

## **Supporting Evidentiary Brief Relating to Information Quality Act Complaint**

June 24, 2024

This “Supporting Evidentiary Brief Relating to Information Quality Act Complaint” is hereby submitted under the evidence section of the “Submit a Hotline Complaint” associated with the Health and Human Services’ (HHS) Officer of Inspector General (IG). This Brief accompanies the “Complaint Relating to CDC’s Violation of the Information Quality Act” (hereinafter referred to as the “**Complaint**”) submitted on the same date as the present Brief via the same Hotline. The present Brief details the allegations made in the complaint with respect to the Center for Disease Control and Prevention (hereinafter the “**CDC**”).

The present Complaint alleges gross misconduct against each of the following HHS employees as they knew, or should have known due to their function, that the CDC was violating several Federal guidelines, as presented in the following complaint:

- **Dr. Mandy Cohen**, Director, CDC;
- **Dr. Bao-Ping Zhu**, Director of the Office of Science Quality and Library Services (OSQLS); and
- **Hon. Xavier Bacerra**, Secretary, HHS.

The Complainant respectfully requests that the HHS’ Office of Inspector General investigate the violations raised in the Complaint, and the Complainant would appreciate acknowledgment by the IG of receipt of this complaint and notice of what action the IG intends to take in response thereto.

**Please note that the Complaint and this Supplementary Brief are being sent to Hon. Xavier Becerra, Dr. Mandy Cohen, Dr. Bao-Ping Zhu and Hon. Xavier Bacerra both via email as a PDF attachment and physically in paper form via Federal Express.**

### **OVERVIEW OF COMPLAINT:**

On or around February 13, 2024, the CDC announced that it reportedly planned to eliminate its recommendation that people testing positive for COVID-19 should isolate for five days. At this

date, the CDC had mentioned that it planned to publish in April this change in guidance for public comment<sup>1</sup>.

However, on March 1, 2024, only two weeks after the prior announcement, and more than a month prior to when the CDC had initially announced that it would update its guidance, the CDC released and implemented its updated isolation guidelines for COVID-19. Complainant notes that the CDC never offered public comment, as initially stated by the CDC that it would in or around February 13, 2024.

The Updated CDC Guidelines with respect to COVID-19 is reproduced herein<sup>2</sup> (hereinafter referred to as the “**Violating CDC Guidelines**” ).

The actions of the CDC and the afore-mentioned HHS employees, tied to the adoption of the Violating CDC Guidelines, are in violation of the federal guidelines described herein, for the reasons provided below.

Congress, in 2001, as the growth of the Internet changed communications globally, recognized that the benefits of widespread communication could lead to harm due to information that was not valid or that was unclear, and legislated a provision, referred to as the *Information Quality Act*, so that federal agencies would protect the safety of Americans based upon careful vetting of information disseminated by these agencies.

As further detailed by the Office of Management and Budget, “[I]s it crucial that information Federal agencies disseminate meet these guidelines [...] the fact that the Internet enables the agencies to communicate information quickly and easily to a wide audience not only offers great benefits to society, but also increases the potential harm that can result from the dissemination of information that does not meet basic information quality guidelines”.

Each agency is therefore required to establish a process based upon the need for high quality information. The law requires that influential scientific or statistical information satisfies certain scientific conditions for validation, that influential information is vetted by peer review, and that highly influential information is subject to specified rigorous processes to ensure that each and every information product, and particularly information that would be important for health, safety, and environmental risks, would be so validated.

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<sup>1</sup> The Guardian, “CDC plans to end five-day Covid isolation guidelines – report”, February 13, 2024, *The Guardian*, <https://www.theguardian.com/world/2024/feb/13/covid-new-cdc-isolation-guidelines-symptoms> (consulted on April 1, 2024)

<sup>2</sup> Respiratory Virus Guidance, CDC, March 1, 2024, <https://www.cdc.gov/respiratory-viruses/guidance/respiratory-virus-guidance.html>

Here we show that the HHS, and particularly the agency responsible for prevention and control of disease transmission, the CDC, which has been authorized to protect the American people from foreign and domestic disease transmission through isolation and quarantine, has violated the Information Quality Act in its isolation guidance for COVID-19. It has also violated the Agency Good Guidance Practices, that specifies the process for achieving good guidance including public comment on economically significant guidance documents.

The CDC could have known and should have known that the information it provides to the American public not only has a direct impact on the American public but has further importance to protect the American public from invalid information spread through the internet. Instead, the CDC did not follow the rules specified by OMB at the direction of congress to ensure high quality information as explained herein.

Furthermore, the present complaint is submitted following an observed gradual drop in the trust of the American population for guidance given by the CDC<sup>3</sup>. The failure of the CDC to act in accordance with the OMB guidelines described herein, whose purpose is to ensure transparency of federal agencies and quality of their disseminated communications, can only further corrode its credibility amongst the American population.

