directly benefitted from determining declarations of novelty in the form of new research funding authorizations and associated patenting and commercial collaboration. Together with CDC, NIAID, WHO, academic and commercial parties (including Johnson & Johnson; Sanofi and their several coronavirus patent holding biotech companies; Moderna; Ridgeback; Gilead; Sherlock Biosciences; and, others), a powerful group of interests constituted what we would suggest are "interlocking directorates" under U.S. anti-trust laws.

These entities also were affiliated with the WHO's Global Preparedness Monitoring Board (GPMB) whose members were instrumental in the Open Philanthropy-funded global coronavirus pandemic "desk-top" exercise EVENT 201 in October 2019. This event, funded by the principal investor in Sherlock Biosciences and linking interlocking funding partner, the Bill and Melinda Gates Foundation into the GPMB mandate for a respiratory disease global preparedness exercise to be completed by September 2020 alerted us to anticipate an "epidemic" scenario. We expected to see such a scenario emerge from Wuhan or Guangdong China, northern Italy, Seattle, New York or a combination thereof, as Dr. Zhengli Shi and Dr. Baric's work on zoonotic transmission of coronavirus identified overlapping mutations in coronavirus in bat populations located in these areas.

This dossier is by no means exhaustive. It is, however, indicative the numerous criminal violations that may be associated with the COVID-19 terrorism. All source materials are referenced herein. An

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<sup>&</sup>lt;sup>2</sup> https://www.pnas.org/content/100/22/12995

additional detailed breakdown of all the of individuals, research institutions, foundations, funding sources, and commercial enterprises can be accessed upon request.

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### 35 U.S.C. § 101

#### From Justice Clarence Thomas' opinion for the majority

Section 101 of the Patent Act provides: "Whoever invents or discovers any new and useful ... composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

We have "long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." <u>Mayo</u>, 566 U.S., at \_\_\_\_, 132 S.Ct., at 1293 (internal quotation marks and brackets omitted). Rather, "'they are the basic tools of scientific and technological work'" that lie beyond the domain of patent protection. Id., at \_\_\_\_, 132 S.Ct., at 1293. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them." Id., at \_\_\_\_, 132 S.Ct., at 1301. This would be at odds with the very point of patents, which exist to promote creation. Diamond v. Chakrabarty, 447 U.S. 303, 309, 100 S.Ct. 2204, 65 L.Ed.2d 144 (1980) (Products of nature are not created, and "`manifestations... of nature [are] free to all men and reserved exclusively to none'").<sup>3</sup>

In their majority opinion in 2013, the U.S. Supreme Court made it abundantly clear that the Court had "long held" that nature was not patentable. Merely isolating DNA does not constitute patentable subject matter. In their patent, the CDC made false and misleading claims to the United States Patent & Trademark Office by stating that, "A newly isolated human coronavirus has been identified as the causative agent of SARS, and is termed SARS-CoV." No "causal" data was provided for this statement.

When they filed their patent application on April 25, 2003 their first claim (and the only one that survived to ultimate issuance over the objection of the patent examiner in 2006 and 2007) was the genome for SARS CoV.

While this patent is clearly illegal under 35 U.S.C. §101, not only did the CDC insist on its granting over non-final and final rejections, but they also continued to pay maintenance fees on the patent after the 2013 Supreme Court decision confirmed that it was illegal.

In addition, the CDC patented the detection of SARS CoV using a number of methods including reverse transcription polymerase chain reaction (RT-PCR). With this patent, they precluded anyone outside of their licensed or conspiring interest from legally engaging in independent verification of their claim that they had isolated a virus, that it was a causative agent for SARS, or that any therapy could be effective against the reported pathogen.

It is important to note that the CDC's patent applications were also rejected in non-final and final rejections for ineligibility under 35 U.S.C. § 102 for being publicly disclosed prior to their own filing. In the first non-final rejection, the USPTO stated that the CDC's genome was published in four Genbank accession entries on April 14, 18, and 21, 2003 with identity ranging from 96.8% to 99.9% identical

<sup>&</sup>lt;sup>3</sup> Association for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. 576 (2013)

<sup>&</sup>lt;sup>4</sup> U.S. Patent 7,220,852

sequences.<sup>5</sup> Dr. Fauci knew, and failed to disclose evidence that the CDC patent was illegal, based on work he had funded in the years leading up to the SARS outbreak.

After seeking an illegal patent, petitioning to override the decision of an examiner to reject it, and ultimately prevailing with the patent's grant, the CDC lied to the public by stating they were controlling the patent so that it would be "publicly available". Tragically, this public statement is falsified by the simple fact that their own publication in Genbank had, in fact, made it public domain and thereby unpatentable. This fact, confirmed by patent examiners, was overridden by CDC in a paid solicitation to override the law.

While not covered under 35 U.S.C. §101, Dr. Fauci's abuse of the patent law is detailed below. Of note, however, is his willful and deceptive use of the term "vaccine" in patents and public pronouncements to pervert the meaning of the term for the manipulation of the public.

In the 1905 Jacobson v. Mass case, the court was clear that a PUBLIC BENEFIT was required for a vaccine to be mandated. Neither Pfizer nor Moderna have proved a disruption of transmission. In Jacobson v. Massachusetts, 197 U.S. 11 (1905), the court held that the context for their opinion rested on the following principle:

"This court has more than once recognized it as a fundamental principle that 'persons and property are subjected to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state..."

The Moderna and Pfizer "alleged vaccine" trials have explicitly acknowledged that their gene therapy technology has no impact on viral infection or transmission whatsoever and merely conveys to the recipient the capacity to produce an S1 spike protein endogenously by the introduction of a synthetic mRNA sequence. Therefore, the basis for the Massachusetts statute and the Supreme Court's determination is moot in this case.

Further, the USPTO, in its REJECTION of Anthony Fauci's HIV vaccine made the following statement supporting their rejection of his bogus "invention"

<sup>&</sup>lt;sup>5</sup> USPTO Non-Final Rejection File #10822904, September 7, 2006, page 4.

<sup>&</sup>lt;sup>6</sup> https://apnews.com/article/145b4e8d156cddc93e996ae52dc24ec0

Application/Control Number: 09/869,003

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Art Unit: 1648

These arguments are persuasive to the extent that an antigenic peptide stimulates an immune response that may produce antibodies that bind to a specific peptide or protein but is not persuasive in regards to a vaccine. The immune response produced by a vaccine must be more than merely some immune response but must be protective. As noted in the previous Office Action, the art recognizes the term "vaccine" to be a compound which prevents infection. Applicant has not demonstrated that the instantly claimed vaccine meets even the lower standard set forth in the specification, let alone the standard art definition, for being operative in this regards. Therefore, claims 5, 7, and 9 are not operative as an anti-HIV-1 vaccine and therefore lack patentable utility.

# 18 U.S.C. §2339 C *et seq.* – Funding and Conspiring to Commit Acts of Terror

Indirectly, unlawfully and willfully provides or collects funds with the intention that such funds be used, or with the knowledge that such funds are to be used, in full or in part, in order to carry out—

- (A) an act which constitutes an offense within the scope of a treaty specified in subsection (e)(7), as implemented by the United States, or
- (B) any other act intended to cause death or serious bodily injury to a civilian, or to any other person not taking an active part in the hostilities in a situation of armed conflict, when the purpose of such act, by its nature or context, is to intimidate a population, or to compel a government or an international organization to do or to abstain from doing any act....

By no later than April 11, 2005, Dr. Anthony Fauci was publicly acknowledging the association of SARS with bioterror potential. Leveraging the fear of the anthrax bioterrorism of 2001, he publicly celebrated the economic boon that domestic terror had directed towards his budget. He specifically stated that NIAID was actively funding research on a "SARS Chip" DNA microarray to rapidly detect SARS (something that was not made available during the current "pandemic") and two candidate vaccines focused on the SARS CoV spike protein. Led by three Chinese researchers under his employment – Zhi-yong Yang, Wing-pui Kong, and Yue Huang – Fauci had at least one DNA vaccine in animal trials by 2004. This team, part of the Vaccine Research Center at NIAID, was primarily focused on HIV vaccine development but was tasked to identify SARS vaccine candidates as well. Working in collaboration with Sanofi, Scripps Institute, Harvard, MIT and NIH, Dr. Fauci's decision to unilaterally promote vaccines as a primary intervention for several designated "infectious diseases" precluded *proven therapies* from being applied to the sick and dying.

The CDC and NIAID led by Anthony Fauci entered into trade among States (including, but not limited to working with EcoHealth Alliance Inc.) and with foreign nations (specifically, the Wuhan Institute of Virology and the Chinese Academy of Sciences) through the 2014 *et seq* National Institutes of Health Grant R01AI110964 to exploit their patent rights. This research was known to involve surface proteins in coronavirus that had the capacity to directly infect human respiratory systems. In flagrant violation of the NIH moratorium on gain of function research, NIAID and Ralph Baric persisted in working with chimeric coronavirus components specifically to amplify the pathogenicity of the biologic material.

By October 2013, the Wuhan Institute of Virology 1 coronavirus S1 spike protein was described in NIAID's funded work in China. This work involved NIAID, USAID, and Peter Daszak, the head of EcoHealth Alliance. This work, funded under R01AI079231, was pivotal in isolating and manipulating viral fragments selected from sites across China which contained high risk for severe human response.<sup>10</sup>

By March 2015, both the virulence of the S1 spike protein and the ACE II receptor was known to present a considerable risk to human health. NIAID, EcoHealth Alliance and numerous researchers lamented the

<sup>&</sup>lt;sup>7</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3320336/

<sup>&</sup>lt;sup>8</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7095382/

<sup>&</sup>lt;sup>9</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1232869/

<sup>&</sup>lt;sup>10</sup> Ge, XY., Li, JL., Yang, XL. *et al.* Isolation and characterization of a bat SARS-like coronavirus that uses the ACE2 receptor. *Nature* **503**, 535–538 (2013).

fact that the public was not sufficiently concerned about coronavirus to adequately fund their desired research.<sup>11</sup>

Dr. Peter Daszak of EcoHealth Alliance offered the following assessment:

"Daszak reiterated that, until an infectious disease crisis is very real, present, and at an emergency threshold, it is often largely ignored. To sustain the funding base beyond the crisis, he said, we need to increase public understanding of the need for MCMs such as a pan-influenza or pan-coronavirus vaccine. A key driver is the media, and the economics follow the hype. We need to use that hype to our advantage to get to the real issues. Investors will respond if they see profit at the end of process, Daszak stated." 12

#### Economics will follow the hype.

The CDC and NIAID entered into trade among States (including, but not limited to working with University of North Carolina, Chapel Hill) and with foreign nations (specifically, the Wuhan Institute of Virology and the Chinese Academy of Sciences represented by Zheng-Li Shi) through U19AI109761 (Ralph S. Baric), U19AI107810 (Ralph S. Baric), and National Natural Science Foundation of China Award 81290341 (Zheng-Li Shi) et al. 2015-2016. These projects took place during a time when the work being performed was prohibited by the United States National Institutes of Health.

The public was clearly advised of the dangers being presented by NIAID-funded research by 2015 and 2016 when the Wuhan Institute of Virology material was being manipulated at UNC in Ralph Baric's lab.

"The only impact of this work is the creation, in a lab, of a new, non-natural risk," agrees Richard Ebright, a molecular biologist and biodefence expert at Rutgers University in Piscataway, New Jersey. Both Ebright and Wain-Hobson are long-standing critics of gain-of-function research.

In their paper, the study authors also concede that funders may think twice about allowing such experiments in the future. "Scientific review panels may deem similar studies building chimeric viruses based on circulating strains too risky to pursue," they write, adding that discussion is needed as to "whether these types of chimeric virus studies warrant further investigation versus the inherent risks involved".

But Baric and others say the research did have benefits. The study findings "move this virus from a candidate emerging pathogen to a clear and present danger", says Peter Daszak, who co-authored the 2013 paper. Daszak is president of the EcoHealth Alliance, an international network of scientists, headquartered in New York City, that samples viruses from animals and people in emerging-diseases hotspots across the globe.

<sup>&</sup>lt;sup>11</sup> Forum on Medical and Public Health Preparedness for Catastrophic Events; Forum on Drug Discovery, Development, and Translation; Forum on Microbial Threats; Board on Health Sciences Policy; Board on Global Health; Institute of Medicine; National Academies of Sciences, Engineering, and Medicine. Rapid Medical Countermeasure Response to Infectious Diseases: Enabling Sustainable Capabilities Through Ongoing Public- and Private-Sector Partnerships: Workshop Summary. Washington (DC): National Academies Press (US); 2016 Feb 12. 6, Developing MCMs for Coronaviruses. Available from: https://www.ncbi.nlm.nih.gov/books/NBK349040/

<sup>12</sup> Ibid.

