IN THE UNITED STATES DISTRICT
COURT WESTERN DIVISION FOR THE
NORTHERN DISTRICT OF OHIO

Ohio Stands Up! and Kristen Beckman ,	)	
Plaintiff	)	CASE NO.
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&		
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(pending *pro hac vice* approval)		
-vs-	)	JUDGE:
The United States Department of Health and Human Services, Center for Disease Control (CDC) , Secretary Azar, Director Redfield,,Nat'l Center for Health Statistics (NCHS), Director Brian C. Moyer, John and/or Jane Does 1-20,	)	COMPLAINT
Defendant(s)	)	

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1. Enjoin the current and future use of the March 24, 2020 rule changing the death reporting procedures as they apply COVID-19. 69

2. Enjoin the current and future reporting using said COVID-19 Death reporting rule unless and until it is properly implemented under existing law. 69

3. Enjoin the use of "Case Reporting" using unreliable testing procedures such as PCR testing without the proper creation of a national standard for PCR tests and a uniform definition of what a "case" is that is scientifically meaningful and in compliance with relevant law and regulation. 70

4. Declare and hold unlawful and set aside the agency rule regarding reclassification of deaths by COVID-19 to the extent it is found to be: arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; or contrary to constitutional rights; or in excess of statutory jurisdiction, authority or limitations, or short of statutory right; or without observance of procedure required by law; or unwarranted by the facts. 70

5. Grant an affirmative injunction that the NCHS report the accurate death data using the traditional reporting methods within 2 weeks from the grant of this injunction. 71

6. Should the Court determine no viable alternatives for relief are available we ask that the Court grant a writ of mandamus and compel Defendant Agency, Director Robert Redfield, Director Azar, and other relevant agency personnel to comply with laws they failed to follow in the new policy or rule on how to code deaths by COVID-19. 71

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COMPLAINT: FEDERAL QUESTION

I. Introduction

1. Plaintiffs open their complaint by humbly requesting that the Court consider two questions in preparation for the issues that must be addressed by the Court. First, is it legal or acceptable to mislead the Supreme Court of the United States? And second, should the Courts afford broad enough power to unelected bureaucrats that they may mislead the people, politicians and Supreme Court of the United States, when those actions result in the abridgement of fundamental rights – such as freedom of religion?

2. Today before the Court, Plaintiffs bring several counts, but really only two major questions:

A. Can a federal agency intentionally mislead the public to an extent that Constitutional freedoms are lost, people are dying from policies based on those misrepresentations, and even an election is potentially impacted by policies created in reaction to this data?

B. Do facts matter in our judicial system or have we come to a point that procedural and judicial precedents may be used to circumvent truth and justice when the law is plainly being violated?[1]

[1] We ask this question with great humility but believe strongly that we are verging on a judicial precipice where procedural and non-statutory rules are, at times, acting as a bar to justice. While Plaintiffs believe the rules and procedure developed over the history of our nation are generally good and very important, we also contend that substantive issues should always take precedence over procedural issues lest we risk running afoul of the principles of justice.

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3. We believe the case can be boiled down to these questions for several very simple reasons.

A. With regards to the first question, as demonstrated in this complaint and as will be further demonstrated at trial, there is no question that the data being published by the Department of Health and Human Services ("DHHS") through the National Center of Vital Statistics ("NCVS") is misleading. Death counts, testing, cases, etc. – these have all been reported using techniques that are not only non-standard, they are intentionally misleading. These actions are a clear violation of the Paperwork Reduction Act ("PRA"), the Information Quality Act ("IQA"), and the Administrative Procedures Act ("APA"), as well as what we will refer to as the implied Constitutional duty of honesty and fair dealing (*see* below).

B. The death count is a clear example where we see the only disease in the United States in which people are being reported to die with – not from – is COVID-19. As it stands, if you were hit by a bus and potentially had COVID-19 when you died, you could rightly be reported as a COVID-19 death, which would then result in the hospital or state receiving additional reimbursement under the CARES Act. It would be difficult to think of a clearer violation of 44 USCS §§ 3501(9) where the purpose of the Act is to "ensure the integrity, quality, and utility of the Federal statistical system" which includes the National Center for Health Statistics ("NCHS").

4. Plaintiffs do not believe that the first question is arguable but also believe the second question is [arguably] equally concerning. The language of the law is clear, and this is a violation. As a result, the Defense will not have a substantive case and will instead make procedural arguments. They may argue standing – despite the fact that Plaintiffs should be

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granted standing – they may argue jurisdiction – though we believe the Court does properly have jurisdiction – and they may even argue immunity – which for the reasons below does not apply. Ultimately though the reality is that the Defendants have not met their legal obligations under the plain language of the law, the actions taken by the Defendants have caused incalculable harm to the Plaintiffs and the entirety of the American public, and this Court has the Constitutional authority and moral duty to remedy that situation by issuing a ruling for the Plaintiffs that would require nothing more than the Department of Health and Human Services to follow the law.

5. With all this in mind we both humbly and respectfully now ask the Court to rule that the DHHS must follow the plain language of the law, that facts and justice are paramount in the American legal system, and that it is illegal for a regulatory agency to mislead the public and other governmental officials.

II. Prayers for Relief

6. State and federal action across the country is being predicated on data that is both incorrect and was promulgated and presented in an illegal manner. As such, we are requesting emergency injunctive relief in the form of a Temporary Restraining Order. Specifically, we humbly request that the Court issue the following relief on an emergency and then permanent basis:

1. Enjoin the current and future use of the March 24, 2020 rule[2] changing the death reporting procedures as they apply COVID-19.

[2] COVID-19 Alert No. 2 https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf

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2. Enjoin the current and future reporting using said COVID-19 Death reporting rule[3] unless and until it is properly implemented under existing law.
3. Enjoin the use of "Case Reporting" using unreliable testing procedures such as PCR testing without the proper creation of a national standard for PCR tests and a uniform definition of what a "case" is.
4. Grant an affirmative injunction that the CDC report the accurate death data using the traditional reporting methods within 2 weeks from the grant of this injunction.
5. Should the Court determine no viable alternatives for relief are available we ask that the Court grant a writ of mandamus and compel Defendant Agency, Director Robert Redfield, Director Azar, and other relevant agency personnel to comply with laws they failed to follow in the new policy or rule regarding how to code deaths by COVID-19.
6. Declare and hold unlawful and set aside the agency rule regarding reclassification of deaths by COVID-19 to the extent it is found to be: arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; or contrary to constitutional rights; or in excess of statutory jurisdiction, authority or limitations, or short of statutory right; or without observance of procedure required by law; or unwarranted by the facts.

III. Parties

A. Plaintiffs and Injury

7. The Plaintiffs in this action are:

[3] Id.

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1. Ohio Stands Up!

Ohio Stands Up! is an Ohio organization whose mission is to challenge the state of emergency, honor our Constitutional rights, and educate about the realities of COVID-19. Ohio Stands Up! and its members have been injured in numerous ways through the unconstitutional actions taken in response to the claimed pandemic. Injuries include:

- Ohio Stands Up! has been accused of reporting false data, censored on social media for reporting information on COVID-19 that differed from the misleading data presented by officials, and were maligned in the press for similar reasons.
- Members of Ohio Stands Up! have had businesses closed or limited, been subjected to discrimination under the Americans with Disabilities Act, had their Constitutional right to free movement violated, experienced serious violations of their first Amendment rights, and faced many other violations due to the orders issued by the State of Ohio and the fear created as a result of the violation of the integrity and utility clauses of the PRA, IQA, and rulemaking procedures of the APA.

2. Kristen Beckman –Oregon, OH.

Kristen Beckman is a private citizen whose rights have been repeatedly trampled due to the response to COVID-19. Kristen has both a medical exemption and a firmly held religious belief that prevents her from wearing a mask. As a result of this requirement, Kristen's 5 year old son was forced to quit hockey because his mother was unable to attend. Kristen has been censored and "fact checked" on social media for reporting information that went against the false narrative causing her embarrassment.

Upon returning from visiting her family for Thanksgiving, Kristen was told by her work that she had to quarantine despite not being sick and not having been exposed to anyone with any

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illness which placed a substantial burden on her well established Constitutional right to travel. Kristen has been ostracized and made unwelcome by members of her own family that are convinced of the truth of the data being presented by NCHS regarding the danger of COVID-19.

B. Defendants

8.The Defendants in this action are:

1. The Department of Health & Human Services
2. Secretary Azar (in his role as Secretary and his individual capacity)
3. Chief Information Officer for the Department of Health and Human Services
4. The Centers for Disease Control and Prevention
5. Director Redfield (in his role as Director and his individual capacity)
6. The National Center for Health Statistics
7. Director Brian C. Moyer (in his role as Director and his individual capacity)
8. John and/or Jane Doe[s] 1-20– Plaintiffs humbly request the Court to hold these unnamed individuals as open until such time as we can ensure we have properly identified all relevant personnel. Plaintiffs have made a good-faith effort to identify relevant personnel but cannot ensure all relevant personnel are included based on available public data.

IV. Jurisdiction, Standing, and Venue

A. Generally

9. This Court has jurisdiction under 28 U.S. Code § 1331 and 28 U.S. Code § 1361. Before the Court are questions stemming from two legal theories:

a. The first stems from a novel application of the requirements under the Paperwork Reduction Act ("PRA") that require "integrity, quality, and utility of the Federal

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statistical system" as well as the more general statements of purpose under 44 USCS § 3501.

b. The second is based on the failure of the DHHS to follow proper rulemaking procedures under the Information Quality Act (aka Data Quality Act), the PRA, and the APA.

10. In both instances the Plaintiffs have been clearly and egregiously injured by the illegal and unconstitutional actions undertaken to combat a disease that is simply nowhere nearly as dangerous as is being reported and cannot even be accurately diagnosed in most cases; these actions are nearly universally being supported by referencing the incorrect and misleading data being reported by HHS and its various sub-agencies; and a judicial decision compelling these HHS agencies to ensure that data related to SARS-COV2 and COVID-19 would clearly allow for redress by allowing for an honest political process, facilitate additional legal actions to be undertaken by the Plaintiffs, and by ensuring an accurately informed public.

11. Further, plaintiffs have suffered direct and concrete injury directly attributable to the false and misleading data disseminated by the CDC to the public concerning COVID-19 deaths and cases. For the past nine months, most of this year, Plaintiffs have been bombarded by constant messages of the high death and case count, and how frighteningly dangerous this disease is. Plaintiffs have been terrorized by the media reports as well as messages from government officials, billboards and flashing highway signs concerning the prevalence and deadliness of the disease, creating anxiety, panic and psychological manipulation. The mental duress[4] from the

[4] Legal duress is defined as *Unlawful pressure exerted upon a person to coerce that person to perform an act that he or she ordinarily would not perform.* https://legal-dictionary.thefreedictionary.com/duress

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constant bombardment of media reports of the disease based upon false death data coerced plaintiffs into giving up many of their Constitutional rights and freedoms in the name of safety for themselves and to ostensibly protect the more vulnerable population who were reported to be at higher risk for dying from the disease, such as elderly and otherwise fragile people.

1. Concerning the PRA

12. The PRA clearly mandates that data reporting be made with due consideration paid to "… integrity, quality and utility…". It also includes the following:

> The purposes of this subchapter [44 USCS §§ 3501 et seq.] are to—
>
> **(4)** improve the quality and use of Federal information to strengthen decision making, accountability, and openness in Government and society; …
>
> **(7)** provide for the dissemination of public information on a timely basis, on equitable terms, and in a manner that promotes the utility of the information to the public and makes effective use of information technology; …
>
> **(11)** improve the responsibility and accountability of the Office of Management and Budget and all other Federal agencies to Congress and to the public for implementing the information collection review process, information resources management, and related policies and guidelines established under this subchapter.

13. Plaintiffs have found limited applicable case law to the question of standing in requests for injunctive relief under the PRA. The cases we have found have been related to requests for money damages which are not being sought here or with the collection of information as opposed to collection and reporting generally. *Teledyne, Inc. v. United States*, 50 Fed. Cl. 155 (2001); *Sutton v. Providence St. Joseph Med. Ctr*., 192 F.3d 826 (1999). There are few other cases on this topic at all and Plaintiffs have not seen any that were actually relevant.

14. Based on the plain language of the statute it is clear the Plaintiffs have standing to bring action when data is being collected improperly and presented inaccurately or in a manner that does not promote utility. This position is further demonstrated by the statement that a goal of the

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legislation is to "improve the responsibility and accountability of the Office of Management and Budget and all other federal agencies to… the public…" [emphasis added].

2. Concerning the IQA

15. The Information Quality Act enacted by Congress in December 2000 requires the Office of Management and Budget (OMB) to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies"… in accordance with the purposes and provisions of …the Paperwork Reduction Act (PRA).

3. Concerning the Administrative Procedures Act (APA)

16. While the APA, 5 U.S.C. §701-706, does not confer subject matter jurisdiction, it does permit challenges to the actions of a federal agency like HHS and CDC. Sec. 702 gives "a person suffering legal wrong because of an agency action or (who) is adversely affected or aggrieved by agency action…" the right to judicial review of the action. This provision, enacted in 1946, was amended in 1976 to remove the defense of sovereign immunity as a bar to judicial review of Federal administrative action that is otherwise subject to judicial review. The scope of review grants broad equitable power to the reviewing Court (Sec. 706).