Studies testing hybrid viruses in human cell culture and animal models are limited in what they can say about the threat posed by a wild virus, Daszak agrees. But he argues that they can help indicate which pathogens should be prioritized for further research attention."<sup>13</sup>

Knowing that the U.S. Department of Health and Human Services (through CDC, NIH, NIAID, and their funded laboratories and commercial partners) had patents on each proposed element of medical counter measures and their funding, Dr. Fauci, Dr. Gao (China CDC), and Dr. Elias (Bill and Melinda Gates Foundation) conspired to commit acts of terror on the global population – including the citizens of the United States – when, in September 2019, they published the following mandate:

"Countries, donors and multilateral institutions must be prepared for the worst. A rapidly spreading pandemic due to a lethal respiratory pathogen (whether naturally emergent or accidentally or deliberately released) poses additional preparedness requirements. Donors and multilateral institutions must ensure adequate investment in developing innovative vaccines and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate non-pharmaceutical interventions. All countries must develop a system for immediately sharing genome sequences of any new pathogen for public health purposes along with the means to share limited medical countermeasures across countries.

#### Progress indicator(s) by September 2020

- Donors and countries commit and identify timelines for: financing and development of a universal influenza vaccine, broad spectrum antivirals, and targeted therapeutics. WHO and its Member States develop options for standard procedures and timelines for sharing of sequence data, specimens, and medical countermeasures for pathogens other than influenza.
- Donors, countries and multilateral institutions develop a multi-year plan and approach for strengthening R&D research capacity, in advance of and during an epidemic.
- WHO, the United Nations Children's Fund, the International Federation of Red Cross and Red Crescent Societies, academic and other partners identify strategies for increasing capacity and integration of social science approaches and researchers across the entire preparedness/response continuum."<sup>14</sup>

As if to confirm the utility of the September 2019 demand for "financing and development of" vaccine and the fortuitous SARS CoV-2 alleged outbreak in December of 2019, Dr. Fauci began gloating that his fortunes for additional funding were likely changing for the better. In a February 2020 interview in **STAT**, he was quoted as follows:

<sup>&</sup>lt;sup>13</sup> https://www.nature.com/news/engineered-bat-virus-stirs-debate-over-risky-research-%201.18787

<sup>&</sup>lt;sup>14</sup> https://apps.who.int/gpmb/assets/annual\_report/GPMB\_annualreport\_2019.pdf (page 8)



 $<sup>^{15}\,</sup>https://www.statnews.com/2020/02/10/fluctuating-funding-and-flagging-interest-hurt-coronavirus-research/$ 

# 18 U.S.C. § 2331 §§ 802 – Acts of Domestic Terrorism resulting in death of American Citizens

Section 802 of the USA PATRIOT Act (Pub. L. No. 107-52) expanded the definition of terrorism to cover "domestic," as opposed to international, terrorism. A person engages in domestic terrorism if they do an act "dangerous to human life" that is a violation of the criminal laws of a state or the United States, if the act appears to be intended to: (i) intimidate or coerce a civilian population; (ii) influence the policy of a government by intimidation or coercion;

Dr. Anthony Fauci has intimidated and coerced a civilian population and sought to influence the policy of a government by intimidation and coercion.

With no corroboration, Dr. Anthony Fauci promoted<sup>16</sup> Professor Neil Ferguson's computer simulation derived claims that,

"The world is facing the most serious public health crisis in generations. Here we provide concrete estimates of the scale of the threat countries now face.

"We use the latest estimates of severity to show that policy strategies which aim to mitigate the epidemic might halve deaths and reduce peak healthcare demand by two-thirds, but that this will not be enough to prevent health systems being overwhelmed. More intensive, and socially disruptive interventions will therefore be required to suppress transmission to low levels. It is likely such measures – most notably, large scale social distancing – will need to be in place for many months, perhaps until a vaccine becomes available." <sup>17</sup>

Reporting to the President that as many as 2.2 million deaths may result from a pathogen that had not yet been isolated and could not be measured with any accuracy, Dr. Fauci intimidated and coerced the population and the government into reckless, untested, and harmful acts creating irreparable harm to lives and livelihoods. Neither the Imperial College nor the "independent" Institute for Health Metrics and Evaluation (principally funded by the Bill and Melinda Gates Foundation) had any evidence of success in estimating previous burdens from coronavirus but, without consultation or peer-review, Dr. Fauci adopted their terrifying estimates as the basis for interventions that are explicitly against medical advice.

- The imposition of social distancing was based on computer simulation and environmental models with NO disease transmission evidence whatsoever.
- The imposition of face mask wearing was directly against controlled clinical trial evidence and against the written policy in the Journal of the American Medical Association.

<sup>&</sup>lt;sup>16</sup> https://www.cato.org/blog/did-mitigation-save-two-million-lives

<sup>&</sup>lt;sup>17</sup> https://www.imperial.ac.uk/news/196234/covid-19-imperial-researchers-model-likely-impact/

 $<sup>^{18} \,</sup> https://www.npr.org/2020/03/31/823916343/coronavirus-task-force-set-to-detail-the-data-that-led-to-extension-of-guideline$ 

<sup>&</sup>lt;sup>19</sup> https://www.gatesfoundation.org/Media-Center/Press-Releases/2017/01/IHME-Announcement

"Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill."<sup>20</sup>

• In both the Imperial College and the IHME simulations, *quarantines were modeled for the sick,* not the healthy.

Insisting on vaccines while blockading the emergency use of proven pharmaceutical interventions may have contributed to the death of many patients and otherwise healthy individuals.<sup>21</sup>

Using the power of NIAID during the alleged pandemic, Dr. Anthony Fauci actively suppressed proven medical countermeasures used by, and validated in scientific proceedings, that offered alternatives to the products funded by his conspiring entities for which he had provided direct funding and for whom he would receive tangible and intangible benefit.

<sup>&</sup>lt;sup>20</sup> https://jamanetwork.com/journals/jama/fullarticle/2762694?fbclid=IwAR2RE-c4V-fhUoduiOJQRbiHRcgEJuDKG\_21N4oL5zAfciQfWCyHAsetJmo

<sup>&</sup>lt;sup>21</sup> https://www.reuters.com/investigates/special-report/health-coronavirus-usa-cost/

## 18 U.S.C. § 1001 – Lying to Congress

(a)Except as otherwise provided in this section, whoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—

- (1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact;
- (2) makes any materially false, fictitious, or fraudulent statement or representation; or
- (3) makes or uses any false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry;

shall be fined under this title, imprisoned not more than 5 years or, if the offense involves international or domestic terrorism (as defined in section 2331), imprisoned not more than 8 years, or both. If the matter relates to an offense under chapter 109A, 109B, 110, or 117, or section 1591, then the term of imprisonment imposed under this section shall be not more than 8 years.

On October 22, 2020, the United States Government Accountability Office (GAO) published a report entitled: *BIOMEDICAL RESEARCH: NIH Should Publicly Report More Information about the Licensing of Its Intellectual Property*. In this document, the authors reported that the National Institutes of Health (NIH) received, "up to \$2 billion in royalties from its contributions to 34 drugs sold from 1991-2019."

A casual review of the NIH Office of Technology Transfer report of active licenses<sup>23</sup> appears to conflict with the GAO report on several important facts. Conspicuously absent from the GAO report are over 30 patents associated with active compounds generating billions of dollars in revenue. Why would it be that the GAO and the NIH couldn't agree on something as simple as drugs generating income for NIH?

Since the passage of the Bayh Dole Act (Pub. L. 96-517, December 12, 1980), federally funded research has been an economic bonanza for U.S. universities, federal agencies, and their selected patronage. For the first decade following Bayh Dole, NIH funding doubled from \$3.4 billion to \$7.1 billion. A decade later, it doubled again to \$15.6 billion. In the wake of September 2001, the National Institute for Allergy and Infectious Diseases (NIAID) saw its direct budget increase over 300% without accounting for DARPA funds of as much as \$1.7 billion annually from 2005 forward. In 2020, NIH's budget was over \$41 billion.

What has become of the \$763 billion of taxpayer funds allocated to making America healthier since inventors have been commercially incentivized? Who has been enriched?

The answer, regrettably, is that no accountability exists to answer these questions.

The NIH is the named owner of at least 138 patents since 1980.

The United States Department of Health and Human Services is the named owner of at least 2,600 patents.

NIAID grants or collaboration have resulted in 2,655 patents and patent applications of which only 95 include an assignment to the Department of Health and Human Services as an owner. Most of these patents are assigned to universities thereby making the ultimate commercial beneficiaries entirely

<sup>&</sup>lt;sup>22</sup> https://www.gao.gov/products/GAO-21-52

<sup>&</sup>lt;sup>23</sup> https://www.ott.nih.gov/reportsstats/hhs-license-based-vaccines-therapeutics

opaque. One of the largest holders is SIGA Technologies (NASDAQ: SIGA) who, while publicly reporting close affiliation with NIAID, is not referenced in the NIH GAO report. SIGA's CEO, Dr. Phillip L. Gomez spent 9 years at NIAID developing its vaccine program for HIV, SARS, Ebola, West Nile Virus, and Influenza before exiting to commercial ventures. While their technology is clearly derived from NIAID science, the company reports revenue from NIAID but no royalty or commercial payments to NIH or any of its programs.

NIAID's Director, Dr. Anthony Fauci is listed as an inventor on 8 granted U.S. patents. None of them are reported in NIAID, NIH, or GAO reports of active licensing despite the fact that Dr. Fauci reportedly was compelled to get paid for his interleukin-2 "invention" – payments he reportedly donated to an unnamed charity.<sup>24</sup>

Of the 21 patents listed in the U.S. Food and Drug Administration's (FDA) Orange book itemized in the GAO report, none of Dr. Anthony Fauci's patents are listed. Furthermore, none of the NIAID patents are listed despite clear evidence that Gilead Sciences and Janssen Pharmaceuticals (a division of Johnson & Johnson) have generated over \$2 billion annually from sales that were the direct result of NIAID funded science. Missing from the GAO report are 2 patents for Velclade® which has been generating sales in excess of \$2.18 billion annually for several years. None of the patents for Yescarta® are listed in the GAO report. None of the Lumoxiti® patents are listed in the GAO report. None of the Kepivance® patents are listed in the GAO report. In violation of 37 USC §410.10 and 35 USC §202(a), over 13 of the 21 patents in the GAO report fail to disclose government interest despite being the direct result of NIH funding.

#### Dr. Anthony Fauci's Own Patent Track Record:

# <u>US Patent 6,190,656 and 6,548,055</u> <u>Immunologic enhancement with intermittent interleukin-2</u> <u>therapy</u>

A method for activating a mammalian immune system entails a series of IL-2 administrations that are effected intermittently over an extended period. Each administration of IL-2 is sufficient to allow spontaneous DNA synthesis in peripheral blood or lymph node cells of the patient to increase and peak, and each subsequent administration follows the preceding administration in the series by a period of time that is sufficient to allow IL-2 receptor expression in peripheral or lymph node blood of the patient to increase, peak and then decrease to 50% of peak value. This intermittent IL-2 therapy can be combined with another therapy which targets a specific disease state, such as an anti-retroviral therapy comprising, for example, the administration of AZT, ddl or interferon alpha. In addition, IL-2 administration can be employed to facilitate in situ transduction of T cells in the context of gene therapy. By this approach the cells are first activated in vivo via the aforementioned IL-2 therapy, and transduction then is effected by delivering a genetically engineered retroviral vector directly to the patient.

This application is a continuation of U.S. patent application Ser. No. 08/487,075, filed Jun. 7, 1995, now abandoned, which is a continuation in part of U.S. patent application Ser. No. 08/063,315, filed May 19, 1993, now issued as U.S. Pat. No. 5,419,900, and U.S. patent application Ser. No. 08/452,440, filed May 26, 1995, now issued as U.S. Pat. No. 5,696,079, which is the National Stage filed under 35 USC 371 of PCT/US94/05397, filed May 19, 1994, the contents of which are incorporated herein by reference.

<sup>&</sup>lt;sup>24</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC545012/

#### Filed May 19, 1993

Issued a Final Rejection January 20, 1998. Rejected after abandonment August 14, 1998 and April 12, 1999. Reduced and modified claims granted May 8, 2000.