17. Original jurisdiction found under 28 U.S.C. §1331 authorizes federal courts to hear claims arising under the APA as well as "non-statutory" and Constitutional claims. *Trudeau v. Fed. Trade Commission,* 456 F.3d 178, 185 (D.C. Cir. 2006) An example of a "non-statutory claim" arises when, as here, Defendants have acted *ultra vires* by plainly violating an unambiguous and mandatory legal requirement of a statute. *Leedom v. Kyne, 358 U.S. 184, 188-89.*

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B. Policy Considerations for Standing

18. Our nation and our judiciary are at a crossroads. Throughout the early 20th Century, the courts allowed the continual abdication of Congress' role as legislature to unelected bureaucrats who have been unaccountable to the electorate. This slippery slope continued, eventually reaching a point where Congress was able to delegate nearly unlimited authority with only minimal checks or oversight on such power. At this point Congress need only provide "intelligible principles" to guide an agency's use of discretion. *Whitman v. American Trucking Assoc., Inc.* (2001) 531 U.S. 457; *National Cable Television Assoc. v. United States,* (1974) 415 U.S. 336.

19. The same issue occurred in the world of the judiciary. The courts not only allowed for Congress to abdicate its powers by allowing executive branch agencies to exercise legislative power, but the courts allowed such agencies to act in a judicial capacity as well. The Administrative Procedures Act has repeatedly been interpreted to, in many cases, require what is essentially judicial review within the agency at question prior to the Courts being granted jurisdiction. The absurdity of placing burdens of additional costs and wasted time on a plaintiff by proceeding through an intra-agency hearing cannot be overstated – imagine if the police department were in charge of trying criminal cases.

20. These issues have become even further exacerbated by the repeated cry from the Courts that they should not review "political questions". Plaintiffs argue that because of the issues already present in the excessive [and arguably] unconstitutional over-delegation of power that the Court must grant the assumption of standing in questions related to administrative actions and also ensure a full review of relevant evidence.

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21. This case provides a clear example of the necessity of this approach. At this point, Constitutional freedoms are being abridged across our nation. The political justification for these (frequently unconstitutional) actions is that the science dictates the necessity. The "science" however, is false. The Department of Human Health and Services through the CDC and NCHS adopted numerous rules related to the counting of COVID-19 deaths and cases that were based on false/incorrect information and done contrary to the methods used for any other disease.

22. Plaintiffs here, are contesting these actions under the PRA and APA. If the Court were to rule against standing, the Plaintiffs would continue to be injured by policies supported by lies. Plaintiffs do not have the capacity to vote those promulgating the lies out of office or even force them to tell the truth without the ability to bring the issue before the Court. We would compare this situation to an individual being arrested and convicted without being able to confront their accuser or appear in court. There literally could not be a greater miscarriage of justice particularly in light of the fact that the plain language of the PRA clearly discusses the involvement of the public in ensuring data be properly and accurately disseminated.

C. Venue

23. Pursuant to 28 USCS § 1391, the FRCP, and local rules venue is proper in this Court.[5]

V. Statement of the Case

24. According to a study by the CDC, 40.9% of respondents reported one or more adverse mental or behavioral health conditions related to the COVID-19 response. This data also included the fact that 25.5% of young adults in the age range of 18-24 years had considered

[5] 28 USCS § 1391(e)(1)(C) – location of a plaintiff where no real property is involved.

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suicide in the last 30 days.[6] There can be no doubt that the response to this disease is both unprecedented and had an incredibly negative effect on almost everyone.

25. On March 24, 2020 the CDC published guidelines changing, for the first time in 17 years, the data collection and reporting methods used to determine the cause of death. This was not done as a general reform for cause of death reporting, but rather only for a single disease – COVID-19. This was also done without following the processes or procedures required by law and the results of this and several other actions discussed below have laid the foundation for the greatest hoax in American history.

A. Death Counts

1. BACKGROUND

26. Actions taken in response to COVID-19 began with a model developed by Neil Ferguson of the Imperial College of London that predicted tens of millions of people would die due to the disease. COVID-19 was compared to the Spanish flu, which killed approximately 50 million people in 1918. Ferguson's report stated that the only way to prevent massive deaths would be for the entire population of the planet to be locked down and for people to remain separated for 18 months until a vaccine was available. Total isolation would be needed because the isolation of just vulnerable populations like the elderly would only reduce deaths by half.[7]

27. Ferguson's report was deemed so convincing that the World Health Organization, which had previously stated that lockdowns were not effective for containing infectious diseases,

[6] CDC Morbidity and Mortality Weekly Report vol69 No12 August 14, 2020
[7] Ferguson NM, Laydon D, Nedjati-Gilani G et al. "Report 9: Impact of non-pharmaceutical interventions (NPIs) to reduce COVID-19 mortality and healthcare demand." *Imperial College COVID-19 Response Team* March 16 2020

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recommended that the world follow China's example, which included mandatory lockdowns and contact tracing.[8]

28. Ferguson's past work, however, seemed to shed doubt on his credibility related to this prediction. In 2002, he predicted that 150,000 people would die from Mad Cow Disease, but only 2704 died – an estimation 55 times higher than the real number. A few years later he predicted that 65,000 people would die of swine flu, and only 457 people died – his estimation was 142 times higher than the real number.[9] His predicted deaths from bird flu was 200,000,000 and only 455 people died – a prediction 439,560 times higher than the real number.[10]

29. As of December 9, total deaths worldwide were improperly claimed to have reached 1.56 million[11] – a number we will show to be overinflated – and certainly not close to tens of millions he predicted.

30. A group of researchers at Stanford Prevention Research Center published an article on June 11 expressing significant concerns about not only Ferguson's, but other models, some of which were not accompanied by any disclosure concerning methodology, and the actions taken in response. They concluded that a misallocation of hospital resources, and unjustified delayed healthcare for non-COVID patients had resulted from reliance on this faulty model. The researchers also pointed out the negative impact on mental health, increased unemployment, the

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[8] World Health Organization, *Non-Pharmaceutical Public Health Measures for Mitigating the Risk and Impact of Epidemic and Pandemic Influenza*, October 2019; World Health Organization, "Considerations for Quarantine of Individuals in the Context of Containment for Coronavirus Disease (COVID-19)," March 19, 2020.
[9] National CJD Research and Surveillance Unit. "Disease in the UK (By Calendar Year." University of Edinburgh May 4 2020
[10] Sturcke J. "Bird flu pandemic could kill 150,000." *The Guardian* Sept 30 2005
[11] https://covid19.who.int/ accessed 12.9.2020

loss of health insurance, prospect of starvation, and the potential spread of other infectious diseases.

31. The Stanford Group listed reasons for this debacle which included lack of expertise; groupthink and the bandwagon effect; and selective reporting. In plain language it simply appeared that decision-makers in the U.S. and in many states were exhibiting some combination of incompetence and/or willing blindness to facts.

32. The researchers also noted that this is not a new problem and expressed surprise that forecasting is still used given its "dubious track record." The Stanford group also wrote that even if a calamity the size of which the models predicted were to occur, policies like lockdowns have little impact on the death rate and generally do more harm than good, and add that exaggerated forecasts "…may cause more harm than the virus itself."[12]

33. AN EARLY TIMELINE FOR U.S. EVENTS

January 23, 2020

- Moderna Inc. announced a collaboration with CEPI and The Vaccine Research Center of the National Institute of Allergy and Infectious Diseases (Fauci's agency) to develop an mRNA vaccine against COVID-19. At the same time, Moderna and Inovio announced that they were working with the National Institutes of Health to develop a vaccine. The

[12] Ioannidis JPA, Cripps S, Tanner MA. "Forecasting for COVID-19 has failed." *International Institute of Forecasters* June 11 2020 https://forecasters.org/blog/2020/06/14/forecasting-for-covid-19-has-failed/

NIAID, led by Fauci, announced that it would allow vaccine makers to bypass animal tests and proceed directly to human tests.[13]

- Gilead announced that it would begin researching the potential for remdesivir, a drug that proved to be useless and harmful for treating Ebola, for the treatment of COVID-19.[14]
- In an article published in the *Journal of the American Medical Association*, Fauci cited Gilead's drug remdesivir as a promising treatment for COVID-19.[15] According to the WHO there were 581 confirmed cases of COVID-19 worldwide on January 23.[16] There was one patient quarantined in Washington State.

March 2020

- An article in the *New England Medical Journal* co-authored by Fauci reported that "…the case fatality rate may be considerably less than 1%. This suggested that the overall clinical consequences of Covid-19 may ultimately be more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%)…"[17]

March 3, 2020

- Fauci reported it will take 12-18 months to develop a vaccine for COVID-19.[18]

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[13] Andrew Dunn. A coalition backed by Bill Gates is funding biotechs that are scrambling to develop vaccines for the deadly Wuhan coronavirus. *Business Insider* Jan 23 2020 https://amp.businessinsider.com/vaccines-for-wuhan-china-cornonavirus-moderna-inovio-cepi-2020-1 accessed 9.1.2020
[14] Gilead Assesses Ebola Drug as Possible Coronavirus Treatment. *Bloomberg Law* Jan 23 2020 https://news.bloomberglaw.com/pharma-and-life-sciences/gilead-assesses-ebola-drug-as-possible-coronavirus-treatment accessed 9.1.2020
[15] Paules CI, Marston HD, Fauci AS. "Coronavirus Infections – More than Just the Common Cold." *JAMA.* 2020;323(8):707-708
[16] World Health Organization. Novel Coronavirus (2019-nCoV) SITUATION REPORT-3 23 January 2020 https://www.who.int/docs/default-source/coronaviruse/situation-reports/20200123-sitrep-3-2019-ncov.pdf?sfvrsn=d6d23643_8 accessed 9.1.2020
[17] Fauci AS, Lane HC, Redfield RR. "Covid-19 – Navigating the Uncharted." *NEJM* 2020 Mar;382:1268-1269
[18] Stephanie Soucheray. Fauci: Vaccine at least a year away, as COVID-19 death toll rises to 9 in Seattle." *CIDRAP* Mar 3 2020 https://www.cidrap.umn.edu/news-perspective/2020/03/fauci-vaccine-least-year-away-covid-19-death-toll-rises-9-seattle accessed 9.1.2020

March 11, 2020

- Fauci reported that the COVID-19 mortality rate was “ten times worse” than seasonal flu.[19] He told a Congressional hearing that "The flu has a mortality rate of 0.1 percent. This has a mortality rate of 10 times that. That's the reason I want to emphasize we have to stay ahead of the game in preventing this."[20] This was said during the same month of his article predicting the case fatality rate being considerably less than 1%.

March 16, 2020

- A Phase I clinical trial for a COVID-19 vaccine began. The first patient receives a vaccine called mRNA-1273 which was developed by NIAID (Fauci’s NIH agency) and Moderna with financial support from CEPI.[21]

April 7, 2020

- Dr. Deborah Birx announced that death certificates for anyone who dies with COVID-19 should reflect death by COVID-19 even if COVID-19 is not the cause of death.[22]

C. INFECTIOUS DISEASE REPORTING AND CAUSES OF DEATH

Before COVID-19

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[19] Ronald Bailey. COVID-19 Mortality Rate ‘Ten Times Worse’ Than Seasonal Flu, Says Dr. Anthony Fauci. *Reason* Mar 11 2020 https://reason.com/2020/03/11/covid-19-mortality-rate-ten-times-worse-than-seasonal-flu-says-dr-anthony-fauci/ accessed 9.1.2020

[20] Joseph Guzman Coronavirus 10 times more lethal than seasonal flu, top health official says. *The Hill* https://thehill.com/changing-america/well-being/prevention-cures/487086-coronavirus-10-times-more-lethal-than-seasonal accessed 9.1.2020

[21] NIH clinical trial of investigational vaccine for COVID begins. NIH News Releases. National Institutes of Health https://www.nih.gov/news-events/news-releases/nih-clinical-trial-investigational-vaccine-covid-19-begins accessed 7 4 2020

[22] Louis Casiano. Birx says government is classifying all deaths of patients with coronavirus as COVID-19 regardless of cause. *Fox News* April 7 2020 https://www.foxnews.com/politics/birx-says-government-is-classifying-all-deaths-of-patients-with-coronavirus-as-covid-19-deaths-regardless-of-cause accessed 9.1.2020

34. For the past 17 years, all infectious diseases and causes of death have been categorized based on the *2003 CDC's Medical Examiners' & Coroners' Handbook on Death Registration and Fetal Death Reporting and the CDC's Physicians' Handbook on Medical Certification of Death*. "The cause-of-death section consists of two parts. Part I is for reporting a chain of events leading directly to death, with the immediate cause of death (the final disease, injury, or complication directly causing death) online (a) and the underlying cause of death (the disease or injury that initiated the chain of events that led directly and inevitably to death) on the lowest used line. Part II is for reporting all other significant diseases, conditions, or injuries that contributed to death but which did not result in the underlying cause of death given in Part I." (Centers for Disease Control and Prevention, 2003).

Unique COVID-19 Reporting and the Impact of Comorbidities on Fatality Data

35. On March 24, 2020 the National Vital Statistics System (NVSS) introduced a new ICD code for Coronavirus Disease 2019 (U07.1) to "accurately capture mortality data for Coronavirus Disease 2019 (COVID-19) on death certificates."[23]

36. Some excerpts from this alert are concerning:

- "…the rules for coding and selection of underlying cause of death are expected to result in COVID-019 being the underlying cause more often than not."
- "If the death certificate reports terms such as "probably COVID-19 or "likely COVID-19," these terms would be classified the new ICD code. It is not likely that NCHS would follow up on these cases."

[23] National Vital Statistics System. CO\VID-19 Alert No. 2. March 24 2020 https://www.cdc.gov/nchs/data/nvss/coronavirus/Alert-2-New-ICD-code-introduced-for-COVID-19-deaths.pdf

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- "COVID-19 should be reported on the death certificate for all decedents where the disease caused **or is assumed to have caused or contributed to death."** *Emphasis added*

37. Additionally, the CDC published the following "guidelines" for COVID-19 death certificates:[24]

COVID-19 Death Certificate Guidelines

Clinical Criteria
At least <u>two</u> of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder(s)

OR

At least <u>one</u> of the following symptoms: cough, shortness of breath, or difficulty breathing

OR

Severe respiratory illness with at least one of the following:
- Clinical or radiographic evidence of pneumonia, OR
- Acute respiratory distress syndrome (ARDS).

AND

No alternative more likely diagnosis.

Laboratory Criteria
Laboratory evidence using a method approved or authorized by the U.S. Food and Drug Administration (FDA) or designated authority:

Confirmatory laboratory evidence:
- Detection of severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) in a clinical specimen using a molecular amplification detection test

Presumptive laboratory evidence:
- Detection of specific antigen in a clinical specimen

[24] Guidance for Certifying Deaths Due to Coronavirus Disease 2019 (COVID-19). Vital Statistics Reporting Guidance. Report no. 3 April 2020 https://www.cdc.gov/nchs/data/nvss/vsrg/vsrg03-508.pdf accessed 9.2.2020

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- Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection*

**Serologic methods for diagnosis are currently being defined.*

Epidemiologic Linkage
One or more of the following exposures in the 14 days before onset of symptoms:

- Close contact** with a confirmed or probable case of COVID-19 disease; **OR**
- Close contact** with a person with:
  - clinically compatible illness **AND**
  - linkage to a confirmed case of COVID-19 disease.
- Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2.
- Member of a risk cohort as defined by public health authorities during an outbreak.

***Close contact is defined as being within 6 feet for at least a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.*

Case Classification
Probable

- Meets clinical criteria **AND** epidemiologic evidence with no confirmatory laboratory testing performed for COVID-19.
- Meets presumptive laboratory evidence **AND** either clinical criteria **OR** epidemiologic evidence.
- Meets vital records criteria with no confirmatory laboratory testing performed for COVID-19.

Confirmed

- Meets confirmatory laboratory evidence.

Other Criteria
Vital Records Criteria

- A death certificate that lists COVID-19 disease or SARS-CoV-2 as a cause of death or a significant condition contributing to death.

38. A critical item of note is that the Coroner's Handbook specifically notes that it was designed following guidelines from the World Health Organization. The WHO has an organization that is responsible for the creation of ICD codes and, in fact, ICD stands for International Classification of Disease.

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39. No formal knowledge of statistics is needed to recognize that, from a statistical standpoint, it is critical that diseases be categorized and tracked similarly across nations so that we can truly understand and study them. If a heart attack is called a stroke and vice versa in two countries it would quickly become confusing and global study of any disease would quickly become futile. In fact, it is so important that the 2003 Coroners Handbooks specifically states:

- "For statistical and research purposes, it is important that the causes of death and, in particular, the underlying cause of death, be reported as specifically and as precisely as possible. Careful reporting results in statistics for both underlying and multiple causes of death (i.e., all conditions mentioned on a death certificate) reflecting the best medical opinion.

- Every cause-of-death statement is coded and tabulated in the statistical offices according to the latest revision of the International Classification of Diseases (6). When there is a problem with the reported cause of death (e.g., when a causal sequence is reported in reverse order), the rules provide a consistent way to select the most likely underlying cause.

40. The Defendants, in the instance of COVID-19, decided to deviate from the international standard. The WHO defined COVID-19 with two codes – U07.1 and U07.2. Those codes were defined as:

- "An emergency ICD-10 code of 'U07.1 COVID-19, virus identified' is assigned to a disease diagnosis of COVID-19 confirmed by laboratory testing."
- "An emergency ICD-10 code of 'U07.2 COVID-19, virus not identified' is assigned to a clinical or epidemiological diagnosis of COVID-19 where laboratory confirmation is inconclusive or not available."[25]

[25] Emergency use ICD codes for COVID-19 disease outbreak (who.int)

41. The March 24, 2020 COVID-19 Alert No. 2 document instructs that only U07.1 be used in the USA. It then goes on to say that:

> "The underlying cause depends upon what and where conditions are reported on the death certificate. However, the rules for coding and selection of the underlying cause of death are expected to result in COVID19 being the underlying cause more often than not."
>
> AND
>
> "If a death certificate reports coronavirus without identifying a specific strain or explicitly specifying that it is not COVID-19, NCHS will ask the states to follow up to verify whether or not the coronavirus was COVID-19."
>
> AND
>
> "If the death certificate reports terms such as "probable COVID-19" or "likely COVID-19," these terms would be assigned the new ICD code. It Is (sic) not likely that NCHS will follow up on these cases."

42. So the CDC expected that COVID-19 would be the cause of death "more often than not", they would expect the states to follow up on death certificates that might be COVID-19, and when a case *might* be COVID-19, it should be assigned the new code and no one will follow up. It is difficult to see how this structure could be used to accurately track statistical data as opposed to being used to increase numbers. The problem of "over-counting" is particularly salient given the financial incentives to do so (discussed below).

43. This is a fundamentally different approach to what is laid out in the Coroner's Handbook and, not only appears arbitrary, but is intentionally misleading. The major issue in this approach stems from the fact that, under the 2003 rule, in any situation where two or more possible reasons for a death exist, the medical examiner and/or coroner "must choose the sequence of conditions that had the greatest impact and report this sequence."[26] Under the new rule that is

[26] Coroners Handbook pp 17

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heavily financially incentivized (*see* below), even an asymptomatic person with known COPD who tested positive for COVID-19 and died of a heart attack could be listed as a COVID-19 death.

Further Explanation of Comorbidities

44. Below is a chart of the top causes of death for the 2018 year, the most recent data available (CDC, 2020a).[27]

Underlying Cause of Death, 1999-2018 Results

Request Form | Results | Map | Chart | About

Dataset Documentation | Other Data Access | Help for Results | Printing Tips | Help with Exports | Save | Export | Reset

Quick Options | More Options | Top | Notes | Citation | Query Criteria

Messages:

When you group results by 15 Leading Causes, results are initially ordered by Death counts; also, total rows, zero rows, suppressed rows, and Percent of Total are not available. Click any green up/down arrow to change the order. More information.

15 Leading Causes of Death	Deaths	Population	Crude Rate Per 100,000
#Diseases of heart (I00-I09,I11,I13,I20-I51)	655,381	327,167,434	200.3
#Malignant neoplasms (C00-C97)	599,274	327,167,434	183.2
#Accidents (unintentional injuries) (V01-X59,Y85-Y86)	167,127	327,167,434	51.1
#Chronic lower respiratory diseases (J40-J47)	159,486	327,167,434	48.7
#Cerebrovascular diseases (I60-I69)	147,810	327,167,434	45.2
#Alzheimer disease (G30)	122,019	327,167,434	37.3
#Diabetes mellitus (E10-E14)	84,946	327,167,434	26.0
#Influenza and pneumonia (J09-J18)	59,120	327,167,434	18.1
#Nephritis, nephrotic syndrome and nephrosis (N00-N07,N17-N19,N25-N27)	51,386	327,167,434	15.7
#Intentional self-harm (suicide) (*U03,X60-X84,Y87.0)	48,344	327,167,434	14.8
#Chronic liver disease and cirrhosis (K70,K73-K74)	42,838	327,167,434	13.1
#Septicemia (A40-A41)	40,718	327,167,434	12.4
#Essential hypertension and hypertensive renal disease (I10,I12,I15)	35,835	327,167,434	11.0
#Parkinson disease (G20-G21)	33,829	327,167,434	10.3
#Pneumonitis due to solids and liquids (J69)	19,239	327,167,434	5.9

Note: A '#' symbol preceding the label indicates a rankable cause of death. More information.

45. At the top of the list is diseases of the heart: 655,381 individuals died of heart conditions in 2018. Heart conditions would qualify as a pre-existing condition. If an individual has COVID-19 and a heart disease and they die, they can still be listed as a COVID-19 death.

46. Other comorbidities that could easily be categorized as COVID-19 deaths under the new guidelines include: 159,000 individuals who died from chronic lower respiratory disease,

[27] https://wonder.cdc.gov/controller/datarequest/D76;jsessionid=77882FF4BD5D3BE7ADC461287433BE6F

diabetes killed nearly 85,000 individuals, and 59,120 deaths were caused by influenza and pneumonia.

47. If we extrapolate those numbers to 2020, that's nearly one million people with comorbidities that could be listed as COVID-19 deaths. According to Statistician Professor Sir David Spiegelhalter, there will be "a substantial overlap" with COVID-19 and "Many people who die of [COVID-19] would have died anyway within a short period."[28]

48. The CDC Morbidity and Mortality Weekly Report for February 12–March 28, 2020 also reported that 94% of COVID-19 patients had at least one underlying condition (comorbidity) (CDC, 2020g). Given these massive cause of death numbers, the rules for listing cause of death are *critical* in separating out the real cause of deaths. The singular cause of death rule for COVID-19 creates a situation where a majority of these deaths will be/have been attributed to COVID-19, thus leading to inflated numbers and inaccurate data on which important decisions are being made—even Supreme Court decisions. [29]

49. Further, while the previous cite shows these issues with death data existed for the *South Bay* case, the CDC "Weekly Updates by Select Demographic and Geographic Characteristics" for the period starting February 1, 2020 and ending December 5, 2020 reports: "For 6% of the deaths, COVID-19 was the only cause mentioned. For deaths with conditions or causes in addition to COVID-19, on average, there were 2.9 additional conditions or causes per death."[30]

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[28] Nick Triggle. Coronavirus: How to understand the death toll. *BBC News* April 16 2020

[29] In *South Bay Pentecostal Church v. Newsome*, 590 U. S. ____ (2020), the majority opinion specifically and wrongly stated that COVID-19 had killed more than 100,000 people nationwide. This opinion was issued on May 29, 2020. Even using the misleading rule promulgated by the NCVS that number was likely inflated due to false positives in testing and misdiagnoses as laid out elsewhere in this complaint.

[30] https://www.cdc.gov/nchs/nvss/vsrr/covid_weekly/index.htm#Comorbidities

Plaintiffs suggest this further demonstrates that the death counts are consistently misleading and not just at that early date.

D. COVID-19 MORTALITY VS. FLU MORTALITY

50. Dr. Fauci and his co-authors reported in their March 2020 editorial in the *New England Journal of Medicine*. "If one assumes that the number of asymptomatic or minimally symptomatic cases is several times as high as the number of reported cases, the case fatality rate may be considerably less than 1%. This suggests that the overall clinical consequences of Covid-19 may ultimately be more akin to those of a severe seasonal influenza (which has a case fatality rate of approximately 0.1%) or a pandemic influenza (similar to those in 1957 and 1968) rather than a disease similar to SARS or MERS, which have had case fatality rates of 9 to 10% and 36%, respectively."[31]

E. VARIATIONS IN HOW STATES REPORT RESULTS IN CONFUSING DATA

51. According to an article in the *Epoch Times,* at least 22 states count probable COVID cases in deaths in their totals, and there are considerable differences in reporting among these states. The publication contacted all 50 states and the District of Columbia, but only 33 responded to inquiries concerning reporting practices. Here is what states reported:

- Some states, such as Arkansas, New Jersey, and Washington, only include probable deaths, but not probable infections.
- Some states only include probable infections, but not deaths. Maine and Kansas may be in this category, their COVID websites indicate.

[31] Fauci AS, Lane HC, Redfield RR. "Covid-19 – Navigating the Uncharted." *NEJM* 2020 Mar;382:1268-1269

- There are at least 12 states, including Alabama, Illinois, Massachusetts, Minnesota, and South Carolina, that report probable cases or deaths or both, but list them separately. In these cases, the CDC still includes the probable cases and deaths in the totals for those states.
- At least eight states, including Alaska, Georgia, Missouri, North Carolina, Nevada, and Oklahoma, report neither probable cases nor deaths.
- There are also special cases. Florida, for example, says in its COVID reports that it counts people who tested positive for COVID antibodies among the case totals. That introduces another problem, because people normally retain coronavirus antibodies for months or longer, so the tests may reveal weeks- or months-old infections.
- Some states include people who tested positive for COVID-19 as COVID deaths, even though they may have died of other causes.
- The Colorado health department reports on its website both "Deaths Among Cases" as well as "Deaths Due to COVID-19." But the CDC only uses the higher "Deaths Among Cases" figure.[32]

The use of many varied methods for determining cause of death inevitably leads to invalid data and statistics.

52. Nationwide, death counts changed based on questionable data and for a myriad of reasons. For example, the New York City Health Department added over 3700 deaths to its count – a 17% increase. This involved the addition of people who were presumed to have COVID but were never tested for it. City Health Commissioner Dr. Oxiris Barbot stated that this was based on an

[32] Peter Svab. At Least 22 States Count 'Probable' COVID Cases or Deaths in Totals. *Epoch Times* July 21 2020

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observation – 3000 more people died between March 11 and April 13 than would have normally been expected.[33] Hardly a scientific way to track deaths.