This family of patents was the basis of Fauci's lie to the **British Medical Journal** in which he falsely stated:

"Dr Anthony Fauci told the BMJ that as a government employee he was required by law to put his name on the patent for the development of interleukin 2 and was also required by law to receive part of the payment the government received for use of the patent. He said that he felt it was inappropriate (sic) to receive payment and donated the entire amount to charity."<sup>25</sup>

He was not "required by law" to commit fraud on the patent office and then get paid for it!

#### US Patent 6,911,527 HIV related peptides

This invention is the discovery of novel specific epitopes and antibodies associated with long term survival of HIV-1 infections. These epitopes and antibodies have use in preparing vaccines for preventing HIV-1 infection or for controlling progression to AIDS.

Filed May 6, 1999

Rejected as unpatentable January 22, 2003. Issued with a final rejection on July 15, 2004 after submitting reconsideration requests. Modified and restricted claims allowed September 29, 2004.

#### US Patent 7,368,114 Fusion protein including of CD4

Novel recombinant polypeptides are disclosed herein that include a CD4 polypeptide ligated at its C-terminus with a portion of an immunoglobulin comprising a hinge region and a constant domain of a mammalian immunoglobulin heavy chain. The portion or the IgG is fused at its C-terminus with a polypeptide comprising a tailpiece from the C-terminus of the heavy chain of an IgA antibody ara tailpiece from a C-terminus of the heavy chain of an IgM antibody. Also disclosed herein are methods for using these CD4 fusion proteins.

Filed October 24, 2002

Rejected as unpatentable August 18, 2006. Paid appeal to overturn examiner's findings February 15, 2007. Rejected again May 11, 2007. On October 10, 2007 applicants further narrowed the construction of what was clearly not a patent and the USPTO granted less than half the claims that had been sought in the original filing.

US Patent 9,896,509, 9,193,790 and 9,441,041 Use of antagonists of the interaction between HIV GP120 and .alpha.4.beta.7 integrin

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<sup>&</sup>lt;sup>25</sup> Ibid.

Methods are provided for the treatment of a HIV infection. The methods can include administering to a subject with an HIV infection a therapeutically effective amount of an agent that interferes with the interaction of gp120 and .alpha.4 integrin, such as a .alpha.4.beta.1 or .alpha.4.beta.7 integrin antagonist, thereby treating the HIV infection. In several examples, the .alpha.4 integrin antagonist is a monoclonal antibody that specifically binds to a .alpha.4, .beta.1 or .beta.7 integrin subunit or a cyclic hexapeptide with the amino acid sequence of CWLDVC. Methods are also provided to reduce HIV replication or infection. The methods include contacting a cell with an effective amount of an agent that interferes with the interaction of gp120 and .alpha.4 integrin, such as a .alpha.4.beta.1 or .alpha.4.beta.7 integrin antagonist. Moreover, methods are provided for determining if an agent is useful to treat HIV.

Rejected May 22, 2017 as Double Patenting. In their response, the applicants acknowledge the illegal act and seek only those components of their application that extend beyond the life of the issued patents. On October 11, 2017, the limited claims were issued.

#### A sample of the convoluted flow of funds that evades public disclosure.

U.S. Patent 8,999,351 was issued to Tekmira Pharmaceuticals Corporation in Burnaby, British Columbia. In their patent, they disclose that their research was supported by a grant from the National Institute of Allergy and Infectious Disease (Grant HHSN266200600012C). Ironically, this \$23 million grant was awarded in 2006 to Alnylam Pharmaceuticals, Inc., not to Tekmira.<sup>26</sup>

In 2012, Alnylam agreed to pay Tekmira \$65 million to settle legal disputes including a \$1 billion damages claim for "relentless and egregious" misappropriation of Tekmira's trade secrets. From the patent filing's earliest priority of November 10, 2008, there is no public record stating Tekmira as the beneficiary of this NIAID grant. Notwithstanding, the lipid nanoparticle technology developed from this grant is the technology now used in the Moderna COVID-19 intervention. In their 10-Q filing, Alnylam reports to have a license to technology from Arbutus – formerly Tekmira – which has accused Acuitas of misappropriating trade secrets and licensing them to Moderna and Pfizer's collaboration with BioNTech.

#### Additional references can be found at:

https://www.ott.nih.gov/nih-and-its-role-technology-transfer

https://www.accessdata.fda.gov/drugsatfda docs/appletter/2017/206288Orig1s000TAltr.pdf

https://www.gao.gov/assets/720/710287.pdf

https://grantome.com/search?q=%22National%20Institute%20of%20Allergy%20and%20Infectious%20Data and the search of the search of

iseases%22

 $^{26}\ https://www.technologynetworks.com/genomics/news/alnylam-awarded-23-million-us-government-contract-to-develop-rnai-therapeutics-186097$ 

## 15 U.S.C. §1-3 – Conspiring to Criminal Commercial Activity

Every contract, combination in the form of trust or otherwise, or conspiracy, in restraint of trade or commerce among the several States, or with foreign nations, is declared to be illegal. Every person who shall make any contract or engage in any combination or conspiracy hereby declared to be illegal shall be deemed guilty of a felony, and, on conviction thereof, shall be punished by fine not exceeding \$100,000,000 if a corporation, or, if any other person, \$1,000,000, or by imprisonment not exceeding 10 years, or by both said punishments, in the discretion of the court.

The National Institute of Health's grant Al23946-08 issued to Dr. Ralph Baric at the University of North Carolina at Chapel Hill (officially classified as affiliated with Dr. Anthony Fauci's NIAID by at least 2003) began the work on synthetically altering the *Coronaviridae* (the coronavirus family) for the express purpose of general research, pathogenic enhancement, detection, manipulation, and potential therapeutic interventions targeting the same. As early as May 21, 2000, Dr. Baric and UNC sought to patent critical sections of the coronavirus family for their commercial benefit.<sup>27</sup> In one of the several papers derived from work sponsored by this grant, Dr. Baric published what he reported to be the full length cDNA of SARS CoV in which it was clearly stated that SAR CoV was based on a composite of DNA segments.

"Using a panel of contiguous cDNAs that span the entire genome, we have assembled a full-length cDNA of the SARS-CoV Urbani strain, and have rescued molecularly cloned SARS viruses (infectious clone SARS-CoV) that contained the expected marker mutations inserted into the component clones."<sup>28</sup>

On April 19, 2002 – the Spring before the first SARS outbreak in Asia – Christopher M. Curtis, Boyd Yount, and Ralph Baric filed an application for U.S. Patent 7,279,372 for a method of producing recombinant coronavirus. In the first public record of the claims, they sought to patent a means of producing, "an infectious, replication defective, coronavirus." This work was supported by the NIH grant referenced above and GM63228. In short, the U.S. Department of Health and Human Services was involved in the funding of amplifying the infectious nature of coronavirus between 1999 and 2002 *before SARS* was ever detected in humans.

Against this backdrop, we noted the unusual patent prosecution efforts of the CDC, when on April 25, 2003 they sought to patent the SARS coronavirus isolated from humans that had reportedly transferred to humans during the 2002-2003 SARS outbreak in Asia. 35 U.S.C. §101 prohibits patenting nature. This legality did not deter CDC in their efforts. Their application, updated in 2007, ultimately issued as U.S. Patent 7,220,852 and constrained anyone not licensed by their patent from manipulating SARS CoV, developing tests or kits to measure SARS coronavirus in humans or working with their patented virus for therapeutic use. Work associated with this virus by their select collaborators included considerable amounts of chimeric engineering, gain-of-function studies, viral characterization, detection, treatment (both vaccine and therapeutic intervention), and weaponization inquiries.

In short, with Baric's U.S. Patent 6,593,111 (Claims 1 and 5) and CDC's '852 patent (Claim 1), no research in the United States could be conducted without permission or infringement.

<sup>&</sup>lt;sup>27</sup> U.S. Provisional Application No. 60/206,537, filed May 21, 2000

<sup>&</sup>lt;sup>28</sup> https://www.pnas.org/content/100/22/12995

We noted that gain-of-function specialist, Dr. Ralph Baric, was both the recipient of millions of dollars of U.S. research grants from several federal agencies but also sat on the World Health Organization's International Committee on Taxonomy of Viruses (ICTV) and the *Coronaviridae* Study Group (CSG). In this capacity, he was both responsible for determining "novelty" of clades of virus species but directly benefitted from determining declarations of novelty in the form of new research funding authorizations and associated patenting and commercial collaboration. Together with CDC, NIAID, WHO, academic and commercial parties (including Johnson & Johnson; Sanofi and their several coronavirus patent holding biotech companies; Moderna; Ridgeback; Gilead; Sherlock Biosciences; and, others), a powerful group of interests constituted what we would suggest are "interlocking directorates" under U.S. anti-trust laws.

1986-1990	NIAID Grant AI 23946 leading to patent U.S. 7,279,327 "Methods for Producing Recombinant Coronavirus" Filed 2002 and issued 2007 <a href="https://patents.google.com/patent/US7279327B2/ru">https://patents.google.com/patent/US7279327B2/ru</a>
	The paper first published from the NIAID grant is <a href="https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC7109931&amp;blobtype=pdf">https://europepmc.org/backend/ptpmcrender.fcgi?accid=PMC7109931&amp;blobtype=pdf</a>
1990	Pfizer files U.S. Patent 6,372,224 on a vaccine for the <i>S</i> -protein on coronavirus November 14, 2000 which was abandoned April 2010 making it public domain.
1990s	Work focused on CoV association with cardiomyopathy (see above)
	Early reference to the "emergence" of CoV as a <i>respiratory pathogen</i> in <a href="https://link.springer.com/content/pdf/10.1007%2F978-1-4615-1899-0_91.pdf">https://link.springer.com/content/pdf/10.1007%2F978-1-4615-1899-0_91.pdf</a>
2000	Ralph Baric Al23946 and GM63228 from the National Institutes of Health actively working recombinant CoV
2001	National Institute of Health, Allergy and Infectious diseases. "Reverse Genetics with a Coronavirus Infectious cDNA Construct." 4/1/2001-3/31/005 \$1.0 million total costs/yr. RS Baric, PI
2002	Asia CoV SARS outbreak
2003	April 25, 2003 CDC Patent filed and ultimately becomes US7,220,852 (the patent on the RNA sequence) and 7,776,521 (the patent on the testing methodology. These patents give the U.S. Department of Health and Human Services the ability to control

the commercial exploitation of SARS coronavirus.

Dr. Anthony Fauci appointed to the Bill and Melinda Gates Foundation's Global Grand Challenges Scientific Advisory Board (served through 2010).

April 28, 2003 Sequoia Pharmaceuticals \$953K for pathogen response and patent US7,151,163 https://www.sbir.gov/node/305319

July 21, 2003 Ralph Baric's team (using Al23946 and GM63228) file U.S. Patent 7,618,802 which issued on November 17, 2009. https://patents.google.com/patent/US7618802B2

Dana Farber Cancer Institute files U.S. Patent 7,750,123 on a monoclonal antibody to neutralize SARS CoV. This research is supported by several NIH grants including National Institutes of Health Grants A128785, A148436, and A1053822.

January 6, 2004 – *SARS and Bioterrorism linked* at Bioterrorism and Emerging Infectious Diseases: antimicrobials, therapeutics and immune modulators.

<a href="https://tks.keystonesymposia.org/index.cfm?e=web.meeting.program&meetingid=706">https://tks.keystonesymposia.org/index.cfm?e=web.meeting.program&meetingid=706</a>

\*\*At this conference, the term "The New Normal" was introduced by Merck

**FAUCI AND BARIC start making money!!!** National Institutes of Health, Allergy and Infectious Diseases. SARS Reverse Genetics. Al059136-01. \$1.7 million total costs, RS Baric, PI. 10% effort. 4/1/04- 3/31/09. The project develops a SARS-CoV full length infectious cDNA, the development of SARS-CoV replicon particles expressing heterologous genes, and seeks to adapt SARS-CoV to mice, producing a pathogenic mouse model for SARS-CoV infection.

National Institutes of Health, Allergy and Infectious Diseases. R01. Remodeling the SARS Coronavirus Genome Regulatory Network. RS Baric, PI 10% effort. 7/1/04-6/30/09. \$2.1 million

November 22, 2004 University of Hong Kong patents SARS associated spike protein on CoV and pursues patent US 7,491,489

DARPA gets in on the game Synthetic Coronaviruses. Biohacking: Biological Warfare Enabling Technologies, June 2005. Washington, DC. DARPA/MITRE sponsored event. Invited Speaker

Review timeline from <a href="https://www.youtube.com/watch?v=rO\_EeYB0i0U">https://www.davidmartin.world/wp-content/uploads/2020/04/20APRBotWslides.pdf</a>

Biodefense Grant U54 Al057157 commences with \$10,189,682 to UNC Chapel Hill https://taggs.hhs.gov/Detail/AwardDetail?arg\_awardNum=U54Al057157&arg\_ProgOffic eCode=104

Biodefense Grant U54 Al057157 continues with \$5,448,656 to UNC Chapel Hill (non-competitive grant from NIAID)

Biodefense Grant U54 Al057157 continues with \$8,747,142 to UNC Chapel Hill (non-competitive grant from NIAID)

Patent issuance for SARS coronavirus patents peak post the Asia outbreak at 391 issued patents.