53. Colorado lowered its death count by almost 20% in May after admitting that deaths from alcohol poisoning and other causes had been erroneously categorized as COVID deaths.[34]

54. This again demonstrates the lack of integrity in the statistics. A true comparison of deaths caused from – not with – COVID-19 and caused from the flu is not possible given that COVID-19 is the only disease to be reported in this way.

F. FINANCIAL INCENTIVE FOR FALSE REPORTING

55. Section 3710 of the CARES (Coronavirus Aid, Relief, and Economic Security) Act increased the amount of payment to hospitals from Medicare by 20% for patients being treated with COVID-19. While there is much discussion on what is actually covered in the treatment of COVID-19 by this Act, the simple fact is that hospitals make 20% more from a COVID-19 patient suffering from acute respiratory distress syndrome or pneumonia than an influenza patient with the same issues. Given the criteria that no testing is required to list COVID-19 as a cause of death there would appear to be a substantial incentive to use a COVID-19 diagnosis whenever possible to obtain the higher reimbursement rate.[35]

56. In fact, CDC Director Robert Redfield acknowledged this in sworn testimony in front of the House Oversight and Reform Select Subcommittee on the Coronavirus Crisis. On Friday, July 31, 2020, he said, "I think you're correct in that we've seen this in other disease processes

[33] J. David Goodman and William K. Rashbaum. N.Y.C. Death Toll Soars Past 10,000 in Revised Virus Count. *New York Times* April 14 2020

[34] Robert Gearty. Colorado amends coronavirus death count – says fewer have died of COVID-19 than previously reported. *Fox News* May 16 2020

[35] https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf

too, really in the HIV epidemic, somebody may have a heart attack, but also have HIV – the hospital would prefer the classification for HIV because there's greater reimbursement."

57. In other words, government mismanagement and misreporting of death counts is not limited to COVID-19 and seems to be an acceptable practice at the CDC.[36] This lends credence to Dr. Deborah Birx' comment that "…there is nothing from the CDC that I can trust."[37]

G. FINAL COMMENTS ON DEATH COUNTING

58. Dr. Ngozi Ezike - Director Illinois Department of Public Health – explained what it means to die "of" COVID. A clip of the press conference found on Redstate shows her making this incredible statement: "The case definition is…is…very simplistic. It means at the time of death…uhm…it was a COVID positive diagnosis. So that means if you were in hospice and had already been given, you know, a few weeks to live, and then you were also found to have COVID that would be counted as a COVID death. It means that if…uhm…technically even if you died of a clear alternate cause but you had COVID at the same time it's still listed as a COVID death. So, uhm, everyone who is listed as a COVID death doesn't mean that that was the cause of the death but they had COVID at the time of death." Nick Arama, Watch: Illinois Explains What Qualifies as a 'COVID Death', REDSTATE, (April 25, 2020) https://www.redstate.com/nick-arama/2020/04/25/watch-illinois-explains-what-qualifies-as-a-covid-death/

59. A combination of the inappropriate use of PCR tests, changes in the way death certificates were completed, and perverse incentives for number of "cases" and "deaths" has

[36] Calvin Freiburger. Hospitals have incentive to inflate COVID-deaths, CDC chief admits. *Lifesite News* August 5 2020 https://www.lifesitenews.com/news/hospitals-have-incentive-to-inflate-covid-deaths-cdc-chief-admits
[37] As deaths mount, Trump tried to convince Americans it's safe to inch back to normal. *Washington Post* may 9 2020

resulted in constantly changing and inconsistent data from the states and CDC. This goes directly against Directive 1 from the OMB which states:

> To operate efficiently and effectively, the Nation relies on the flow of objective, credible statistics to support the decisions of individuals, households, governments, businesses, and other organizations. Any loss of trust in the accuracy, objectivity, or integrity of the Federal statistical system and its products causes uncertainty about the validity of measures the Nation uses to monitor and assess its performance, progress, and needs by undermining the public's confidence in the information released by the Government…
>
> And
>
> Responsibility 2: Conduct credible and accurate statistical activities. Federal statistical agencies and recognized statistical units apply sound statistical methods to ensure statistical products are accurate. [38]

56. The CDC acknowledges that only 6% of deaths were due to COVID-19 only, which means that a huge portion of the other 94% of deaths categorized as COVID are being miscategorized resulting in the promulgation of incorrect data.

VI. Testing for COVID-19

57. From the beginning, COVID-19 testing in the U.S. has been flawed. While the World Health Organization had developed testing specifications for COVID-19 by January 2020, the CDC decided to develop its own test, which was ready by early February. The test was manufactured and distributed by the CDC to health centers throughout the U.S., and within a few days, the tests were found to be inaccurate. In response the FDA insisted that hospitals, academic centers, and private companies ***should not develop their own tests.*** When the agency finally lifted the ban on test development at the end of February, there was a rush to get tests ready for

[38] Federal Register / Vol. 79, No. 231 / Tuesday, December 2, 2014.

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market. The FDA provided no standards for how COVID-19 was to be detected, meaning all test makers could decide what standard to use.

58. Over 280 companies are currently producing tests for COVID-19, and these tests were approved by the FDA under emergency authorization with minimal validation. The test makers were only required to show that the tests performed well in test tubes, and no real-world demonstration of clinical viability was required.[39] Each vendor established its own and as-yet-unmeasured accuracy. The variations are myriad, with some tests able to detect as few as 100 copies of a viral gene while others require 400 copies for detection.[40] In fact, the QuantVirus Real-Time PCR Coronavirus Test can detect as low as 1 copy of viral RNA within 2hrs which means the test will almost always be positive.[41] Additionally, most will show positive results for as long as 6 months, while the actual time a person is contagious is only a few days.

59. Several issues were never addressed. One is the potential cross-reactivity with other viruses. Another is that the presence of coronavirus is likely to remain for several months after the infectious period has passed. This means the tests are useless for determining who should be quarantined. Yet another is the risk of cross contamination, particularly when testing large numbers of people in crowded settings. Even the tiniest amount of cross contamination can lead

[39] David Pride. Hundreds of different coronavirus tests are being used – which is best? *The Conversation* April 4 2020 https://www.marketwatch.com/story/hundreds-of-different-coronavirus-tests-are-being-used-which-is-best-2020-04-02 accessed 9.2.2020

[40] IBID

[41] https://www.clinisciences.com/en/read/newsletter-26/ce-ivd-qpcr-covid-19-test-in-2-2261.html

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to a false positive result, which means people who have never been exposed to COVID-19 could be subjected to unwarranted quarantines.

60. As if all of this is not absurd enough, there are even PCR test kits that contain the warning they are for clinical reference only, and it should not be used as the only evidence for clinical diagnosis and treatment.[42]

61. The accuracy of tests is important since the number of "cases" is the metric used to determine business and school closures, event cancellations, lockdowns, withdrawal of civil rights and liberties, whether people can congregate, and if the useless masks are required.

62. There are two primary processes used to test for the coronavirus. The first method requires a sample of mucus from a person's nose or throat and then attempting to replicate the RNA through a Polymerase Chain Reaction (PCR) machine. The second is through the antibody test, a blood test that is not supposed to determine if one is infected, but if they have ever been infected. Both tests are flawed.

63. PCR is sometimes referred to as "molecular photocopying" because it copies small pieces of DNA. The use of PCR is necessary because it is almost impossible to study small, isolated samples of DNA, and PCR can multiply the amount of material that is present to facilitate research. PCR technology is considered one of the most important developments in molecular biology research. In fact, the inventor, Kary Mullis, won the Nobel Prize for Chemistry in 1993 for his invention.

64. Here's how PCR technology works. A tiny segment of DNA is heated so that it can be separated into two pieces of single-strand DNA. Then an enzyme is used to build two new

[42] This is from the "Kit Information" for Creative Diagnostics retrieved from: https://www.creative-diagnostics.com/pdf/CD019Rt.pdf

strands using the original ones as templates. Then each strand can be used again to make more copies. The cycle can be repeated until there are as many as a billion copies of the original DNA fragment. Each duplication is called a cycle and most of the time in lab settings the cycle is repeated 30-40 times.[43]

65. While useful in a lab setting, inventor Kary Mullis stated clearly in 2013 that his technology was never designed for diagnosing disease and should not be used for that purpose. In fact, PCR testing was already shown to be wildly inaccurate almost 15 years ago. In 2006, massive PCR testing was performed at the Dartmouth Hitchcock Medical Center when it was thought that the medical center was experiencing an epidemic of whooping cough. Almost 1000 healthcare workers were furloughed until their test results were returned. Over 140 employees were told that they had whooping cough, and thousands of others who tested positive were given antibiotics and/or a vaccine for whooping cough.

66. Almost eight months later, employees received an email from the hospital administration which stated that the entire episode was due to PCR testing error. Not even one case of whooping cough was confirmed with a more reliable follow-up test, and it was determined that the employees just had a common cold, not whooping cough.[44]

67. Apparently, this history was ignored as public health officials decided that ginning up cases was more important than following the science. Thus, a test that the developer said was not

[43] Polymerase Chain Reaction (PCR) Fact Sheet. National Human Genome Research Institute. National Institutes of Health. https://www.genome.gov/about-genomics/fact-sheets/Polymerase-Chain-Reaction-Fact-Sheet accessed 11.6.220

[44] Gina Kolata. Faith in Quick Test Leads to Epidemic That Wasn't. *New York Times* Jan 22 2007 https://www.nytimes.com/2007/01/22/health/22whoop.html accessed 9.2.2020

useful for diagnosis, and that had been previously shown to be inaccurate 100% of the time, was recommended to detect COVID-19.

68. Despite the inventor's cautions and its historical failure rate, PCR is used more than any other method to diagnose "cases" of COVID-19. According to the FDA and the CDC, 40 cycles should be used to amplify specimens for COVID-19 testing.[45] Even Dr. Anthony Fauci is aware that PCR is useless and unreliable for diagnosing COVID-19 when run at 35 cycles or higher. In fact, he said this in a podcast on July 16, 2020 called *This Week in Virology*:

> What is now evolving into a bit of a standard is that if you get a cycle threshold of 35 or more that the chances of it being replication competent are miniscule…We have patients, and it is very frustrating for the patients as well as for the physicians…somebody comes in and they repeat their PCR and it's like 37 cycle threshold…you can almost never culture virus from a 37 threshold cycle. So I think if somebody does come in with 37, 38, even 36, you gotta say, you know, it's dead nucleotides, period." In other words, it is not a COVID-19 infection.

He goes on to say that when someone has a positive test, "…they don't give them the cycle threshold unless they go back and ask for it."[46]

69. Assuming that most labs in the U.S. are following the FDA and CDC instructions, many if not most positive PCR tests are false positives. The false "cases" are then used daily to scare the public and to justify lockdowns, business and school closures, requirements to wear masks, and other violations of our constitutional rights.

70. A September 2020 letter to the editor, which appeared in the *Journal of Clinical Infectious Diseases,* included research conducted by the authors concerning PCR testing. Supported by a grant from the French government, the authors performed 250,566 COVID-19

[45] CDC 2019-Novel Coronavirus (2019-nCCoV) Real Time RT-PCR Diagnostic Panel Instructions for Use. https://www.fda.gov/media/134922/download accessed 11.6.2020

[46] https://www.youtube.com/watch?v=a_Vy6fgaBPE&feature=youtu.be&t=260

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PCR tests on 179,151 patients and found that 13,161 were positive. They selected 3790 samples and attempted to grow a virus. They were only successful in growing coronavirus in about half of the samples. For those samples, in which the cutoff was 25 cycles for a positive test, 70% grew a live virus. But when the cutoff was 35 cycles, only 3% of the samples grew a live virus.[47] This is important since the CDC and FDA recommend 40 cycles when testing for COVID-19,[48] which means that we can expect a false positive rate of 97% based on this study.

71. Below are examples of other PCR tests approved by the FDA under the Emergency Use Authorization, along with the number of recommended cycles:

SARS-CoV-2 Test Kit (Real-time PCR)	45 cycles[49]
Opti Sars CoV-2 RT-PCR Test	45 cycles[50]
Wren Labs COVID-19 PCR Test	38 cycles[51]
LabCorp COVID-19 RT-PCR	35 cycles[52]

A meta-analysis published in the *British Medical Journal* looked at the accuracy of PCR testing specifically for COVID-19. The researchers reported that while no test is 100% accurate, the sensitivity and specificity of a test is evaluated by comparison with a gold standard, and there

[47] Jaafar R, Aherfi S, Wurtz N et al. "Correlation Between 3790 Quantitative Polymerase Chain Reaction-Positive Samples and Positive Cell Cultures, Including 1941 Severe Acute Respiratory Syndrome Coronavirus 2 Isolates." *Clin Infect Dis* 2020 Sep; https://doi.org/10.1093/cid/ciaa1491

[48] CDC 2019-Novel Coronavirus (2019-nCCoV) Real Time RT-PCR Diagnostic Panel Instructions for Use. https://www.fda.gov/media/134922/download accessed 11.6.2020

[49] https://www.fda.gov/media/140717/download accessed 12.5.2020

[50] https://www.fda.gov/media/137739/download accessed 12.5.2020

[51] https://www.fda.gov/media/140776/download accessed 12.5.2020

[52] https://www.fda.gov/media/136151/download accessed 12.5.2020

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is no gold standard for COVID-19. One of the reasons is that it is impossible to know the false positive rate without having tested people who don't have the virus along with people who do, and this was never done.