2005

2008

2009

2010

August 6, 2010, Moderna (prior to its establishment) files U.S. Patent 9,447,164 which attracted the investment of (and "inventorship" for) venture capitalists at Flagship Ventures. This patent grew out of the work of Dr. Jason P. Schrum of Harvard Medical School supported by National Science Foundation Grant #0434507. While the application claims priority to August 2010, the application didn't get finalized until October, 2015. On November 4, 2015, the USPTO issued a non-final rejection on this original patent rejecting all claims.

https://www.nsf.gov/awardsearch/showAward?AWD\_ID=0434507 with reference to the grant funding in

https://molbio.mgh.harvard.edu/szostakweb/publications/Szostak\_pdfs/Schrum\_et\_al\_ JACS\_2009.pdf

2011 Crucell joined the Janssen Pharmaceutical Companies of Johnson & Johnson in February taking with it all of its SARS technology.

Biodefense Grant U54 Al057157 continues with \$7,344,820 to UNC Chapel Hill (non-competitive grant from NIAID)

2012 MERS isolated in Egypt

Biodefense Grant U54 Al057157 continues with \$7,627,657 to UNC Chapel Hill (non-competitive grant from NIAID)

- Biodefense Grant U54 Al057157 continues with \$7,226,237 to UNC Chapel Hill (non-competitive grant from NIAID)
- April 23, 2014, Moderna files patent on nucleic acid vaccine with Patents US9872900 and US10022435
- 2015 Moderna signs a vaccine development agreement with NIAID and executes it with the lead on the mRNA-1273 lead developer and inventor Guiseppe Ciaramella.

  <a href="https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html">https://www.documentcloud.org/documents/6935295-NIH-Moderna-Confidential-Agreements.html</a>

NIH through Scripps Institute and Dartmouth College file patent application WO 2018081318A1 "Prefusion Coronavirus Spike Proteins and their Use" disclosing mRNA technology that overlaps (and is used in tandem with) Moderna's technology. <a href="https://patents.google.com/patent/WO2018081318A1/en">https://patents.google.com/patent/WO2018081318A1/en</a> Lead Inventor Barney Scott Graham was well known to Moderna as he's the person at NIH that Moderna "e-mailed" to get the sequence for SARS CoV-2 according to Moderna's report here ("In January 2020, once it was discovered that the infection in Wuhan was caused by a novel coronavirus, Bancel quickly emailed Dr. Barney Graham, deputy director of the Vaccine Research Center at the National Institutes of Health, asking him to send the genetic sequence for the virus.") <a href="https://www.wsws.org/en/articles/2020/05/26/vacc-m26.html">https://www.wsws.org/en/articles/2020/05/26/vacc-m26.html</a> In addition, co-inventor Jason McLellan worked with Graham on a vaccine patent jointly owned with the Chinese government filed in Australia in 2013 <a href="https://patents.google.com/patent/AU2014231357A1/en?inventor=Jason+MCLELLAN">https://patents.google.com/patent/AU2014231357A1/en?inventor=Jason+MCLELLAN</a>.

2017	August – Sanofi buys Protein Science Corp with considerable SARS patent holdings
2018	June – Sanofi buys Ablynx with considerable SARS patent holdings
2019	March, <a href="https://wyss.harvard.edu/news/sherlock-biosciences-licenses-wyss-technology-to-create-affordable-molecular-diagnostics/">https://wyss.harvard.edu/news/sherlock-biosciences-licenses-wyss-technology-to-create-affordable-molecular-diagnostics/</a> funded by Open Philanthropy — the same organization that would be the financial sponsor of the Event 201 "table-top" exercise that laid out the entire "pandemic" plan in October 2019.

# 15 U.S.C. §8 – Market Manipulation and Allocation

Every combination, conspiracy, trust, agreement, or contract is declared to be contrary to public policy, illegal, and void when the same is made by or between two or more persons or corporations, either of whom, as agent or principal, is engaged in importing any article from any foreign country into the United States, and when such combination, conspiracy, trust, agreement, or contract is intended to operate in restraint of lawful trade, or free competition in lawful trade or commerce, or to increase the market price in any part of the United States of any article or articles imported or intended to be imported into the United States, or of any manufacture into which such imported article enters or is intended to enter. Every person who shall be engaged in the importation of goods or any commodity from any foreign country in violation of this section, or who shall combine or conspire with another to violate the same, is guilty of a misdemeanor, and on conviction thereof in any court of the United States such person shall be fined in a sum not less than \$100 and not exceeding \$5,000, and shall be further punished by imprisonment, in the discretion of the court, for a term not less than three months nor exceeding twelve months.

Through non-competitive grant awards to UNC Chapel Hill's Ralph Baric, to selection of the Bio-Safety Level 4 laboratory locations, to the setting of prices for Remdesivir and mRNA therapies from Moderna and Pfizer, NIAID, CDC, and the U.S. Department of Health and Human Services have been involved in allocating Federal funds to conspiring parties without independent review.

Around March 12, 2020, in an effort to enrich their own economic interests by way of securing additional funding from both Federal and Foundation actors, the CDC and NIAID's Dr Fauci elected to suspend testing and classify COVID-19 by capricious symptom presentation alone. Forcing the public to rely on The COVID Tracking Project – funded by the Bloomberg, Zuckerberg and Gates Foundation and presented by a media outlet (*The Atlantic*) – not a public health agency – Dr. Fauci used fraudulent testing technology (RT-PCR) to conflate "COVID cases" with positive PCR tests in the living while insisting that COVID deaths be counted by symptoms alone. This perpetuated a market demand for his desired vaccine agenda which was recited by him and his conspiring parties around the world until the present. Not surprisingly, this was necessitated by the apparent fall in cases that constituted Dr. Fauci's and others' criteria for depriving citizens of their 1st Amendment rights.

# 15 U.S.C. § 19 – Interlocking Directorates

- (1) No person shall, at the same time, serve as a director or officer in any two corporations (other than banks, banking associations, and trust companies) that are—
  - (A) engaged in whole or in part in commerce; and
  - (B) by virtue of their business and location of operation, competitors, so that the elimination of competition by agreement between them would constitute a violation of any of the antitrust laws; if each of the corporations has capital, surplus, and undivided profits aggregating more than \$10,000,000 as adjusted pursuant to paragraph (5) of this subsection.

Dr. Fauci is on the Leadership Council of the Bill and Malinda Gates Global Vaccine Action Plan

Dr. Fauci while controlling the economic dispensation of Federal research funding, Dr. Fauci has been, and continues to be, on the World Health Organization's Global Preparedness Monitoring Board. He is joined on this board by the conflicted donor from the Bill and Melinda Gates Foundation's Dr. Chris Elias and the State Council of China's Dr. George F. Gao of the Chinese CDC. This GPMB stipulated that all member states must take part in a global simulation of the release of a respiratory pathogen.

Dr. Baric is one of the primary beneficiaries of U.S. Federal funds, runs a BSL-4 facility and sits on the International Committee on Taxonomy of Virus *Coronaviridae* Working Group tasked to confirm the presence of absence of the pathogen for which he is directly compensated.

As referenced in the section covering violations of 18 U.S.C. § 1001 above, numerous undisclosed commercial relationships exist between funded researchers, their funding agencies, and commercial interests in which disclosed and undisclosed commercial terms exist. A complete list of all potential implicated parties is listed in the section below entitled "The Commercial Actors".

It appears that, during the period of patent enforcement and after the Supreme Court ruling confirming that patents on genetic material were illegal, the CDC and National Institute of Allergy and Infectious Diseases led by Anthony Fauci (hereinafter "NIAID" and "Dr Fauci", respectively) entered into trade among States (including, but not limited to working with Ecohealth Alliance Inc.) and with foreign nations (specifically, the Wuhan Institute of Virology and the Chinese Academy of Sciences) through the 2014 et seq National Institutes of Health Grant R01AI110964 to exploit their patent rights.

It further appears that, during the period of patent enforcement and after the Supreme Court ruling confirming that patents on genetic material was illegal, the CDC and National Institute of Allergy and Infectious Diseases (hereinafter "NIAID") entered into trade among States (including, but not limited to working with University of North Carolina, Chapel Hill) and with foreign nations (specifically, the Wuhan Institute of Virology and the Chinese Academy of Sciences represented by Zheng-Li Shi) through U19AI109761 (Ralph S. Baric), U19AI107810 (Ralph S. Baric), and National Natural Science Foundation of China Award 81290341 (Zheng-Li Shi) et al. 2015-2016.

It further appears that, during the period of patent enforcement and after the Supreme Court ruling confirming that patents on generic material was illegal, the CDC and NIAID entered into trade among States (including, but not limited to working with University of North Carolina, Chapel Hill) and with foreign nations to conduct chimeric construction of novel coronavirus material with specific virulence properties prior to, during, and following the determination made by the National Institutes for Health

in October 17, 2014 that this work was not sufficiently understood for its biosecurity and safety standards.

In this inquiry, it is presumed that the CDC and its associates were: a) fully aware of the work being performed using their patented technology; b) entered into explicit or implicit agreements including licensing, or other consideration; and, c) willfully engaged one or more foreign interests to carry forward the exploitation of their proprietary technology when the U.S. Supreme Court confirmed that such patents were illegal and when the National Institutes of Health issued a moratorium on such research.

Reportedly, in January 2018, the U.S. Embassy in China sent investigators to Wuhan Institute of Virology and found that, "During interactions with scientists at the WIV laboratory, they noted the new lab has a serious shortage of appropriately trained technicians and investigators needed to safely operate this high-containment laboratory." The Washington Post reported that this information was contained in a cable dated 19 January 2018. Over a year later, in June 2019, the CDC conducted an inspection of Fort Detrick's U.S. Army Medical Research Institute of Infectious Diseases (hereinafter "USAMRIID") and ordered it closed after alleging that their inspection found biosafety hazards. A report in the journal Nature in 2003 (423(6936): 103) reported cooperation between CDC and USAMRIID on coronavirus research followed by considerable subsequent collaboration. The CDC, for what appear to be the same type of concern identified in Wuhan, elected to continue work with the Chinese government while closing the U.S. Army facility.

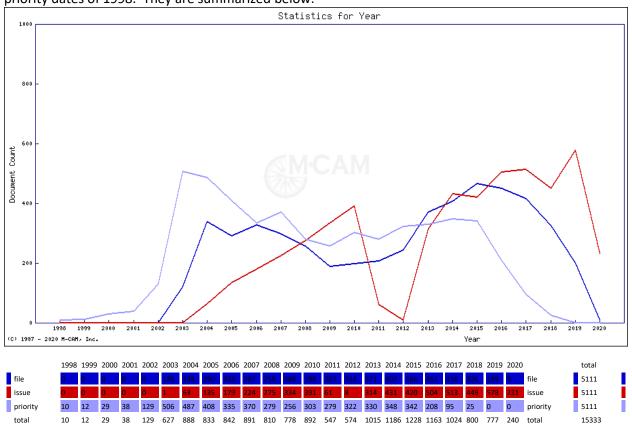
The CDC reported the first case of SARS-CoV like illness in the United States in January 2020 with the CDC's Epidemic Intelligence Service reporting 650 clinical cases and 210 tests. Given that the suspected pathogen was first implicated in official reports on December 31, 2019, one can only conclude that CDC: a) had the mechanism and wherewithal to conduct tests to confirm the existence of a "novel coronavirus"; or, b) did not have said mechanism and falsely reported the information in January. It tests credulity to suggest that the WHO or the CDC could manufacture and distribute tests for a "novel" pathogen when their own subsequent record on development and deployment of tests has been shown to be without reliability

## 35 U.S.C. §200 - 206 – Disclosure of Government Interest

#### 35 U.S.C. §202 (c)(6)

An obligation on the part of the contractor, in the event a United States patent application is filed by or on its behalf or by any assignee of the contractor, to include within the specification of such application and any patent issuing thereon, a statement specifying that the invention was made with Government support and that the Government has certain rights in the invention.

Over 5000 patents and patent applications have included reference to SARS Coronavirus dating back to priority dates of 1998. They are summarized below.



On July 23, 2020, the Patent Trial and Appeal Board of the United States Patent and Trademark Office rejected Moderna's efforts to invalidate U.S. Patent 8,058,069. This patent, owned by Arbutus Biopharma Corp (principally owned by Roivant Science Ltd), covers the lipid nanoparticle (LNP) required to deliver an mRNA vaccine. Some of the core technology was based on work originally done at the University of British Columbia and was first licensed in 1998.

mRNA-1273 – the experimental vaccine developed by Moderna for COVID-19 – uses the LNP technology that Moderna thought it had licensed from Acuitas Therapeutics Inc., a firm developed by a former principal of Arbutus' prior company Tekmira. That license did not authorize Moderna to use the technology for the COVID-19 vaccine.

M·CAM and Knowledge Ecology International have independently confirmed that Moderna has violated U.S. law in failing to disclose the U.S. government's funding interest in their patents and patent applications. While this negligence impacts all of Moderna's over 130 granted U.S. patents, it is particularly problematic for U.S. Patent 10,702,600 ('600) which is the patent relating to, "a messenger ribonucleic acid (mRNA) comprising an open reading frame encoding a betacoronavirus (BetaCoV) S protein or S protein subunit formulated in a lipid nanoparticle." The specific claims addressing the pivot to the SARS Coronavirus were patented *on March 28, 2019 – 9 months before the SARS CoV-2 outbreak!* Both the patent and the DARPA funding for the technology were disclosed in scientific publication (*New England Journal of Medicine*) but the government funds were not acknowledged in the patent.

In 2013, the Autonomous Diagnostics to Enable Prevention and Therapeutics (ADEPT) program awarded grant funding to Moderna Therapeutics for the development of a new type of vaccine based on messenger RNA. The initial DARPA grant was W911NF-13-1-0417. *The company used that technology to develop its COVID-19 vaccine, currently undergoing Phase I clinical trials in conjunction with NIH.*<sup>29</sup>

Under the Federal Acquisition Regulation (FAR) rules, contractor to the Federal Government must provide information regarding intellectual property infringement issues as part of their contract. Under FAR §27.201-1(c) and (d), the Government both requires a notice of infringement or potential infringement as well as retention of economic liability for patent infringements. Specifically, in FAR §52.227.3 (a), the "Contractor shall indemnify the Government and its officers, agents, and employees against liability, including costs for infringement of any United States Patent...". In addition to the patents cited by the USPTO in their examination of '600, M·CAM has identified fourteen other issued patents preceding the '600 patent which were used by patent examiners to limit patents arising from the same funded research including patents sought by CureVac.

In short, while Moderna enjoys hundreds of millions of dollars of funding allegiance and advocacy from Anthony Fauci and his NIAID, since its inception, it has been engaged in illegal patent activity and demonstrated contempt for U.S. Patent law. To make matters worse, the U.S. Government has given it financial backing in the face of undisclosed infringement risks potentially contributing to the very infringement for which they are indemnified.

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<sup>&</sup>lt;sup>29</sup> https://crsreports.congress.gov/product/pdf/IN/IN11446

# 21 C.F.R. § 50.24 et seq., Illegal Clinical Trial

It is unlawful to conduct medical research (even in the case of emergency) without a series of steps taken to:

- a. Establish the research with a duly authorized and independent institutional review board;
- b. Secure informed consent of all participants including a statement of risks and benefits; and,
- c. Engage in consultation with the community in which the study is to be conducted.

Dr. Anthony Fauci has forced upon the healthy population of the United States an unlawful clinical trial in which the U.S. Department of Health and Human Services are extrapolating epidemiologic data. No informed consent has been sought or secured for any of the "medical countermeasures" forced upon the population and no independent review board – as defined by the statute – has been empaneled.

Through April 2020, the official recommendation by the *Journal of the American Medical Association* was unambiguous.

"Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill."<sup>30</sup>

Part of that lack of evidence in fact showed that cloth facemasks actually <u>increased</u> influenza-linked illness.<sup>31</sup>

In contravention to <u>established science</u>, States, municipalities, and businesses have violated the legal requirements for the promulgation of medical counter measures during a public health emergency stating a "belief" that face masks limit the spread of SARS CoV-2. To date, not a single study has confirmed that a mask prevented the transmission of, or the infection by SARS CoV-2.

All parties mandating the use of facemasks are not only willfully ignoring established science but are engaging in what amounts to a whole population clinical trial. This conclusion is reached by the fact that facemask use and COVID-19 incidence are being reported in scientific opinion pieces promoted by the United States Centers for Disease Control and Prevention and others.<sup>32</sup>

Social distancing of up to 6 feet has been promoted as a means of preventing person-to-person transmission of influenza-like viruses. While one study hypothesized that infection could happen in a 6 foot range, the study explicitly states that person-to-person transfer was not tested and viability of the virus at 6 feet was not even a subject of the investigation.<sup>33</sup> That did not stop the misrepresentation of the study to be used as the basis for an unverified medical counter measure of social distancing. To date, no study has established the efficacy of social distancing to modify the transmission of SARS CoV-2. Public health officials have referenced:

<sup>30</sup> https://jamanetwork.com/journals/jama/fullarticle/2762694

<sup>31</sup> https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4420971/

<sup>32</sup> https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/cloth-face-cover-guidance.html

<sup>&</sup>lt;sup>33</sup> Werner E. Bischoff, Katrina Swett, Iris Leng, Timothy R. Peters, Exposure to Influenza Virus Aerosols During Routine Patient Care, The Journal of Infectious Diseases, Volume 207, Issue 7, 1 April 2013, Pages 1037–1046, <a href="https://doi.org/10.1093/infdis/jis773">https://doi.org/10.1093/infdis/jis773</a>

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5907354/#CR43

In contravention to <u>established science</u>, States, municipalities, and businesses have violated the legal requirements for the promulgation of medical counter measures during a public health emergency stating a "belief" that social distancing of a healthy population limits the spread of SARS CoV-2. To date, not a single study has confirmed that social distancing of any population prevented the transmission of, or the infection by SARS CoV-2.

It is unlawful under the FTC Act, 15 U.S.C. § 41 et seq., to advertise that a product or service can prevent, treat, or cure human disease unless you possess competent and reliable scientific evidence, including, when appropriate, well-controlled human clinical studies, substantiating that the claims are true at the time they are made. As a result, every party promoting the use of face masks is violating the FTC Act.

All of these laws have been broken. All relevant authorities in the United States must cease and desist the use of face masks until the matters above are rectified.

**Subject: Corona Criminal Conspiracy** 

Michelle

# The Criminal Conspiracy of Coronavirus

#### Dr. David E. Martin

Throughout the decade of the 90s Pfizer sought to research, develop and patent a coronavirus (CoV) vaccine. Their first patent filing specifically recognizing the S-protein as the immunologic target for vaccines was filed on November 14, 1990 (U.S. Patent 6,372,224). With a focus on swine and canine gastroenteritis, these efforts showed little commercial promise and the patent was abandoned in April of 2000. During the same period, the National Institute for Allergy and Infectious Disease (NIAID) under the vaccine obsession of Dr. Anthony Fauci, funded Professor Ralph Baric at the University of North Carolina Chapel Hill. This program designed to commercially weaponize a naturally occurring toxin is the beginning of the criminal conspiracy and <u>violates 18</u> <u>USC § 175, 15 USC § 1-3, and 15 USC § 8</u>) Dr. Baric's expertise was understanding how to modify components of the coronavirus associated with cardiomyopathy. NIAID Grants AI 23946 and GM63228 (leading to patent U.S. 7,279,327 "Methods for Producing Recombinant Coronavirus") was the NIH's first Gain-of-Function (GOF) project in which Dr. Baric created an "infectious, replication defective" clone of recombinant coronavirus. This work clearly defined a means of making a natural pathogen more harmful to humans by manipulating the Spike Protein and other receptor targets. A year after filing a patent on this GOF CoV, the world experienced the first outbreak of Severe Acute Respiratory Syndrome (SARS).

Under the guise of responding to a public health emergency, the United States Centers for Disease Control and Prevention (CDC) filed a patent application on the genome of SARS CoV on April 25, 2003. Accessing and manipulating the genomic data (which came from China making an "invention" claim by a U.S. entity illegal violating 35 USC ng 35 USC §101, 103), Dr. Baric, Dr. Fauci, and the CDC violated 18 USC § 175 (a felony). One year earlier, Dr. Baric and his team had already filed a patent which clearly the pathogen CDC claimed as novel in 2003. Three days after filing a patent on the genome, NIH-funded Sequoia Pharmaceuticals filed a patent for the vaccine on the virus invented a mere three days earlier. At the same time, in violation of 15 USC § 19 Dr. Fauci was appointed to a board position with the Bill and Melinda Gates Foundation (a competitor in vaccine manufacturing) thereby beginning the interlocking directorate anti-trust crime.

In 2005, the DARPA and MITRE hosted a conference in which the intentions of the U.S. Department of Defense was explicit. In a presentation focused on "Synthetic Coronaviruses Biohacking: Biological Warfare Enabling

These entities were affiliated with the WHO's Global Preparedness Monitoring Board (GPMB) whose members were instrumental in the Open Philanthropy-funded global coronavirus pandemic "desk-top" exercise EVENT 201 in October 2019. This event, funded by the principal investor in Sherlock Biosciences (a beneficiary of the SARS CoV-2 EUA for CRISPR technology) and linking interlocking funding partner, the Bill and Melinda Gates Foundation into the GPMB mandated a respiratory disease global preparedness exercise to be completed by September 2020 and alerted us to anticipate an "epidemic" scenario. We expected to see such a scenario emerge from Wuhan or Guangdong China, northern Italy, Seattle, New York or a combination thereof, as Dr. Zhengli Shi and Dr. Baric's work on zoonotic transmission of coronavirus identified overlapping mutations in coronavirus in bat populations located in these areas.

¹ We note that gain-of-function specialist, Dr. Ralph Baric, was both the recipient of millions of dollars of U.S. research grants from several federal agencies and sat on the World Health Organization's International Committee on Taxonomy of Viruses (ICTV) and the Coronaviridae Study Group (CSG). In this capacity, he was both responsible for determining "novelty" of clades of virus species but directly benefitted from determining declarations of novelty in the form of new research funding authorizations and associated patenting and commercial collaboration. Together with CDC, NIAID, WHO, academic and commercial parties (including Johnson & Johnson; Sanofi and their several coronavirus patent-holding biotech companies; Moderna; Pfizer; Merck; BioNTech; AstraZeneca; Janssen; Ridgeback; Gilead (Dr. Baric's alter ego); Sherlock Biosciences; and others), a powerful group of interests constituted what are "interlocking directorates" under U.S. anti-trust laws. Further, most of these entities, including the Federal Government ones violated 35 USC § 200-206 by failing to disclose Federal Government interest in the remedies proposed.

Technologies", Dr. Baric presented the malleability of CoV as a biological warfare agent. <u>Violating 18 USC § 175</u> and inducing the non-competitive market allocation (<u>violating 15 USC § 8</u>) for years to follow, Dr. Baric and the U.S. Department of Defense spent over \$45 million in amplifying the toxicity of CoV and its chimeric derivatives.

From 2011 until the alleged COVID-19 pandemic, Dr. Fauci has routinely lamented about the inadequacy of public funding for his vaccine programs and the public's general unwillingness to succumb to his insistence that every MUST be vaccinated against influenza. Despite repeated appropriations to advance vaccine dependency, his efforts have been largely unsuccessful. NIAID – under Dr. Fauci's direct authorization – encouraged UNC Chapel and Dr. Baric's lab to ignore the GoF moratorium in a letter dated October 21, 2014. At that time, Drs. Fauci, Baric and EcoHealthAlliance's Peter Daszak were in possession of an extremely dangerous Chinese pathogen identified a year earlier in Wuhan.<sup>2</sup>

While many illegal acts were committed by the conspirators leading up to 2015, the domestic terrorism program (<u>in violation of 18 USC § 2339</u>) was announced by NIAID-funded Daszak at the National Academy of Sciences. Here, he announced what was to become the domestic and global terrorism event branded COVID-19.

"...until an infectious disease crisis is very real, present, and at an emergency threshold, it is often largely ignored. To <u>sustain the funding base</u> beyond the crisis, he said, we need to increase public understanding of the need for MCMs such as a pan-influenza or pancoronavirus vaccine. A key driver is the media, and the economics follow the hype. We need to use that hype to our advantage to get to the real issues. Investors will respond if they see profit at the end of process, Daszak stated."