72. The analysis showed that the false-negative rate ranges between 2% and 29%. Accuracy of viral RNA swabs was highly variable. In one study, sensitivity was 93% for bronchoalveolar lavage, 72% for sputum, 63% for nasal swab, and only 32% for throat swabs. The researchers stated that results vary for many reasons, including stage of disease.[53] This analysis was published in May, long after Mr. Fauci and his accomplices had succeeded in creating a false pandemic, in part, by insisting that more and more people should be tested.

73. Fortunately, many people are far more diligent than Fauci in scrutinizing facts.

Investigators from *OffGuardian* contacted the authors of four papers published in early 2020 in which researchers claimed that they had discovered a new coronavirus. The investigators asked for proof that electron micrographs showed purified virus and all four groups replied that they did not. The responses from the four groups were:

- "The image is the virus budding from an infected cell. It is not purified virus."
- "We could not estimate the degree of purification because we do not purify and concentrate the virus cultured in cells."
- "[We show] an image of sedimented virus particles, not purified ones."
- "We did not obtain an electron micrograph showing the degree of purification."

The investigators also contacted virologist Charles Calisher and asked if he knew of any research group that had isolated and purified SARS-CoV-2 and he replied that he did not. They

[53] Watson J, Whiting PF, Brush JE. "Interpreting a covid-19 test result." *BMJ* 2020 May;369:m1808

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concluded, at this time, no one knows whether the RNA gene sequences, used in the in vitro trials and also used to calibrate the tests, actually came from SARS-CoV-2.[54]

74. All of this may explain why some of the testing results from around the world have been so difficult to understand or explain. For example, testing in Guangdong Province in China showed that 10% of people who recovered from COVID-19, tested negative and then tested positive again.[55] Twenty-nine patients tested in Wuhan tested negative, then positive, and then the results were "dubious."[56]

75. According to Wang Chen, president of the Chinese Academy of Medical Sciences, PCR tests are only 30-50% accurate.[57]

76. The FDA agrees. A statement in its online instruction manual for PCR testing includes these statements:

- "Detection of viral RNA may not indicate the presence of infectious virus or that 2019-nCoV is the causative agent for clinical symptoms."
- "This test cannot rule out diseases caused by other bacterial or viral pathogens."[58]

[54] Engelbrecht T, Demeter K. "COVID19 PCR Tests are Scientifically Meaningless." Bulgarian Pathology Association. Jan 7 2020 https://bpa-pathology.com/covid19-pcr-tests-are-scientifically-meaningless/ accessed 9.2.2020

[55] Fermin Koop. A startling number of coronavirus patients get reinfected. *ZME Science* Feb 26 2020 https://www.zmescience.com/science/a-startling-number-of-coronavirus-patients-get-reinfected/ accessed 9.2.2020

[56] Li Y, Yao L, Li J et al. "Stability issues of RT-PCR testing of SARS-CoV-2 for hospitalized patients clinically diagnosed with COVID-19." *J Med Virol* 2020 Jul;92(7):903-908

[57] Coco Feng, Minghe Hu. Race to diagnose coronavirus patients constrained by shortage of reliable detection kits. *South China Morning Post* Feb 11 2020 https://www.scmp.com/tech/science-research/article/3049858/race-diagnose-treat-coronavirus-patients-constrained-shortage accessed 9.2.2020

[58] CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. Centers for Disease Control and Preention. https://www.fda.gov/media/134922/download accessed 9.2.2020

77. The FDA's online emergency use authorization includes this statement:

"positive results […] do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease."[59]

78. In fact, the manufacturer's instruction manual for one PCR test includes these statements:

- "These assays are not intended for use as an aid in the diagnosis of coronavirus infection"
- "For research use only. Not for use in diagnostic procedures."[60]

79. Recently, 22 researchers called for the retraction of an article published in January 2020, referred to as the Corman-Drosten Report, in which prior researchers claimed to have validated the use of PCR testing for COVID-19.[61] The researchers listed ten serious flaws in the paper and called for its retraction.[62] The ten major flaws in the paper include:

(1) The results were based on theoretical sequences supplied by a laboratory in China because these were the only samples available. The researchers acknowledged this by stating in their paper: "We aimed to develop and deploy robust diagnostic methodology for use in public health laboratory settings without having virus material available."

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[59] ACCELERATED EMERGENCY USE AUTHORIZATION (EUA) SUMMARY COVID-19 RT-PCR TEST (LABORATORY CORPORATION OF AMERICA) U.S. Food and Drug Administration. https://www.fda.gov/media/136151/download accessed 9.2.2020

[60] BIO-RAD SARS-CoV-2/Covid-19 Diagnosis and Confirmation Solutions. https://www.bio-rad.com/featured/en/sars-cov-2-covid-19-testing-solutions.html accessed 9.2.2020

[61] Corman VM, Landt O, Kaiser M et al. "Detection of 2019 novel coronavirus (2019-nCoV) by real time RT-PCR." *Euro Surveill* 2020 Jan;25(3):2000045

[62] Borger P, Malhotra BR, Yeadon M et al. "Review report Corman-Drosten et al. Eurosurveillance 2020." https://cormandrostenreview.com/report/?fbclid=IwAR0sSncAmhHhhwzQ21ODbrVgEtYZ0zfZDkG9ZGqRFGQocXDNM8KW7YBd41A accessed 12.5.2020

They also wrote, “the establishment and validation of a diagnostic workflow for 2019-nCoV screening and specific confirmation, designed in absence of available virus isolates or original patient specimens. Design and validation were enabled by the close genetic relatedness to the 2003 SARS-CoV and aided by the use of synthetic nucleic acid technology.”

It is impossible to develop a valid test without actual viral material, and the use of viral material referred to as “closely related” is not a proper substitute.

(2) The test cannot discriminate between whole virus and viral fragments which means that it is not a specific diagnostic tool for identifying SARS-CoV-2.

(3) “A difference of 10° C with respect to the annealing temperature Tm for primer pair1 (RdRp_SARSr_F and RdRp_SARSr_R) also makes the test unsuitable as a specific diagnostic tool to identify the SARS-CoV-2 virus.”

(4) The failure to establish a standardized and verifiable Ct value at which a sample is considered positive and negative.

(5) The PCR test does not contain a unique positive control to evaluate specificity for SARS-CoV-2 or a negative control to exclude the presence of other coronaviruses – lack of specificity.

(6) The test design described in the Corman-Drosten paper is vague, nothing is standardized and there is no standard operating procedure.

(7) Conflicts of interest were identified for four authors. Two of the authors serve on the editorial board for the journal in which the paper was published. Conflicts of interest were not disclosed for all authors. Corman and Drosten did not mention that they were affiliated with a laboratory involved in PCR testing.

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(8) PCR tests were distributed before the paper was submitted.

Noting also that the paper was not peer-reviewed, the authors conclude: "In light of our re-examination of the test protocol to identify SARS-CoV-2 described in the Corman-Drosten paper we have identified concerning errors and inherent fallacies which render the SARS-CoV-2 PCR test useless." They call for the retraction of the paper.

80. There are a limited number of studies on the accuracy of the tests and Colin West MD, PhD at Mayo Clinic says that the studies reviewing currently used tests have been "filled with flaws." One of those flaws is that the sensitivity estimates are based on testing people who the researchers already knew had been diagnosed with COVID-19. This resulted in significant bias. He says that without control groups and blinded testing, it is impossible to determine the magnitude of the inaccuracy.[63]

81. The results of an analysis of five studies that included 957 patients and that had yet to be peer-reviewed concluded that, "The certainty of the evidence was judged as very low, due to the risk of bias, indirectness, and inconsistency issues. Conclusions: The collected evidence has several limitations, including risk of bias issues, high heterogeneity, and concerns about its applicability."[64]

82. The bottom line is that this test is nearly useless for diagnosing COVID-19 and not very useful in actually determining if there is an active infection of SARS-CoV2. If the error rate is only 5% this could mean that the number of cases worldwide is off by millions. But the error rate

[63] Heather Boerner. COVID-19 Test Results: Don't Discount Medical Intuition. *Medscape* May 16 2020 https://www.medscape.com/viewarticle/930650 accessed 9.2.2020

[64] Arevalo-Rodriguez I, Buitrago-Garcia D, Simancas-Racines D et al. "FALSE NEGATIVE RESULTS OF INITIAL RT-PCR ASSAYS FOR COVID-19: A SYSTEMATIC REVIEW." *MedRxiv* doi: https://doi.org/10.1101/2020.04.16.20066787

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has been shown to be much higher, which means that the world's population is suffering due to a made-up pandemic.

A. Other Testing Issues

83. Some county and state health departments state that the cases for coronavirus are typically reported via a primary care physician or pulmonologist.[65] These providers are not required to send a patient for laboratory testing and typically do not have an expensive PCR machine at their disposal. Thus, it would appear as though the virus is often-times being diagnosed by health care providers the same way they would diagnose any common cold or flu, which is by physical examination and observation of symptoms. This despite the fact that the symptoms of COVID-19 are nearly identical to those of a typical influenza.

84. Several Governors in the U.S. requested billions of dollars in federal aid to "assist with the impact of the coronavirus," the amount of which was based on the presumed infection rate. Collectively, they requested a total of $500 billion.[66] At this time there is no accountability for exactly how and where this aid was spent. It is interesting that the states with the worst per capita debt (such as California and New York) have requested the most money.[67] Coincidence? Perhaps not. Naturally, it could make sense to report a higher rate of infection in order to receive a larger piece of the stimulus funding.

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[65] Michael Mendizza. Why The Coronavirus Will Soon Vanish Overnight. https://ttfuture.org/blog/michael/why-coronavirus-will-soon-vanish-overnight accessed 9.2.2020

[66] Ana Radelat. Lamont, other governors, seek $500 billion in new coronavirus stimulus money for states. *The CT Mirror* https://ctmirror.org/2020/04/16/lamont-other-governors-seek-500-billion-in-new-coronavirus-stimulus-money-for-states/ accessed 9.2.2020

[67] Monthly Federal Spending/Revenue/Deficit Charts Federal Coronavirus/COVID-19 Response. https://www.usgovernmentspending.com/compare_state_debt 9.2.2020

85. There have been numerous problems with the testing procedures, some political, some scientific. The CDC went against the guidance of the World Health Organization (WHO).[68] Regardless of the wisdom of the WHO (which is also in question), the missteps that occurred regarding testing were massive. On April 20, 2020, it was reported that the tests used by the CDC were contaminated with the coronavirus itself.[69] There was no way to know the number of false negatives and false positives.

86. The Food and Drug Administration (FDA) sent Timothy Stenzel, chief of in vitro diagnostics and radiological health, to the CDC and found the primary culprit to be poor laboratory practices. Robert Redfield, director of the CDC, acknowledged that the agency's quality control measures were not adequate during the time the tests were being developed.[70]

87. Testing was not much better in other parts of the world. For example, Spain and the Czech Republic spent millions on a test purchased from a Chinese company called "Shenzhen Bioeasy Technology" and later found that the tests were only 30% accurate. Gordon Chang, who has covered Chinese economics and policy for decades stated, "It [China] creates the poison and then sells the cure to it."[71]

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[68] Has COVID-19 Testing Made the Problem Worse? Confusion Regarding "The True Health Impacts". Centre for Research on Globalization. https://www.globalresearch.ca/has-covid-19-testing-made-the-problem-worse-confusion-regarding-the-true-health-impacts/5709323 accessed 9.2.2020

[69] Beth Mole. CDC's failed coronavirus tests were tainted with coronavirus, feds confirm. *Ars Technica* April 20 2020 https://arstechnica.com/science/2020/04/cdcs-failed-coronavirus-tests-were-tainted-with-coronavirus-feds-confirm/ accessed 9.2.2020

[70] Sheila Kaplan. C.D.C. Labs Were Contaminated, Delaying Coronavirus Testing, Officials Say. *New York Times* April 18 2020 https://www.nytimes.com/2020/04/18/health/cdc-coronavirus-lab-contamination-testing.html accessed 12.7.2020

[71] Jorge Gonzalez-Gallarza Hernandez. China challenges the world with flawed COVID-19 test kits. March 30 2020. https://www.washingtontimes.com/news/2020/mar/30/china-challenges-the-world-with-flawed-covid-19-te/ accessed 9.2.2020

88. Even if the test kits are not faulty, more false negatives can result from the swabbing method used to collect samples. The tests typically require a swab to be inserted into the nasal passage. The CDC guidelines for appropriate test methodology includes the following:

- Tilt patient's head back 70 degrees.
- Slowly insert the swab through the nostril parallel to the palate (not upwards) until resistance is encountered in the back of the throat.
- Leave swab in place for 15 seconds to absorb secretions.
- Slowly remove swab while rotating it.
- If the patient has a deviated septum or blockage creates difficulty in obtaining the specimen from one nostril, use the same swab to obtain the specimen from the other nostril
- If a delay in shipping will result in the specimen arriving at the CDC more than 72 hours after collection, store specimens at -70°C or below (-94F) and ship overnight to CDC on dry ice.