It is not surprising that one year later NIAID's funding paid off with Dr. Baric's lab announcing that the Wuhanderived pathogen was "poised for human emergence".4

Knowing that the U.S. Department of Health and Human Services (through CDC, NIH, NIAID, and their funded laboratories and commercial partners) had patents on each proposed element of medical counter measures and their funding, Dr. Fauci, Dr. Gao (China CDC), and Dr. Elias (Bill and Melinda Gates Foundation) conspired to

<sup>&</sup>lt;sup>2</sup> By October 2013, the Wuhan Institute of Virology 1 coronavirus S1 spike protein was described in NIAID's funded work in China. This work involved NIAID, USAID, and Peter Daszak, the head of EcoHealth Alliance. This work, funded under R01AI079231, was pivotal in isolating and manipulating viral fragments selected from sites across China which contained high risk for severe human response. (Ge, XY., Li, JL., Yang, XL. et al. Isolation and characterization of a bat SARS-like coronavirus that uses the ACE2 receptor. Nature 503, 535–538 (2013).) The GoF work NIAID allowed to persist in the face of the moratorium was Dr. Baric's work with this pathogen

<sup>&</sup>lt;sup>3</sup> Forum on Medical and Public Health Preparedness for Catastrophic Events; Forum on Drug Discovery, Development, and Translation; Forum on Microbial Threats; Board on Health Sciences Policy; Board on Global Health; Institute of Medicine; National Academies of Sciences, Engineering, and Medicine. Rapid Medical Countermeasure Response to Infectious Diseases: Enabling Sustainable Capabilities Through Ongoing Public- and Private-Sector Partnerships: Workshop Summary. Washington (DC): National Academies Press (US); 2016 Feb 12. 6, Developing MCMs for Coronaviruses. Available from: https://www.ncbi.nlm.nih.gov/books/NBK349040/

<sup>&</sup>lt;sup>4</sup> Menachery VD, Yount BL Jr, Sims AC, Debbink K, Agnihothram SS, Gralinski LE, Graham RL, Scobey T, Plante JA, Royal SR, Swanstrom J, Sheahan TP, Pickles RJ, Corti D, Randell SH, Lanzavecchia A, Marasco WA, **Baric RS**. 2016. <u>SARS-like WIV1-CoV poised for human emergence</u>. **Proc Natl Acad Sci U S A. 2016** Mar 14. pii: 201517719

commit acts of terror on the global population – including the citizens of the United States – when, in September 2019, they published the following mandate in *A World At Risk*:

"Countries, donors and multilateral institutions must be prepared for the worst. A rapidly spreading pandemic due to a lethal respiratory pathogen (whether naturally emergent or accidentally or deliberately released) poses additional preparedness requirements. Donors and multilateral institutions must ensure adequate investment in developing innovative vaccines and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate non-pharmaceutical interventions. All countries must develop a system for immediately sharing genome sequences of any new pathogen for public health purposes along with the means to share limited medical countermeasures across countries.

Progress indicator(s) by September 2020

- Donors and countries commit and identify timelines for: financing and development of a universal influenza vaccine, broad spectrum antivirals, and targeted therapeutics. WHO and its Member States develop options for standard procedures and timelines for sharing of sequence data, specimens, and medical countermeasures for pathogens other than influenza.
- Donors, countries and multilateral institutions develop a multi-year plan and approach for strengthening R&D research capacity, in advance of and during an epidemic.
- WHO, the United Nations Children's Fund, the International Federation of Red Cross and Red Crescent Societies, academic and other partners identify strategies for increasing capacity and integration of social science approaches and researchers across the entire preparedness/response continuum."5

As if to confirm the utility of the September 2019 demand for "financing and development of" vaccine and the fortuitous SARS CoV-2 alleged outbreak in December of 2019, Dr. Fauci began gloating that his fortunes for additional funding were likely changing for the better. In a February 2020 interview in *STAT*, he was quoted as follows:

"The emergence of the new virus is going to change that figure, likely considerably, Fauci said. "I don't know how much it's going to be. But I think it's going to generate more sustained interest in coronaviruses because it's very clear that coronaviruses can do really interesting things." 6

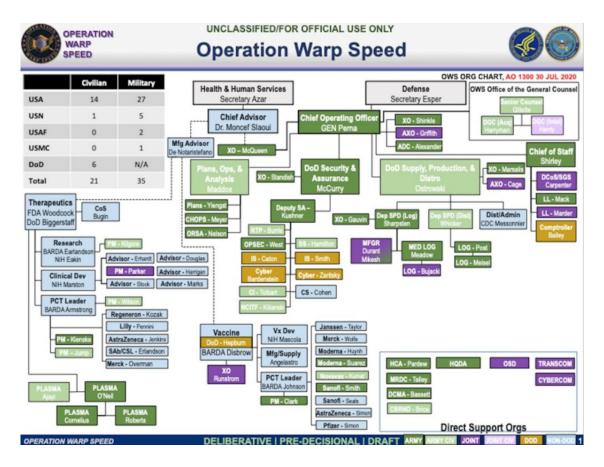
In November 2019 – one month before the alleged "outbreak" in Wuhan, Moderna entered into a material transfer agreement – brokered by the Vaccine Research Center at NIAID (at which UNC Chapel Hill alum Dr. Kizzy Corbett worked – to access Dr. Baric's Spike Protein data to commence vaccine development. In his own written statement obtained by the *Financial Times*, he refers to this agreement as being the foundation for the mRNA Moderna vaccine.<sup>7</sup>

To finalize the nature of the racketeering and anti-trust criminal conspiracy, when it came time to commercialize the NIH and DARPA owned spike protein and pass it off as a "vaccine" (in conflict with the standard for vaccines in statutory and scientific application), the Operation Warp Speed contract was awarded to DoD contraction ATI, a subsidiary of ANSER. In a graph reminiscent of the anti-trust hearings at the formation of the Clayton Act in the early 20th century, the identify of the interlocking conflicts of interests are presented in graphic relief. It is with no surprise that the result of this price-fixing conspiracy was the enrichment of the conspiring parties and the harm of consumers.

<sup>&</sup>lt;sup>5</sup> https://apps.who.int/gpmb/assets/annual\_report/GPMB\_annualreport\_2019.pdf (page 8)

<sup>&</sup>lt;sup>6</sup> https://www.statnews.com/2020/02/10/fluctuating-funding-and-flagging-interest-hurt-coronavirus-research/

<sup>&</sup>lt;sup>7</sup> https://pubmed.ncbi.nlm.nih.gov/32756549/



Indeed, the money followed the hype and they used the hype to get to the real issues. Investors follow where they see profit at the end of the process.

And real Americans are dying each day because a criminal organization unleashed terror resulting in the deaths of Americans.

#### 18 U.S.C. § 2331 §§ 802 – Acts of Domestic Terrorism resulting in death of American Citizens

Pub. L. No. 107-52 expanded the definition of terrorism to cover "domestic," as opposed to international, terrorism. A person engages in domestic terrorism if they do an act "dangerous to human life" that is a violation of the criminal laws of a state or the United States, if the act appears to be intended to: (i) intimidate or coerce a civilian population; (ii) influence the policy of a government by intimidation or coercion;

Every single Act, the declaration of the State of Emergency, the Emergency Use Authorization, the fraudulent face masks, the business closures, and the OSHA and CMS vaccine mandates are ALL admitted by the conspirators to be acts to coerce the population into taking a vaccine. They announced it in 2015, the prepared the pathogen in 2016, and laid out the terror campaign in September 2019. And now they profit from the death of Americans.

Very short video. Daszak explains how they sequenced it and then had China make it.

#### Michelle



Peter Daszak.mp4

Look at Immunity then #3 Are There Any Limitations to Immunity
Michelle

Emergency

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#### PREP Act Q&As

The following is intended to address an overview of the PREP Act and frequently asked questions from the manufacturing industry, the healthcare community, and state and local government officials. It is not an exhaustive review of the PREP Act's provisions in all contexts or a protocol for the HHS's implementation of the PREP Act. In addition, other legal protections may be available at the federal, state, and local government level.

The Public Readiness and Emergency Preparedness Act (PREP Act):

- > adds new legal authorities to the Public Health Service (PHS) Act
- provides liability immunity related to the manufacture, testing, development, distribution, administration and use of medical countermeasures against chemical, biological, radiological and nuclear agents of terrorism, epidemics, and pandemics
- adds authority to establish a program to compensate eligible individuals who suffer injuries from administration or use of products covered by the PREP Act's immunity provisions

The PREP Act authorizes the Secretary of the Department of Health and Human Services (Secretary) (HHS) to issue a PREP Act Declaration ("Declaration") that provides immunity from liability for any loss caused, arising out of, relating to, or resulting from administration or use of countermeasures to diseases, threats and conditions determined in the Declaration to constitute a present or credible risk of a future public health emergency.

#### **Liability Immunity and Compensation**

In general, the liability immunity applies to entities and individuals involved in the development, manufacture, testing, distribution, administration, and use of medical countermeasures described in a Declaration. The only statutory exception to this immunity is for actions or failures to act that constitute willful misconduct.

The PREP Act also authorizes a United States Treasury fund that compensates eligible individuals for serious physical injuries or deaths directly caused by administration or use of a countermeasure covered by the Declaration.

#### PREP Declaration

- 1. What Information is Included in a PREP Act Declaration?
- 2. Where is the Declaration Published?
- 3. What Factors Are Considered by the Secretary?
- 4. How is a PREP Act Declaration Different from a Declaration of Public Health Emergency under section 319 of the Public Health Service Act?

#### **Immunity**

- 1. What is Immunity from Liability?
- 2. Who May be Afforded Immunity from Liability under a PREP Act Declaration?
- 3. Are There Any Limitations on Immunity from Liability?
- 4. What Countermeasures May be Covered by Immunity from Liability?
- 5. When Does Immunity Under the PREP Act Become Available?

#### PREP Act

- Public Readiness and Emergency Preparedness (PREP) Act Overview
- ▶ PREP Act Glossary of Terms
- ▶ PREP Act Question and Answers

#### **Legal Authorities**

- ▶ Legal Authorities Overview
- ▶ Legal Authority of the Secretary
- ▶ Public Health Emergency (PHE) Declaration
- ▶ PHE Frequently Asked Questions
- ▶ 1135 Waivers
- ▶ Emergency Use Authorization
- ▶ Pandemic and All-Hazards
  Preparedness Act of 2006
- ▶ Pandemic and All-Hazards
  Preparedness and Advancing
  Innovation Act (PAHPAIA) of
- ▶ Pandemic and All-Hazards
  Preparedness Reauthorization
  Act of 2013

#### Claims and Compensation

- 1. Is There Any Compensation for Injury?
- 2. How Does an Individual File a Claim for Benefits?
- 3. What Options does an Injured Individual have if Congress has not funded the Compensation Fund?rt. Can I receive funding priority in another way?

#### Litigation

1. Has there been any litigation related to the PREP Act?

#### **PREP Declaration**

1. What Information is Included in a PREP Act Declaration?

#### A Declaration includes:

- ▶ A determination that a disease or health condition or threat to health constitutes a public health emergency, or that there is a credible risk that it will in the future constitute an emergency;
- ▶ The category of diseases, health conditions, or health threats for which administration and use of the countermeasure is recommended. During the time period covered by the Declaration, it is presumed that the recommended countermeasure;
- ▶ The effective time period (the Secretary may specify an extended time period for manufacturers to dispose of the countermeasure and for others to cease administration and use of the countermeasure);
- ▶ The population of individuals receiving the countermeasure and the geographic area of administration and use of the countermeasure for which immunity from liability is in effect for program planners and qualified persons (manufacturers and distributors are provided liability immunity regardless of who receives the countermeasure or where it is administered or used);
- ▶ Limitations (if any) on the geographic area or areas for which immunity is in effect with respect to administration or use of the countermeasure;
- ▶ Limitations (if any) on the means of distribution;
- Any additional persons identified as qualified to prescribe, dispense, or administer the countermeasure; and
- Any other limitations or conditions.

#### 2. Where is the Declaration Published?

The Declaration and any amendments are published in the Federal Register. It is important to note, however, that unless the Declaration specifies otherwise, it is effective upon the Secretary's signature, not upon publication in the Federal Register.

3. What Factors Are Considered by the Secretary?

In deciding whether to issue a PREP Act Declaration, HHS must consider the desirability of encouraging the design, development, clinical testing or investigation, manufacture, labeling, distribution, formulation, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administering, licensing, and use of the countermeasure recommended in the Declaration. HHS may also consider other relevant factors.

4. How is a PREP Act Declaration Different from a Declaration of Public Health Emergency under section 319 of the Public Health Service Act?

Under section 319 of the Public Health Service Act, HHS may issue a declaration of a public health emergency based upon a determination that a:

- b disease or disorder presents a public health emergency; or
- public health emergency, including significant outbreaks of infectious disease or bioterrorist attacks, otherwise exists.

Following a section 319 declaration, the HHS can take a number of emergency actions, including:

- Waiving certain Medicare, Medicaid, State Children's Health Insurance Program, and Health Insurance Portability and Accountability Act requirements;
- Allowing States and localities to temporarily reassign personnel supported with federal funds during the period of the emergency.

A determination of a public health emergency is different from a PREP Act declaration. The declarations are made on different public health determinations, and have different legal effects. A PREP Act Declaration may be made in advance of a public health emergency and may provide liability immunity for activities both before and after a declared public health emergency. A separate declaration under section 319 or other statutes is not needed for immunity under the PREP Act to take effect unless the PREP Act Declaration states that a public health or other emergency Declaration is needed to trigger immunity.

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#### **Immunity**

#### 1. What is Immunity from Liability?

Immunity means that courts must dismiss claims brought against any entity or individual covered by the PREP Act. Claims that courts must dismiss include claims for any loss that is related to any stage of design, development, testing, manufacture, labeling, distribution, formulation, labeling, packaging, marketing, promotion, sale, purchase, donation, dispensing, prescribing, administration, licensing or use of a countermeasure recommended in a Declaration. This includes, but is not limited to, claims for:

- death;
- physical, mental, or emotional injury, illness, disability, or condition or fear of any such injury, illness, disability, or condition;
- > any need for medical monitoring; or
- property damage or loss, including business interruption loss.

The only exception is for claims of willful misconduct. (See Question: Are There Any Limitations on Immunity From Liability?).

#### 2. Who May be Afforded Immunity from Liability under a PREP Act Declaration?

A Declaration may provide liability immunity for covered persons. Covered persons may include, at the Secretary's discretion:

- ▶ Manufacturers of countermeasures;
- Distributors of countermeasures;
- Program planners, i.e., individuals and entities involved in planning, administering, or supervising programs for distribution of a countermeasure (e.g., State or local governments, Indian tribes, or private sector employers or community groups that establish requirements or provide guidance, technical or scientific advice or assistance, or provide a facility);
- Qualified persons, i.e., persons who prescribe, administer, or dispense countermeasures such as healthcare and other providers or other categories of persons named in a Declaration, e.g., volunteers;
- Officials, agents, and employees of any of these entities or persons; and
- ▶ The United States.

#### 3. Are There Any Limitations on Immunity from Liability?

Immunity from liability under the PREP Act is not available for death or serious physical injury caused by willful misconduct. A "serious physical injury" is one that is life-threatening, or results in or requires medical or surgical intervention to preclude permanent impairment of a body function or results in permanent damage to a body structure. Willful misconduct is misconduct that is greater than any form of recklessness or negligence. It is defined in the PREP Act as an act or failure to act that is taken:

- intentionally to achieve a wrongful purpose;
- knowingly without legal or factual justification; and
- in disregard of a known or obvious risk that is so great as to make it highly probable that the harm will outweigh the benefit. All three of these conditions must be proven with clear and convincing evidence. Willful misconduct cannot be found against:
- A manufacturer or distributor for actions regulated by HHS under the Public Health Service Act or the

be appropriated by Congress into this account to pay claims. If funds are appropriated, compensation for serious physical injuries may then be available to eligible requesters under the HRSA's Countermeasures Injury Compensation Program (CICP). Requests for Benefits must be made to HRSA's CICP.

Serious physical injury means an injury that warranted hospitalization (whether or not the person was actually hospitalized) or that led to a significant loss of function or disability. The CICP pays reasonable and necessary medical benefits, and/or lost wages for eligible injured countermeasure recipients. Death benefits may also be available to certain survivors of eligible individuals who died as a direct result of the administration or use of a covered countermeasure.

The CICP is payer of last resort, so benefits are reduced by the amounts payable by all other public and private third-party payers (such as health insurance and workers' compensation). The regulations implementing the CICP are at 42 CFR part 110.

#### 2. How Does an Individual File a Claim for Benefits?

An individual who may have suffered a serious physical injury from the administration or use of a countermeasure under a Declaration may seek compensation by filing a Request for Benefits with the CICP. A Request for Benefits form must be filed within one year of receiving the countermeasure.

A legal or personal representative may file on the individual's behalf, but is generally not required unless the injured person is a minor or an adult who lacks legal capacity to receive payments. If the injured person has died (regardless of cause of death), the executor or administrator of the estate may file for benefits on behalf of the estate. If the injured person died as a direct result of receiving the countermeasure, certain survivors may file a request for death benefits.

As well as filing a Request for Benefits Form, the requester must submit all required medical records and other supporting documentation. Further information on filing a Request for Benefits is available on the CICP's website

#### 3. What Options does an Injured Individual have if Congress has not funded the Compensation Fund?

If no funds have been appropriated to the compensation program, or the Secretary does not make a final determination on the individual's request within 240 days, or the individual decides not to accept the compensation, the injured individual or his representative may pursue a tort claim in the United States District Court for the District of Columbia, but only if the claim involves willful misconduct and meets the other requirements for suit under the PREP Act. If the individual accepts compensation from the CICP, or if there is no willful misconduct, the individual does not have a tort claim that can be filed in a United States Federal or a State court.

Any award is reduced by public or private insurance or worker's compensation available to the injured individual. Awards for non-economic damages, such as pain, suffering, physical impairment, mental anguish, and loss of consortium are also limited.

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#### Litigation

#### 1. Has there been any litigation related to the PREP Act?

On November 21, 2012, the Appellate Division of the New York Supreme Court in *Parker v. St. Lawrence County Public Health Department*, 102 A.D.3d 140 (2012) upheld PREP Act protections for a county that conducted a school based vaccination clinic in response to the H1N1 outbreak.

During the clinic, a nurse employed by St. Lawrence County inadvertently vaccinated a kindergartener in the absence of parental informed consent. The child's mother filed suit, arguing that the county had committed negligence and battery. The county moved to dismiss the complaint on the basis that the claim was preempted under the PREP Act. The lower court denied the defendant's motion to dismiss, asserting that the PREP Act was not intended by Congress to protect against claims arising from failure to obtain informed consent. The county appealed and the United States submitted an amicus brief supporting the county.

The appellate court dismissed the plaintiffs claims, finding that the federal PREP Act preempted the claims under state law and that the breadth of liability immunity provided under the PREP Act precluded the plaintiff's claims of negligence and battery. The court noted the alternative remedy provided by the countermeasure injury compensation program and the possibility of a federal cause of action for willful misconduct claims.

The period for appeal of the case has expired.

In another case, *Kehler v. Hood*, 2012 WL 1945952 (E.D.Mo.), plaintiffs alleged that the physician and her employing hospital were negligent in failing to obtain the adult patient's informed consent and a consult from a specialist prior to the administration of the vaccination, which resulted in a severe case of transverse myelitis to the patient, and loss of consortium to the spouse. Defendants then brought third party product liability/failure to warn claims against the manufacturer.

The parties did not dispute that the manufacturer, was protected by the PREP Act, nor did they allege that it engaged in willful misconduct. As a result, the federal Eastern District Court of Missouri dismissed the claim against the manufacturer. Finding that it had no jurisdiction over plaintiffs' remaining claims, the federal court remanded the case to state court for further consideration of the plaintiffs' claims.

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This page last reviewed: January 13, 2021

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Assistant Secretary for Preparedness and Response (ASPR), 200 Independence Ave., SW, Washington, DC 20201

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# Subject: Dr Dave Martin CEO Terrorism https://www.brighteon.com/3d2299e3-b420-446f-a8d1-7f3e10b80df0 Michelle

Here is the FDA's own slide presentation. Look at page 17. They were aware of ALL these side effects BEFORE they released the injections onto the public.
Michelle

### Vaccines and Related Biological Products Advisory Committee October 22, 2020 Meeting Presentation

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# CBER Plans for Monitoring COVID-19 Vaccine Safety and Effectiveness

Steve Anderson, PhD, MPP
Director, Office of Biostatistics & Epidemiology, CBER

VRBPAC Meeting October 22, 2020

### FDA Vaccine Surveillance: Pre-licensure Pharmacovigilance Planning

#### "Safety throughout the lifecycle" approach for vaccines (pre- and post-licensure):

- Manufacturer submits pharmacovigilance plans (PVP) of proposed post-licensure surveillance activities
  - Submitted for BLA and for EUA
  - Post-licensure commitment (PMC) studies, registries for general safety
     concern
  - Post-licensure requirement (PMR) clinical study, epidemiological study, registries, etc. to verify a specific safety signal
  - Routine pharmacovigilance Passive surveillance (VAERS), review of safety literature, available studies, etc.

#### FDA Vaccine Surveillance Programs: Post-Licensure

#### 1. Passive Surveillance of Vaccines

- Vaccine Adverse Event Reporting System (VAERS)
  - Management shared by CDC and FDA

#### 2. Active Surveillance Monitoring Program

- FDA BEST
- FDA-CMS partnership

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#### **VAERS**



Vaccine Adverse Event Reporting System

### Co-managed by CDC and FDA





#### VAERS Vaccine Adverse Event Reporting System www.vaers.hhs.gov

About VAERS

Report an Adverse Event

**VAERS Data** 

Resources

Submit Follow-Up Information

#### Have you had a reaction following a vaccination?

- 1. Contact your healthcare provider.
- Report an Adverse Event using the VAERS online form or the new downloadable PDF. New!

Important: If you are experiencing a medical emergency, seek immediate assistance from a healthcare provider or call 9-1-1. CDC and FDA do not provide individual medical treatment, advice, or diagnosis. If you need individual medical or health care advice, consult a qualified healthcare provider.

#### ¿Ha tenido una reacción después de recibir una vacuna?

- 1. Contacte a su proveedor de salud.
- Reporte una reacción adversa utilizando el formulario de VAERS en línea o la nueva versión PDF descargable. Nuevo!



What is VAERS?



REPORT AN ADVERSE EVENT

Review reporting requirements and submit reports.



SEARCH VAERS DATA

Download VAERS Data and search the CDC WONDER database.



REVIEW RESOURCES

Find materials, publications, learning tools, and other resources.



SUBMIT FOLLOW-UP INFORMATION

Upload additional information related to VAERS reports.

#### VAERS – FDA CBER Efforts



- CDC presentation covered VAERS so will provide summary of FDA efforts
- FDA and CDC have weekly and bi-weekly coordination meetings on VAERS and Pharmacovigilance activities between CBER OBE and OBE Division of Epidemiology (DE) and CDC Immunization Safety Office
- CBER DE Physicians will be reviewing the serious adverse event reports from VAERS for COVID-19 vaccines review of individual reports, death reports, conduct aggregate analyses, case-series, etc.
- FDA will utilize statistical data-mining methods to detect disproportional reporting of specific vaccine-adverse event combinations to identify AEs that are more frequently reported

#### FDA Vaccine Surveillance Programs: Post-Licensure

- 1. Passive Surveillance of Vaccines
  - Vaccine Adverse Event Reporting System (VAERS)
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- 2. Active Surveillance Monitoring Program
  - FDA BEST
  - FDA-CMS partnership

#### FDA Vaccine-Legislative Authorization Active Surveillance

Legislation, mandates and Current Surveillance

#### FDA Amendments Act of 2007:

Directed FDA to develop an active risk identification and analysis system –
 such as Sentinel, and later BEST, and others and covers >100 million persons

#### **Prescription Drug User Fee Act VI (2017)**

- Discussion between FDA and Industry on Priority Areas Renewed every 5 yrs
- Provides resources/funding for Sentinel, BEST, real-world evidence, etc.

# COVID-19 Vaccine Monitoring Data Considerations



- Rapid data access for near real time surveillance
- Large databases of tens of millions of patients for evaluating vaccine rare serious adverse events
- Data representing integrated care spectrum outpatient, physician, inpatient, etc.
- High quality data to assess and confirm potential adverse events or safety concerns for COVID-19 vaccines
- Data with significant clinical detail or medical chart access

#### 1. FDA Biologics Effectiveness and Safety (BEST) System

- Several partners Acumen, IBM Watson, IQVIA, OHDSI, HealthCore, Humana, Optum, Healthagen, Academic organizations
- Represents variety of healthcare settings inpatient, emergency department, outpatient, etc.