89. This is a common method used in the "drive-thru" testing sites set up in many cities. In order to be properly detected, the swab must be inserted deep into the nasal passage, causing considerable discomfort. Many of those performing the tests were either not properly trained or tended to withdraw the swab early when the patient exhibited discomfort or resistance. [72]

90. Dr. Michael Pintella, Director of the State Hygienic Lab in Iowa, stated "Tests involve a multi-step process and each step might lead to a false negative result for any number of reasons,

[72] Higgins TS, Wu AW, Ting JY. "SARS-CoV-2 Nasopharyngeal Swab Testing-False-Negative Results From a Pervasive Anatomical Misconception." *JAMA Otolaryngol Head Neck Surg* 2020 Sep doi: 10.1001/jamaoto.2020.2946. published online ahead of print

including a poorly collected specimen, a delay in transport of the specimen to the lab, not storing or transporting specimens at the appropriate temperature, problems encountered during testing extraction, analysis errors and more."[73] In the same news release, Dr. Austin Baeth, who was very outspoken about wanting to administer a state lockdown for Iowa, admitted that the tests only have a 63% accuracy rate.

91. The other common method for testing is the antibody test, which uses a blood sample. The problem with this test is that it does not determine if one has the virus, only if one has had it before. This is also problematic, as there are many false positives due to detecting antibodies created from exposure to or infection by other coronaviruses (such as the common cold).[74] The methodology is flawed as well. According to a report released in early May, the FDA had to tighten restrictions on the hundreds of companies that were profiting from the sale of fraudulent testing kits.[75] Some of these kits were even being advertised as "do it yourself from home" products.

92. To make matters worse, the CDC had been mixing the reporting of positive test results from both the PCR test and the antibody tests. Ashish Jha, the K.T. Li Professor of Global Health at Harvard University said, "You've got to be kidding me. How could the CDC make that

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[73] Laura Terrell. 'False negatives are harmful' according to medical professionals. *KCCI* April 3 2020 https://www.kcci.com/article/false-negatives-are-harmful-according-to-medical-professionals/32038917 accessed 9.2.2020

[74] Amanda Morris. People look to COVID-19 antibody testing for answers, but no test offers guarantees. *Azcentral* April 27 2020 https://www.azcentral.com/story/news/local/arizona-health/2020/04/27/questions-linger-covid-19-antibody-tests-even-demand-grows/5170052002/ accessed 9.2.2020

[75] Associated Press. FDA tightens rules on antibody test after false claims, accuracy problems. *NBC News* May 4 2020 https://www.nbcnews.com/health/health-news/fda-tightens-rules-antibody-tests-after-false-claims-accuracy-problems-n1199431 accessed 9.2.2020

mistake? This is a mess." [76] William Hanage, an epidemiology professor at Harvard, concurred by stating, "Combining a test that is designed to detect current infection with a test that detects infection at some point in the past is just really confusing and muddies the water." One test is like looking backward to see who was infected and the other [arguably] tests to see if there is an infection now.

B. Examples of Testing Failures

93. The head of Tanzania's health laboratory in charge of coronavirus was suspended after President John Magufuli of Tanzania had a security detail obtain random samples of pawpaw, jackfruit, and animals which tested positive for SARS-CoV2.

94. Samples of fruit were taken from inside the fruit, to avoid possible positive results from someone touching the fruit. The samples were given names and sent to the laboratory. The results:

- Sample of car oil named Jabil Hamza, 30 years old, male – negative
- Sample from Jackfruit named Sarah Samuel, 45 years old, female – inconclusive test results
- Sample of liquid from Pawpaw named Elizabeth Anne, 26 years old female – positive
- Samples from Kware (type of bird) – positive
- Samples from rabbit – undetermined
- Goat – positive
- Sheep – negative

[76] Alexis Madrigal, Robinson Meyer. 'How Could the CDC Make That Mistake?' *The Atlantic* May 21 2020 https://www.theatlantic.com/health/archive/2020/05/cdc-and-states-are-misreporting-covid-19-test-data-pennsylvania-georgia-texas/611935/ accessed 9.2.2020

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Magufuli said that this means the pawpaw named Elizabeth must be placed in isolation, goats should be in isolation, and Jackfruit named Sara should be in isolation. But, he reported, the pawpaw is not dying, it's just getting ripe. Magufuli says, "a dirty game is being played with these tests." He reported that the tests were imported and said the WHO should do something about this. He told Reuters that this indicates that some people are testing positive who do not have the disease.

The Centers for Disease Control and Prevention says there is no way that fruit can contract COVID-19.

94. As of May 6, 2020, there were 480 cases and 17 deaths in Tanzania. There was no report as to whether the goats, sheep, bird, pawpaw and jackfruit were included in the count.[77] [78]

95. Another absurd example of this preoccupation with COVID-19 came from NBC. NBC referred to Dr. Joseph Fair as "…Today's most knowledgeable expert on the coronavirus outbreak." Dr. Fair reported that he was recently diagnosed with COVID-19, and tweeted that he was hospitalized with it.

According to Dr. Fair, he flew home from New York City to New Orleans wearing a mask and gloves, wiped everything down but says he must have contracted it through his eyes. He said that his symptoms were not classic symptoms, but when he developed shortness of breath, he called an ambulance and was admitted to Tulane Medical Center. He had four COVID

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[77] Ben Cost "Faulty Coronavirus Kits suspected as goat and fruit test positive in Tanzania" *New York Post* May 6 2020 https://nypost.com/2020/05/06/faulty-coronavirus-kits-suspected-as-goat-and-fruit-test-positive-in-tanzania/ accessed 9.2.2020

[78] Tanzania COVID-19 lab head suspended as president questions data. Al Jazeera May 5 2020 https://www.aljazeera.com/news/2020/05/tanzania-covid-19-lab-head-suspended-president-questions-data-200505065136872.html accessed 9.2.2020

tests and they were all negative, but he knows he had it and his doctors confirmed that this was the case.

96. It seems that anyone determined to have COVID-19 will have it – testing does not matter. Apparently, neither does wearing masks and gloves and wiping things down.[79]

C. Other Countries Inflated Numbers Too

97. Public health officials in the UK have inflated the number of cases by counting each test twice. When diagnostic tests were used that involved taking both saliva and nasal samples from the same patient, the results were counted as two separate tests. This led to inflated case numbers. Both the Department of Health and Social Care and Public Health England acknowledged that they had engaged in this practice.

98. This is not the only instance in which the UK government was caught inflating data. In April, public health authorities included thousands of home tests which had been mailed out but not completed in order to make it look like the goal of 100,000 tests was being met. Apparently using fake numbers to promote a fake pandemic is not limited to the U.S.[80]

D. The CDC's Strange Definition of a "Case"

99. Clearly the lab tests were flawed but the CDC's definition of a "case" does not actually require any testing at all. In fact, the CDC has listed over one dozen ways in which a person

[79] Maura Hohman.. NBC's Dr. Joseph Fair hospitalized with coronavirus: 'Not out of the woods yet.' *Today* May 13 2020 https://www.today.com/health/nbc-news-contributor-dr-joseph-fair-sick-coronavirus-t181487 accessed 9.2.2020

[80] Mason Boycott-Owen, Paul Nuki. Tens of thousands of coronavirus tests have been double-counted, officials admit. *The Telegraph* May 21 2020 https://www.telegraph.co.uk/global-health/science-and-disease/tens-thousands-coronavirus-tests-have-double-counted-officials/ accessed 9.2.2020

could be diagnosed with COVID-19. Below are excerpts from the CDC's "2020 Interim Case Definition"[81] with commentary following each section.

E. Clinical Criteria

100. At least two of the following symptoms: fever (measured or subjective), chills, rigors, myalgia, headache, sore throat, new olfactory and taste disorder(s)

OR

At least one of the following symptoms: cough, shortness of breath, or difficulty breathing

OR

Severe respiratory illness with at least one of the following:

- Clinical or radiographic evidence of pneumonia **OR**
- Acute respiratory distress syndrome

AND

No alternative more likely diagnosis

F. Commentary on "Clinical Criteria"

101. Some comments on "clinical criteria"

- Note that fever can be "subjective."
- Headache, sore throat and cough can be symptoms of many things, including allergies and the common cold.
- "New olfactory and taste disorders." An article published in the *Lancet* referred to COVID testing as "inadequate" and suggests that new symptom profiles be developed to help identify those who should be quarantined.

[81] Coronavirus Disease 2019 (COVID-19). 2020 Interim Case Definition, Approved April 5 2020. Canters for Disease Control and Prevention. https://wwwn.cdc.gov/nndss/conditions/coronavirus-disease-2019-covid-19/case-definition/2020/ accessed 9.2.2020

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- The article suggests that loss of taste and smell are highly predictive of COVID-19 and anyone experiencing these symptoms should self-isolate.[82]

  In fact, there are many causes of loss of taste and smell. These include:

  - Aging especially after age 60
  - Allergies
  - Nasal and sinus problems like sinusitis or nasal polyps
  - Medications including beta blockers and ACE inhibitors
  - Dental problems
  - Cigarette smoking
  - Head or facial injury
  - Alzheimer's disease
  - Parkinson's disease
  - Common cold or other viral infections (40%)[83]

102. In fact, as much as 20% of the general population has a prolonged smell disorder.[84]

There are also many problems with the *Lancet* article. The basis for the recommendation to use taste and smell as a diagnostic tool is based on data collected from patients answering questions using an online app. Almost 60% of 579 people who reported testing positive said they had lost their sense of smell and taste; but almost 18% of the 1123 who tested negative also reported loss of taste and smell.[85]

103. The researchers acknowledge many limitations which include that these symptoms are non-specific and lack predictive power, and their report relied on self-reported information,

[82] Menni C, Sudre CH, Steves CJ, Ourselin S, Spector TD. "Quantifying additional COVID-19 symptoms will save lives." *Lancet* published online June 4, 2020

[83] Weige-Lussen A, Wolfensberger M. "Olfactory Disorders following Upper Respiratory Tract Infections." In Hummel T, Welge-Lüssen A (eds): Taste and Smell. An Update. Adv Otorhinolaryngol. Basel, Karger, 2006, vol 63, pp 125-132

[84] Boesveldt S, Postma EM, Boak D et al. "Anosmia – A Clinical Review." *Chem Senses* 2017 Sep;42(7):513-523.

[85] Menni C, Sudre CH, Steves CJ, Ourselin S, Spector TD. "Quantifying additional COVID-19 symptoms will save lives." *Lancet* 2020 Jun;395(10241):E107-E108

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which is generally unreliable. Yet, they write, "We believe that having added loss of smell and taste to the list of COVID-19 symptoms is of great value as it will help trace almost 16% of cases that otherwise would have been missed. Loss of smell and taste, together with fever or cough, should now enable us to identify 87.5% of symptomatic COVID-19 cases, although this is likely to be less in the early phases of the infection." This conclusion is hard to fathom in consideration of the facts, although facts have not seemed to matter much these days.

104. A much more realistic assessment from Eric Holbrook, director of rhinology at Massachusetts Eye and Ear was offered when he stated: "Physicians are collecting data so quickly, but a lot of it is subjective data. I haven't seen a careful study that looks at when patients get the diagnosis, and how severe it is, and how long the smell loss lasts."[86]

G. Laboratory Criteria

105. Laboratory evidence using a method approved or authorized by the U.S. Food and Drug Administration (FDA) or designated authority:

Confirmatory laboratory evidence:

- Detection of severe acute respiratory syndrome coronavirus 2 ribonucleic acid (SARS-CoV-2 RNA) in a clinical specimen using a molecular amplification detection test

Presumptive laboratory evidence:

- Detection of specific antigen in a clinical specimen
- Detection of specific antibody in serum, plasma, or whole blood indicative of a new or recent infection*

[86] Sarah Elizabeth Richards. "Lost your sense of smell? It may not be coronavirus." *National Geographic* April 7 2020 https://www.nationalgeographic.com/science/2020/04/lost-your-sense-of-smell-it-may-not-be-coronavirus/ accessed 9.2.2020

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**Serologic methods for diagnosis are currently being defined*

H. Commentary on Laboratory Criteria:

106. Note that these are the tests discussed above to be inaccurate, and that the CDC admits that the serological methods for diagnosis are currently being defined, but they are ok to use for purposes of diagnosis now.

I. Epidemiologic Linkage

107. One or more of the following exposures in the 14 days before onset of symptoms:

- Close contact** with a confirmed or probable case of COVID-19 disease; **OR**
- Close contact** with a person with:
  - clinically compatible illness **AND**
  - linkage to a confirmed case of COVID-19 disease.
- Travel to or residence in an area with sustained, ongoing community transmission of SARS-CoV-2.
- Member of a risk cohort as defined by public health authorities during an outbreak.

***Close contact is defined as being within 6 feet for at least a period of 10 minutes to 30 minutes or more depending upon the exposure. In healthcare settings, this may be defined as exposures of greater than a few minutes or more. Data are insufficient to precisely define the duration of exposure that constitutes prolonged exposure and thus a close contact.*

108. Commentary on Epidemiologic Linkage:

- A person who has been within 6 feet of someone for 10 minutes who may have but is not confirmed to have COVID-19 is now considered a case.

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- A person who has been within 6 feet of a person who has a headache or a sore throat or has changes in smell or taste is now considered a case.
- A person who has been in contact with a person who is linked to a person with COVID-19 is now a case.
- Travel to an area in which there are COVID-19 cases qualifies a person as a case.
- Being a member of a "risk cohort" also qualifies a person as a case. There are no examples, but a statement that health authorities can just name a group as a risk category.
- The CDC acknowledges that the length of exposure required to cause a problem is not known, but uses this metric anyway.