#### **BEST Initiative Expansion**



#### **CLAIMS Data Sources**

Data Sources	Туре	Patients (millions)
MarketScan	Claims	254
Blue Health Intelligence	Claims	33.6
Optum	Claims	70
HealthCore	Claims	56
Healthagen	Claims	26
OneFlorida Clinical Research Consortium (Medicaid)	Claims	6.7

#### **BEST Initiative Expansion**

#### **EHR Data Sources**



Data Sources	Туре	Patients (millions)
MedStar Health	EHR	6
IBM Explorys	EHR	90
Regenstrief Institute	Claims and EHR	20.2
Columbia University	EHR	6.6
University of Colorado	EHR	17
University of California San Francisco	EHR	3.2
PEDSnet Clinical Research Consortium	EHR	6.2
Optum EHR	EHR	105
OneFlorida Clinical Research Consortium	EHR	5.6
OneFlorida Clinical Research Consortium	Linked EHR-Claims	1.5
MarketScan Explorys Claims-EHR (CED)	Linked EHR-Claims	5.5
Optum	Linked EHR-Claims	50

#### 2. CMS (Center for Medicare & Medicaid Services)

#### Federal Partners

- Ongoing FDA-CMS partnership on vaccine safety since 2002
- Data cover very large population of approximately 55 million elderly US beneficiaries <u>></u>65yrs of age
- >92% of US elderly use Medicare so database represents the elderly population and not a sample
- Represents variety of healthcare settings inpatient, outpatient, etc.
- Consists of claims data with access to medical charts

### **Limitations of Data Systems**



 Not all claims and EHR data systems can be used to address a vaccine safety or effectiveness regulatory question

- Each data system has its limitations
  - Populations, healthcare settings, clinical detail, necessary parameters, data lag, exposures and outcomes that are captured





#### "Near real-time surveillance" or rapid-cycle analyses (RCA)

- FDA plans on monitoring 10 -20 safety outcomes of interest to be determined based on:
  - Pre-market review of sponsor safety data submitted to FDA
  - In coordination with federal partners, international regulatory partners and organizations, academic experts, others
  - Literature and regulatory experience with similar vaccines, novel vaccine platforms, and using other relevant data
  - FDA plans on using <u>CMS data</u> for COVID-19 vaccine RCA near real time with efforts

# FDA Safety Surveillance of COVID-19 Vaccines: <u>DRAFT</u> Working list of possible adverse event outcomes \*\*\*Subject to change\*\*\*

- Guillain-Barré syndrome
- Acute disseminated encephalomyelitis
- Transverse myelitis
- Encephalitis/myelitis/encephalomyelitis/ meningoencephalitis/meningitis/ encepholapathy
- Convulsions/seizures
- Stroke
- Narcolepsy and cataplexy
- Anaphylaxis
- Acute myocardial infarction
- Myocarditis/pericarditis
- Autoimmune disease

- Deaths
- Pregnancy and birth outcomes
- Other acute demyelinating diseases
- Non-anaphylactic allergic reactions
- Thrombocytopenia
- Disseminated intravascular coagulation
- Venous thromboembolism
- Arthritis and arthralgia/joint pain
- Kawasaki disease
- Multisystem Inflammatory Syndrome in Children
- Vaccine enhanced disease

# FDA Experience with Near Real Time Surveillance / RCA



#### FDA and CMS - RCA

- Conduct "near real-time" surveillance for annual influenza vaccine and Guillain-Barre Syndrome(GBS) since 2007
- Support confirmation of CDC rapid-cycle analyses of safety for seasonal influenza vaccine, Shingrix, and others

#### FDA Sentinel – Rapid Surveillance

 Near real-time, rapid surveillance in 2017-2018 seasonal influenza vaccine – evaluation of 6 health outcomes of interest



#### FDA COVID-19 vaccine safety surveillance Plans

#### Epidemiological analyses

- Need capability to resolve potential safety signals identified from near real-time surveillance, TreeScan and other sources
- Rapid queries and small epidemiological studies
- Larger self-controlled, cohort, comprehensive protocol-based studies

# **COVID-19 Vaccine <u>Effectiveness</u> Surveillance Plans**



- COVID-19 vaccine(s) there may be limited information available at licensure on level and duration of effectiveness
- Manufacturers may conduct certain COVID-19 vaccine effectiveness postlicensure studies
- FDA may conduct COVID-19 vaccine effectiveness studies
  - General effectiveness studies including subpopulations of interest
  - Duration of protection studies
  - Others
- FDA coordinating COVID-19 Vaccine Effectiveness efforts with the CDC NCIRD through monthly, bi-monthly meetings

### FDA-CMS-CDC Vaccine Effectiveness Experience



 Extensive experience with the data and methods needed to conduct vaccine effectiveness studies

 Produced several vaccine effectiveness and relative vaccine effectiveness studies for influenza and zoster vaccines

Conducted duration of effectiveness analysis of Zostavax vaccine





- Actively studying risk factors for COVID-19 and preparing to study safety and effectiveness of vaccines and biologics therapies
- More than 30 publications since 2012
- Results included in Congressional testimony

# CBER COVID-19 Vaccine Monitoring Transparency Considerations



- Master Protocols for Safety and Effectiveness outcomes
- Posting of draft protocols for public comment
- Posting of final protocols and final study reports on the BESTinitiative.org website

# US Government-wide Efforts COVID-19 Vaccine Monitoring



#### **Large US Government Effort**

FDA Coordinating its COVID-19 vaccine safety and effectiveness monitoring efforts with other government agencies:

- Centers for Disease Control (CDC)
- Centers for Medicare& Medicaid Services (CMS)
- Veterans Administration (VA)
- National Institutes of Health
- Department of Defense
- Indian Health Services

# US Government-wide Efforts COVID-19 Vaccine Monitoring (2)



### **Large US Government Effort**

- Weekly meetings between FDA and CDC, regular meetings with VA and CMS
- Planned sharing of protocols, discussion safety and effectiveness outcomes of interest
- Coordinated planning and conduct of surveillance activities such as near real time surveillance/ RCA between FDA, CDC, CMS, VA, and DOD

#### Acknowledgments



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- Manette Niu
- CBER OBE Colleagues
- CDC Colleagues
- CMS Colleagues
- VA Colleagues
- FDA Partners: Acumen, IBM Watson and new partners in FY2021



### Thank you!

Questions?

And now the world knows the truth.
Michelle



#### NFWS

## Bayer executive: mRNA shots are 'gene therapy' marketed as 'vaccines' to gain public trust

'We probably would have had a 95% refusal rate' for these shots two years ago, but the pandemic and marketing of the injections as 'vaccines' has made them popular with the public, said Stefan Oelrich.



Stefan Oelrich, president of Bayer's Pharmaceuticals Division, speaks at the 2021 Global Health
Summit
Screenist Stefan Oelrich, president of Bayer's Pharmaceuticals Division, speaks at the 2021 Global Health
Screenist Stefan Oelrich, president of Bayer's Pharmaceuticals Division, speaks at the 2021 Global Health

YouTube / screenshot

#### <u>Jack Bingham</u>

#### Wed Nov 10, 2021 - 10:40 am EST

BERLIN (<u>LifeSiteNews</u>) – The president of Bayer's Pharmaceuticals Division told international "experts" during a globalist health conference that the mRNA COVID-19 shots are indeed "cell and gene therapy" marketed as "vaccines" to be palatable to the public.

Stefan Oelrich, president of Bayer's Pharmaceuticals Division, made these comments at this year's World Health Summit, which took place in Berlin from October 24-26 and hosted 6,000 people from 120 countries. Oelrich <u>told</u> his fellow international "experts" from academia, politics, and the private sector that the novel mRNA COVID "vaccines" are actually "cell and gene therapy" that would have otherwise been rejected by the public if not for a "pandemic" and favorable marketing.

"We are really taking that leap [to drive innovation] — us as a company, Bayer — in cell and gene therapies ... ultimately the mRNA vaccines are an example for that cell and gene therapy. I always like to say: if we had surveyed two years ago in the public — 'would you be willing to take a gene or cell therapy and inject it into your body?' — we probably would have had a 95% refusal rate," stated Oelrich.

"Our successes over these 18 months [the duration of the COVID 'pandemic'] should embolden us to fully focus much more closely on access, innovation and collaboration to unleash health for all, especially as we enter, on top of everything else that is happening, a new era of science – a lot of people talk about the Bio Revolution in this context," continued the businessman.

According to the McKinsey Global Institute, the "Bio Revolution" is "a confluence of advances in biological science and accelerating development of computing, automation, and artificial intelligence [that] is fueling a new wave of innovation. This Bio Revolution could have significant impact on economies and our lives, from health and agriculture to consumer goods, and energy and materials."

In addition to gene therapy and a biological "revolution," Oelrich also mentioned the role his company has, along with other prominent institutions and figures, in pushing contraception on developing countries.

"We also need to focus on what is socially responsible outside of Europe and ensure sustainable action there. We pledged, this past year, to give an additional hundred million women access to contraception in the world. We've invested 400 million this year into new plants that are dedicated to produce long-acting contraceptives for women in low-and-middle income countries ... Together with Bill and Melinda Gates we're working very closely on family planning initiatives," said Oelrich, implying one of the methods of attaining a "sustainable" world is by reducing births, and subsequently reducing the planet's population.

Oelrich's words echo a similar agenda as the infamous "<u>Great Reset</u>," a radical <u>socialist plan</u> designed by globalist elites, gathering at the World Economic Forum (WEF) in Davos, Switzerland once a year, <u>which</u> "seeks to 'push the reset button' on the global economy."

In the announcement of the Great Reset initiative, the WEF also credited the COVID-19 "pandemic" for putting them in an advantageous position to march towards their global revolutionary goals.

"COVID-19 lockdowns may be gradually easing, but anxiety about the world's social and economic prospects is only intensifying. There is good reason to worry: a sharp economic downturn has already begun, and we could be facing the worst depression since the 1930s. But, while this outcome is likely, it is not unavoidable," wrote the WEF's founder Klaus Schwab in June 2020.

But, "one silver lining of the pandemic is that it has shown how quickly we can make radical changes to our lifestyles. Almost instantly, the crisis forced businesses and individuals to abandon practices long claimed to be essential, from frequent air travel to working in an office," added the economist.

"To achieve a better outcome, the world must act jointly and swiftly to revamp all aspects of our societies and economies, from education to social contracts and working conditions. Every country, from the United States to China, must participate, and every industry, from oil and gas to tech, must be transformed. In short, we need a 'Great Reset' of capitalism," stressed Schwab.

#### READ: World Economic Forum head's prediction of microchips 'in our brains' is coming true, thanks to Big Tech

Both Oelrich and Schwab have been major advocates for the widespread use of the novel and experimental mRNA COVID vaccines. These same shots, which <u>do not complete clinical trials</u> until 2023, have been linked to <u>millions of injuries</u> and tens of thousands of deaths worldwide.

Seemingly in line with Bayer, WEF, and the Gates Foundation's goal of reducing births, many of the notable COVID-19 vaccine adverse effects have also played a role in reducing births. World Health Organization (WHO) data <u>reports</u> many cases of stillbirths, vaginal hemorrhaging, menstrual cycle irregularities, and miscarriages linked to the injections.

According to an ex-vice president at Pfizer, Dr. Michael Yeadon, the COVID jabs present "a severe risk to your ability to conceive and carry a baby to term," and even worse, Yeadon says "[the infertility risks] are deliberate acts which I believe whoever is doing it is lying about it to hide it and they're smearing people who are trying to warn you."

Further pushing the birth control agenda, earlier this month the U.S. State Department <u>announced</u> a gift of \$5 million in taxpayer funds to the United Nations Population Fund (UNFPA) supplies program, another organization tied to Gates, which aids women abroad in accessing contraceptives, abortion-inducing drugs, and abortion-performing "manual vacuum aspirator" (MVA) devices. The U.N.'s "Sustainable Development Goals" seek to "Ensure universal access to sexual and reproductive health and reproductive rights," which is phraseology commonly used to refer to abortion and contraception.

Concluding his statements, the "globally thinking" Oelrich told the summit that the global health system "is not just about donating medicines, or giving medicines at a lower price. It is also being on-site to help put this into practice."

"I think this pandemic has also opened many people's eyes to innovation in a way that was not possible before," stated Oelrich. "We need to make sure that the knowledge that is created in our universities, in our academia, is translated... before it goes into 'shiny' paper publications, it is translated into patents."

"In my vision I see a joint effort of government, working hand-in-hand with science organizations and civil society."

LifeSiteNews has produced an extensive COVID-19 vaccines resources page. <u>View it here.</u>

#### **RELATED:**

mRNA COVID-19 vaccines are really 'gene therapy' and not vaccines: ethicist

'Natural immunity 20 times more protective than vaccines': mRNA pioneer

#### **TOPICS**

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