J. Criteria to Distinguish a New Case from an Existing Case

109. Not applicable (N/A) until more virologic data are available.

K. Commentary on Criteria to Distinguish a New Case from an Existing Case:

110. The CDC does not know how to determine a new from an existing case, but when trying to boost the number of cases, this is a distinction without difference to them.

XI. THE LAW

A. The Paperwork Reduction Act

111. 44 USCS § 3501 describes the purpose of what has become known as the Paperwork Reduction Act ("PRA"). Within that subsection are the following excerpts:

> The purposes of this subchapter [44 USCS §§ 3501 et seq.] are to—
>
> **(2)** ensure the greatest possible public benefit from and maximize the utility of information created, collected, maintained, used, shared and disseminated by or for the Federal Government;
>
> **(3)** coordinate, integrate, and to the extent practicable and appropriate, make uniform Federal information resources management policies and practices as a means to improve

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the productivity, efficiency, and effectiveness of Government programs, including the reduction of information collection burdens on the public and the improvement of service delivery to the public;

(4) improve the quality and use of Federal information to strengthen decision making, accountability, and openness in Government and society;…

(6) strengthen the partnership between the Federal Government and State, local, and tribal governments by minimizing the burden and maximizing the utility of information created, collected, maintained, used, disseminated, and retained by or for the Federal Government;

(7) provide for the dissemination of public information on a timely basis, on equitable terms, and in a manner that promotes the utility of the information to the public and makes effective use of information technology;…

(9) ensure the integrity, quality, and utility of the Federal statistical system;..

(11) improve the responsibility and accountability of the Office of Management and Budget and all other Federal agencies to Congress and to the public for implementing the information collection review process, information resources management, and related policies and guidelines established under this subchapter [44 USCS §§ 3501 et seq.].

It is beyond question that a major goal of this Act is to ensure accurate and truthful information is available to the public and decisionmakers. Beyond the purpose statement, 44 USCS § 3506 of the PRA also requires that:

(d) With respect to information dissemination, each agency shall—

(1) ensure that the public has timely and equitable access to the agency's public information, including ensuring such access through—

(B) in cases in which the agency provides public information maintained in electronic format, providing timely and equitable access to the underlying data (in whole or in part); and

(C) agency dissemination of public information in an efficient, effective, and economical manner;

(2) regularly solicit and consider public input on the agency's information dissemination activities;

(3) provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products;

(4) not, except where specifically authorized by statute—

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(A) establish an exclusive, restricted, or other distribution arrangement that interferes with timely and equitable availability of public information to the public;

(B) restrict or regulate the use, resale, or redissemination of public information by the public;

(6) engage the public in using public data assets of the agency and encourage collaboration by—

(B) providing the public with the opportunity to request specific data assets to be prioritized for disclosure and to provide suggestions for the development of agency criteria with respect to prioritizing data assets for disclosure;

(e) With respect to statistical policy and coordination, each agency shall—

(1) ensure the relevance, accuracy, timeliness, integrity, and objectivity of information collected or created for statistical purposes;

(2) inform respondents fully and accurately about the sponsors, purposes, and uses of statistical surveys and studies;

(4) observe Federal standards and practices for data collection, analysis, documentation, sharing, and dissemination of information;

(5) ensure the timely publication of the results of statistical surveys and studies, including information about the quality and limitations of the surveys and studies; and

(6) make data available to statistical agencies and readily accessible to the public.

112. While the entirety of the excerpt is valid to provide context, let us reiterate that "With respect to information dissemination, each agency shall… provide adequate notice when initiating, substantially modifying, or terminating significant information dissemination products;…" and "With respect to statistical policy and coordination, each agency shall… ensure the relevance, accuracy, timeliness, integrity, and objectivity of information collected or created for statistical purposes; [and] inform respondents fully and accurately about the sponsors, purposes, and uses of statistical surveys and studies…"

113. Absolutely no notice in any form was given to the public prior to the March 24, 2020 changes, nor was the public involved in such changes. The public has also not been informed fully about the individuals that created the unique rules for data collection and usage pertaining

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to COVID-19. These changes remain in place over 8 months later, still with no opportunity for public input.

114. The discussion of Death Counts and Case Counts (*see* above) clearly demonstrate that the agency has failed miserably in ensuring accuracy, integrity, and objectivity of the information collected. Let us reiterate the following statements from the NVSS COVID-19 Alert No.2 issued March 24,2020:

1. "The underlying cause depends upon what and where conditions are reported on the death certificate. However, the rules for coding and selection of the underlying cause of death are expected to result in COVID19 being the underlying cause more often than not." – why would we categorize COVID-19 in this way but no other disease?
2. "If the death certificate reports terms such as "probable COVID-19" or "likely COVID-19," these terms would be assigned the new ICD code. It is not likely that NCHS will follow up on these cases." The new code being referred to is U07.1 and indicates a COVID-19 death. Why are deaths that are likely or probable automatically reported as confirmed COVID-19 deaths? This is particularly concerning given that the WHO also created another code U07.2 that was specifically designated for probable or likely cases; why would the CDC not use the same designations?
3. Under the heading "Should "COVID-19" be reported on the death certificate only with a confirmed test?" the printed answer was: "COVID-19 should be reported on the death certificate for all decedents where the disease caused **or is assumed to have caused or contributed to death**. Certifiers should include as much detail

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as possible based on their knowledge of the case, medical records, laboratory testing, etc. If the decedent had other chronic conditions such as COPD or asthma that may have also contributed, these conditions can be reported in Part II. (See attached Guidance for Certifying COVID-19 Deaths)." (Emphasis in original)

115. Given that COVID-19 is the ONLY disease reported this way it is clear that the goal of death reporting for COVID-19 was less about "ensuring accuracy, integrity, and objectivity of the information collected" and more about promoting a political narrative in violation of the plain language of the law.

116. We expect the Defendants will claim this change was done in response to an emergency situation but that statement holds no water 8 months later. Further, given the numerous statements by agency heads and experts around the world that this disease is here to stay, the fact that we are seeing over a 99.9% recovery rate, and that even with the data being manipulated the fatality rate is still akin to the yearly flu, it simply cannot be stated that there is still an emergency – particularly one that would prevent this situation from being remedied. If in fact COVID-19 actually did still constitute an emergency, it would be even more important that the data be honest and clear.[87]

117. Plaintiffs also have no administrative remedy available pursuant to the PRA or IQA. Under 44 USCS § 3517 states "Any person may request the Director to review any collection of information conducted by or for an agency to determine, if, under this subchapter [44 USCS §§ 3501 et seq.], a person shall maintain, provide, or disclose the information to or for the agency." While this does allow for a person to challenge a personal requirement to disclose information it

[87] Under *Home Building & Loan Assn. v. Blaisdell*, 290 U.S. 398 (1934) the Court stated, "Emergency does not create power. Emergency does not increase granted power or remove or diminish the restrictions imposed upon power granted or reserved."

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does not allow for an individual to challenge the rule or compilation procedures/methodologies of such a collection generally. To be clear, Plaintiffs are not requesting judicial review of an agency decision on a petition for correction of individual data, but rather the rule promulgated that governs the collection and dissemination of data in an arbitrary and illegal way. If such actions are not reviewable the IRA and PRA are essentially rendered pointless as they simply could not be enforced despite a Congressionally mandated public interest.

118. The discussion of facts related to this case make it clear the PRA is intentionally being violated. The data being provided by the CDC is clearly and intentionally being done in a way that is misleading as demonstrated by the discussion of Death Counts and Case Counts. The Plaintiffs and the American public at large have been injured profoundly by the COVID-19 response that has been based entirely on false data promulgated under this illegal rule. The only recourse available to the public is injunctive relief from the Courts.

119. As a final note, Plaintiffs affirmatively reject the notion that the *Chevron* analysis would apply to this particular action and instead believe that this action should be reviewed with the burden of proof placed squarely on the unelected bureaucracy that is violating both statutory law and (we believe) Constitutional law by interfering with the performance of the legislative and judicial branches. That said, Plaintiff also strongly contend that, given the egregious violation of the plain language of the law and the monumental damage being done to our nation in response to this non-crisis it would be nothing short of a clear miscarriage of justice to suggest these actions should stand even under the *Chevron* doctrine.

B. The Administrative Procedures Act

120. The Administrative Procedures Act broadly allows judicial review of "agency actions" by any person "adversely affected or aggrieved" by the action. 5 U.S.C.S. § 702 Envtl. Prot. Info.

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Ctr. v. United States Fish & Wildlife Serv., 2005 U.S. Dist. LEXIS 30843. With regard to judicial review of an administrative action, a party must show that the challenged guidelines either (1) reflect "final agency action;" or (2) constitute a de facto rule or binding norm that could not properly be promulgated absent the notice-and-comment rulemaking required by the Administrative Procedure Act (APA). When a party can demonstrate the latter proposition, they will implicitly prove the former, because the agency's adoption of a binding norm obviously will reflect final agency action. Nat'l Mining Ass'n v. Jackson, 880 F. Supp. 2d 119.

121. Given what has occurred in our nation as a result of the reported "danger" related to COVID-19 and the amount of money transferred pursuant to statutory law (within the CARES Act) based entirely on COVID-19 case and death reporting, it is difficult to think of a more critical instance where the procedures in notice and comment rule-making should apply. Further, even if Plaintiffs were to accept the position that this could not be done due to the claimed emergency, which we do not[88], we believe this rule should be invalidated due to the changes in circumstances that have occurred since that time under Chastleton Corp. v. Sinclair, (1924) 264 U.S. 543 where the Court held that "A law depending upon the existence of an emergency or other certain state of facts to uphold it may cease to operate if the emergency ceases or the facts change. (*Id* at P. 264 U. S. 547).

122. Under the Administrative Procedures Act ("APA"), 5 USCS § 551, "(4) rule means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency and includes the approval or prescription for

[88] There was time to convene a panel of experts and it has been many months since this has begun – timing simply cannot be claimed to be an issue at this point.

the future of rates, wages, corporate or financial structures or reorganizations thereof, prices, facilities, appliances, services or allowances therefor or of valuations, costs, or accounting, or practices bearing on any of the foregoing." This statement has been interpreted broadly to include nearly any statement an agency can make. Chaney v. Heckler, 718 F.2d 1174, 231 U.S. App. D.C. 136, 1983 U.S. App. LEXIS 16070 (D.C. Cir. 1983), reh'g denied, 724 F.2d 1030, 233 U.S. App. D.C. 146, 1984 U.S. App. LEXIS 26347 (D.C. Cir. 1984), rev'd, 470 U.S. 821, 105 S. Ct. 1649, 84 L. Ed. 2d 714, 15 Envtl. L. Rep. 20335, 1985 U.S. LEXIS 78 (1985).

123. The rule issued on March 24, 2020 is clearly a substantive rule given that it provides guidelines that have a dramatic future effect by both changing eligibility for reimbursement under the CARES Act[89] and also altering the methods by which the cause of death is recorded – which is literally a change in process for the individuals responsible for recording deaths. If this process were not followed and an individual were to sue for damages based on not being reimbursed under the CARES Act the Court would be bound by this regulation thus demonstrating it is substantive. Energy Consumers & Producers Asso. v. Department of Energy, 632 F.2d 129, 1980 U.S. App. LEXIS 18952 (Temp. Emer. Ct. App.), cert. denied, 449 U.S. 832, 101 S. Ct. 102, 66 L. Ed. 2d 38, 1980 U.S. LEXIS 2772 (1980).

124. In addition to the above, the COVID-19 Alert No. 2 document, in response to the heading "What happens if certifiers report terms other than the suggested terms?" states:

> If a death certificate reports coronavirus without identifying a specific strain or explicitly specifying that it is not COVID-19, NCHS will ask the states to follow up to verify whether or not the coronavirus was COVID-19. As long as the phrase used indicates the 2019 coronavirus strain, NCHS expects to assign the new code. However, it is preferable and more straightforward for certifiers to use the standard terminology (COVID-19).

[89] Point to section that provides additional reimbursement for COVID patients

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125. This is clear evidence that this rule was meant to be substantive. Essentially the NVSS has stated that if the rule is not followed, what is reported will be ignored and a COVID-19 death will be reported.

126. This means that rules issued related to data collection and reporting were subject to the APA rulemaking processes. We remind the Court that this agency did not even attempt to suggest this was an interpretive rule – it simply ignored the rulemaking process and that even if it did claim interpretative rule, such a claim would not have been dispositive. Detroit Edison Co. v. United States EPA, 496 F.2d 244, 6 Env't Rep. Cas. (BNA) 1568, 4 Envtl. L. Rep. 20388, 1974 U.S. App. LEXIS 9101 (6th Cir. 1974). Further, given the lack of clarity at the time this rule was issued, the Courts have typically not given great weight to post hoc characterizations of a rule being exempt. Ultimately, this was a rule, subject to rulemaking requirements, and these requirements were simply not followed in any way, shape, or form.

127. Again under 5 USCS § 551, "(5) "rule making" means agency process for formulating, amending, or repealing a rule." The rule making process is defined in 5 USCS § 553. There are two exemptions to the rulemaking process. The first is for interpretive rules which should not apply here and the second is, "(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest."

128. The first exemption is addressed above and so we now turn to the second. As noted, if an agency is using the emergency rule exemption, it is required to make a brief statement as to why the standard rulemaking requirements are not followed. No such statement was made and so Plaintiffs request this rule be declared invalid.

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129. Further, even if this rule were allowed to stand under the second exemption, the exigency of the circumstances giving rise to said emergency no longer exists. As noted above this disease is now known to have over a 99.99% recovery rate and has been acknowledged to be roughly as dangerous as the yearly flu.[90] Pursuant to *Chastleton Corp. v. Sinclair*, 264 U.S. 543 (1924) "A law depending upon the existence of an emergency or other certain state of facts to uphold it may cease to operate if the emergency ceases or the facts change." P. 264 U. S. 547. This language would clearly include an administrative action taken under the guise of an emergency and, as such, would necessitate the proper rulemaking process be undertaken as quickly as possible after any necessary emergency actions were taken. Any other interpretation would allow for the declaration of an emergency to act as a pretense for permanent rules which is clearly not the intent of the APA.

130. It has been over 8 months since this rule was promulgated, we now know this disease is not the mass killer it was claimed to be, and there clearly is no need for this rule to continue without having been promulgated under the proper rulemaking procedure of the APA. It is clear from the facts of this case that allowing the CDC to circumvent the rulemaking process to create a new rule regarding the methods of tracking death counts would open the door for flawed or even corrupt definitions of diseases to be used as a pretense for overriding the rights of the Plaintiffs here. As such we ask that this order be enjoined.

C. Writ of Mandamus

131. Plaintiffs strongly believe that the Court should grant injunctive relieve based on the PRA and APA, and further believe that no administrative remedy exists to compel the Defendants to follow the plain language of the law. However, in the interest of preserving the Court's resources Plaintiffs include here a writ of mandamus to compel the Defendants to fulfill their duties under the PRA.

[90] Cite Fauci's statement and the WHO statement

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132. Because it is impossible to identify the specific HHS employees responsible for creating, enforcing, and disseminating information related to COVID-19 prior to discovery and also that mandamus is typically granted against individuals we list John and Jane Doe's as placeholders until such time as the proper parties can be identified.

D. Implied Constitutional/Statutory Duty of Honesty and Fair Dealing

133. Plaintiffs contend that there exists an implied Constitutional/Statutory duty to honesty that applies here. We base this argument on three general premises:

1. Because unelected bureaucrats are not accountable to the public through elections and cannot even be fired easily due to a recognized legal interest in their positions, an implied right of action must exist for the public where said bureaucrats are not performing their jobs with honesty and fair dealing. To hold otherwise would be to invalidate our most fundamental rules of accountability within government.
2. Separation of powers has been dramatically diminished over the years and without an implied duty of honesty and fair dealing then there would exist unconstitutionally overbroad powers consolidated into what would essentially be a fourth quasi-branch of government.
3. Legal and evidentiary rules as well as numerous cases have relied on the truthfulness of executive-branch agencies. This implies a duty of honesty and fair dealing must exist within those agencies.

134. Within the two-plus centuries of jurisprudence since the founding of our nation, the Courts have developed numerous instances where reliance is placed on honesty in the presentation of facts – data and/or information – by the government. This issue is only becoming

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more critical as science continues to become more complex and is also forming the basis of regulation. Given the Court's continual expansion of the authority of unelected bureaucrats and the difficulties in holding them accountable to the public, it is incumbent that the people be able to hold these officials accountable in court.

135. The doctrine of the separation of powers has been eroded over the years to the point that we have even, in some cases, expanded the *Chevron* analysis[91] (Chevron, U.S.A., Inc. v. NRDC, Inc., 467 U.S. 837, 104 S. Ct. 2778, 81 L. Ed. 2d 694, 1984 U.S. LEXIS 118, 52 U.S.L.W. 4845, 14 ELR 20507, 21 ERC (BNA) 1049) to essentially allow for a regulatory agency to do anything even remotely related to the enabling legislation despite the fact that the enabling legislation need only provide a vaguely cognizable limitation on regulatory power. Plaintiffs believe it is a stretch to argue that this was what the founding fathers had in mind when authoring the Constitution but argue that it is quite clearly unconstitutional to suggest this deference should be granted when dishonesty is involved.

136. If, as the Courts have mandated in past decisions, regulatory agencies only need a minimal rational basis to take actions, would it not be implicit that this already low standard at least be based on an "honest" rational basis? The alternative is that we are sanctioning regulatory agencies to do anything without even an honest basis for doing so.

137. This approach is illegal for several reasons. The first and most clear stems from the rules of evidence. Three evidentiary rules give preferential treatment to public records: Fed. Rule Evidence 902 (4) and (5); and Rule 803(9). Fed. Rule Evid. 902(4) allows for certified copies of

[91] "If Congress has explicitly left a gap for the agency to fill, there is an express delegation of authority to the agency to elucidate a specific provision of the statute by regulation. Such legislative regulations are given controlling weight unless they are arbitrary, capricious, or manifestly contrary to the statute. Sometimes the legislative delegation to an agency on a particular question is implicit rather than explicit. In such a case, a court may not substitute its own construction of a statutory provision for a reasonable interpretation made by the administrator of an agency."

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public records to be self-authenticating. The implication is that if the government is producing it then it must be true and accurate. While it may be argued that it is the presentation of the data that is authenticated, the reality is that if the underlying approach lacks integrity then we still end up with the same result. In the case at hand, if integrity is not a factor in determining the number of cases or COVID-19 deaths then the NCHS could have chosen to include people whose sole cause of death was cancer as COVID-19 deaths. The fact that this sounds absurd illustrates that integrity is an assumed part of data and statistics gathering and reporting from administrative agencies. Rule 902(5) gives the same authentication preference to Official publications which are purported to be issued by a public authority, like a governmental agency. The authentication lays the foundation, and the admissibility is governed under Rule 803(9), which contains an exception to the rule against hearsay for Public records of vital statistics such as birth, death or marriage records.

138. The second clear example of the illegality of an executive branch agency lying is found in nearly the entire field of criminal law. There is no shortage of examples or cases found in the world of criminal law where the Courts have held it unconstitutional for executive agencies to lie or mislead. In many such instances the result of such a lie is the abridgment of an individual's rights. In the case at hand the Plaintiffs have lost more fundamental rights than many criminals based on misleading data – this is illegal.

139. A third instance pointing to the implied duty of honesty and fair dealing with regards to regulatory agencies would stem from the nature of Constitutional review. We see a number of rights reviewed by the Courts as being subject only to rational basis scrutiny. In some instances the Courts will not even review evidence of violation of rights subject to rational basis review because they have held that the actions are, "not subject to courtroom fact-finding and may be

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based on rational speculation unsupported by evidence or empirical data." *FCC v. Beach Commc'ns, Inc*., 508 U.S. 307, 313–15 (1993). While it is quite difficult to suggest that this statement in any way constitutes a test for rationality, even with precedence this bad, it seems that the Court could not have meant to allow for such violations to occur based on dishonest motives and if they had, in the instance before the Court here, it would be clearly in violation of the plain language of the PRA and IQA.

140. A final demonstration of the implied duty of honesty and fair dealing by an executive branch agency is actually not implied at all. It is simply a recognition of that duty in the PRA and IQA. That enforcement actions by executive branch agencies must be based on honest facts is beyond question, why then would we allow other actions and/or rulemakings to occur without such a duty?

141. There is no direct means to hold an unelected bureaucrat accountable. This fact is only exacerbated by the reality that the Courts have held federal employees may have legal rights in their jobs. It simply cannot be Constitutional to delegate so much authority away from our elected officials and to people that cannot even be fired without at least providing a mechanism for the public to file suit. As such, where a regulatory agency has acted dishonestly there must exist an implied right of standing to challenge and the Courts would necessarily need to enforce that right.

XII Prayers for Relief:

142. The PRA and IQA make it clear that Congress intended for honesty and integrity in data reporting. The OMB backs this position in its many rules interpreting these statutes and even the NCHS itself not the critical nature of ensuring integrity and utility in statistics. The public has,

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again, according to the plain language of the law, a strong interest and even a role in ensuring the data is based on integrity and useful.

143. HHS is not following the law. As a result of HHS's failure to follow the law Plaintiffs have been injured. They have been injured by the policies implemented in response to this misleading data. No two better examples of abuse of discretion could be imagined than these:

1. Changing the method for accounting for death for a single disease thus rendering data about deaths for that disease useless in understanding the danger of said disease. This happened when precautions should have been taken to prevent overcounting since additional funds were offered for diagnosis/death from that disease.
2. Using a test that even Dr. Fauci admits is useless in diagnosing a disease – particularly when run above 35 cycles that is approved, most times, at 40 or more cycles as a means of measuring the danger of a disease. Further this same test is approved without any national standard.

144. When Congress delegated power to these regulatory agencies to leverage their limited legislative power it was Constitutionally required to ensure it did so with standards. In this case Congress did set standards – utility and integrity amongst them.

145. While the Court may not create law or policy it is clearly the Court's role to interpret law that is written. The facts as alleged within this complaint, indisputably show that the statistics, information, data, etc. related to COVID-19 deaths and cases are neither being promulgated in a way that involves integrity or utility. The substantive rules, rules that had a substantial legal impact – were created without following procedures required by law and the result has reaped unthinkable levels of destruction on our nation.

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146. But for the violation of the integrity, utility, and other standards set out in the PRA and IQA, our nation and the Plaintiffs would not be suffering through this nonsense. But for the violation of the APA, PRA, and IQA perhaps these errors would not have occurred and none of this debacle would have happened. Now, if the Plaintiffs do not have the right to challenge one of the most egregious and impactful mistakes in American history we will be left to continue to suffer for the foreseeable future. The APA, PRA, and IQA were all put in place as checks on the already overly broad powers on regulatory agencies – the people do and must have a right to enforce those rights and so we humbly ask the Court for the following relief:

1. Enjoin the current and future use of the March 24, 2020 rule changing the death reporting procedures as they apply COVID-19.

As discussed above, the process by which the substantive rules for reporting of deaths related to COVID-19 were not followed either pursuant to the PRA or APA. Those improperly passed rules have created chaos throughout the nation, cost untold trillions of dollars, and facilitated policies, an environment, and specific actions that have harmed the Plaintiffs. A ruling by the Court that ordered that the issuance of this rule was illegal and that reporting should be carried out has it has been with every other disease since 2003 would begin to allow the political process to repair the damage that has occurred. As such, we humbly request that the Court grant the injunction against the implementation of this illegal rule.

2. Enjoin the current and future reporting using said COVID-19 Death reporting rule unless and until it is properly implemented under existing law.

The reporting of data that is known to be misleading by a regulatory agency charged with ensuring statistics are gathered and disseminated with integrity and in a useful manner is facially illegal. This reporting has caused innumerable damages to states, regulatory agencies, private businesses, and individuals through essentially coercing them into creating policies to save lives from something that is killing far fewer than reported. The Plaintiffs humbly request that the

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Court remedy this situation by enjoining the Defendants from continuing to report what can only be described as intentionally misleading information.

3. Enjoin the use of "Case Reporting" using unreliable testing procedures such as PCR testing without the proper creation of a national standard for PCR tests and a uniform definition of what a "case" is that is scientifically meaningful and in compliance with relevant law and regulation.

No less than Dr. Fauci himself stated that PCR tests ran over 35 cycles are meaningless. There could be no clearer statement that the collection and dissemination of information related to the use of PCR testing, as approved by the FDA, is a violation of the PRQ and IQA. This false data is being used as a cornerstone for both public and private policies throughout the nation and particularly in the state of Ohio that are injuring the Plaintiffs. We humbly request the Court enjoin the future use of "Case Reporting" based on PCR testing given that it is not reliable and thus cannot be reported with integrity or in a way that is useful which is in clear violation of the PRA and IRQ.

4. Declare and hold unlawful and set aside the agency rule regarding reclassification of deaths by COVID-19 to the extent it is found to be: arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; or contrary to constitutional rights; or in excess of statutory jurisdiction, authority or limitations, or short of statutory right; or without observance of procedure required by law; or unwarranted by the facts.

As discussed above, the agency rule reclassifying deaths related to COVID-19 as being deaths with COVID-19 as opposed to from COVID-19 is not only arbitrary and capricious but is actually intentional and misleading. The action was taken directly contrary to established law regarding substantive rule changes and completely without following the procedures laid out in the PRA, IQA, and APA. As such we humbly request to set aside this rule in its entirety.

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5. Grant an affirmative injunction that the NCHS report the accurate death data using the traditional reporting methods within 2 weeks from the grant of this injunction.

Given the critical nature of true and accurate data related to COVID-19 being available to the public, policy makers, and elected officials, Plaintiffs request that the Court grant affirmative injunctive relief in the way of ordering that correct data based on both integrity and utility be made available within two weeks of the issuance of such an order. Our nation has suffered due to the violations of statutory and Constitutionally mandated duties to ensure information is useful and reliable. A proper analysis must be completed in a timely manner.

6. Should the Court determine no viable alternatives for relief are available we ask that the Court grant a writ of mandamus and compel Defendant Agency, Director Robert Redfield, Director Azar, and other relevant agency personnel to comply with laws they failed to follow in the new policy or rule on how to code deaths by COVID-19.

While Plaintiffs strongly believe they have standing and that the Court has a duty to order the relief requested above, we request that, should the Court disagree, it grant a writ of mandamus to compel the appropriate Defendants to follow the law and/or order their staff to do the same.

Respectfully submitted,

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