The Complainant is an organization composed of scientists and doctors who study COVID-19 and work with COVID-19 patients and are concerned that the Violating CDC Guidelines do not adequately assess the current risk posed to the American population by COVID-19. The Complainant is submitting the present complaint because the global impact of the COVID-19 pandemic persists, causing significant harm. Extensive evidence indicates that even mild infections and reinfections can result in symptomatic and subclinical health damage, disability, and persistent infection. Vascular impacts, neurotropism, and immune dysregulation lead to impaired organ function, increased morbidity and mortality, compromised work productivity, and a decline in overall health and quality of life. The uncontrolled spread of the virus is accelerating its evolution, outpacing the effectiveness of vaccines, treatments, and immune system adaptation. This preventable disease and others magnified by immune dysfunction are driving staff shortages, supply chain disruptions, and overwhelming healthcare systems. Despite the

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<sup>3</sup> TIN, Alexander. "A Quarter of Americans Distrust CDC Recommendations, Survey Finds", March 7, 2023, CBS News <https://www.cbsnews.com/news/cdc-recommendations-survey-trust/> (consulted on April 1, 2024)

dire nature of the current conditions, knowledge and means are present to solve these problems.<sup>4</sup>

Isolation guidance has long been a key component of infection prevention and control, and remains critical in stopping the spread of infectious diseases. Scientists worldwide have shifted their focus to studying COVID's characteristics, including its symptomatic, incubation and infectious periods, in order to develop measures that can reduce the risk of harm to all individuals, especially those who are vulnerable. The establishment of current infection prevention standards will have a significant impact on the health and well-being of all Americans, as well as their ability to work and go to school without fear of infection. This is particularly important for vulnerable individuals, disabled Americans, and family members of these groups. In view of the need for the use of sound scientific information to inform the public and public health guidance the process of communicating information to the public should follow the legal requirements that are placed upon them to ensure risks are well evaluated and the quality of communication is high.

As will be shown herein, the CDC has failed to meet its obligations under different federal statutes and provisions by implementing the Violating CDC Guidelines.

As such, the Complainant respectfully requests the IG to compel the CDC under their watch to follow the OMB guidelines when the CDC, as a federal agency, operates.

**SUMMARY:**

The CDC has violated the following provisions through their adoption of the Violating CDC Guidelines:

- by failing to disclose the names of the peer reviewers: Section II of the “Final Information Quality Bulletin for Peer Review” (hereinafter the “**Peer Review Quality Bulletin**”), defining further responsibilities of agencies related to the *Information Quality Act*, 70 FR 2664, pages 2664-2677 (per the memorandum M-19-15 of April 19, 2019 of the OMB, entitled “Memorandum for the Heads of Executive Departments and Agencies”);
- Section III of the Peer Review Quality Bulletin by:
  - o omitting to disclose the identities of the peer reviewers of the Violating CDC Guidelines;

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<sup>4</sup> Špela Šalamon, MD, PhD Andrew Ewing, PhD Greta Fox Stephane Bilodeau, PhD Carlos Gershenson, PhD Matti TJ Heino Yaneer Bar-Yam, PhD SARS-CoV-2 and COVID-19: From Crisis to Solution. WHN Science Communications 2024; 5 (1): 1-1. <https://doi.org/10.59454/whn-2401-334>

- failing to provide the opportunity for public participation (Paragraph III(5)); and
- neglecting to generate a peer review report (Paragraph III(6));
- as required under the HHS Information Quality Guidelines (hereinafter “**your HHS Guidelines**”) (developed in accordance with provisions of P.L. 106-554 and Office of Management and Budget (herein referred to as “**OMB**”), implementing the 1996 amendments to the *Safe Drinking Water Act* (42 U.S.C. 300g-1(b)(3)(A) & (B) ), and more particularly paragraphs 42 U.S.C. 300 g-1(b)(3)(B)(iii), (iv), (v)), by failing to provide, at least with respect to long COVID:
  - each appropriate upper-bound or lower-bound estimate of risk regarding long COVID;
  - each significant uncertainty identified in the process of the assessment of public health effects and studies that would assist in resolving the uncertainty; and
  - peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support the estimate of public health effects; and
- Section IV of the *Bulletin for Agency Good Guidance Practices*, as found in the Federal Register, Vol. 72, No. 16, of January 25, 2007, pages 3439 and following (hereinafter the “**Bulletin for Guidance Practices**”) by:
  - failing to publish a notice to the Federal Register that a draft version of the Violating CDC Guidelines is available;
  - failing to make the draft document of the Violating CDC Guidelines available to the public;
  - failing to invite public comment on the draft of the Violating CDC Guidelines; and
  - never preparing and posting on the CDC’s website a response-to-comments resulting from the invitation for public comment pertaining to the Violating CDC Guidelines.

**DETAILED ANALYSIS:**

**1. The CDC is in violation of Section II of the Peer Review Quality Bulletin by failing to divulge the identity of the peer reviewers of the Violating CDC Guidelines:**

First, the Violating CDC Guidelines qualify as “influential scientific information” per Section II of the Peer Review Quality Bulletin. The Violating CDC Guidelines contains “scientific information”, as its content relates to “factual inputs, data, models, analyses, technical information, or scientific assessments related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences” per the definition section of the Peer Review Quality Bulletin. Additionally, it is apparent that the Violating CDC Guidelines contain data, models, analyses, technical information, scientific information relating to management of COVID-19 in the United States, and as such, the Violating CDC Guidelines relate to public health and life sciences, meeting the definition of “influential scientific information” per Section II of the Peer Review Quality Bulletin. The Violating CDC Guidelines do not relate to an opinion, as they have not been identified as such by the CDC, as would be required under the definition section of the Peer Review Quality Bulletin.

Moreover, the Violating CDC Guidelines are considered “influential scientific information” per the definition section of the Peer Review Quality Bulletin. The CDC agency could reasonably determine that the Violating CDC Guidelines will have or does have a clear and substantial impact on important public policies or private sector decisions. In fact, when the CDC Guidelines had last, in December 2021, made the decision to update its COVID isolation guidelines to change isolation from 10 days to 5 days, this decision was at least in part influenced by the pressure exerted by Delta Airlines on the CDC, demonstrating that the CDC’s COVID-19 guidelines do have an influence on private sector decisions<sup>5</sup>. The Letter written by the CEO of Delta Airlines to the CDC is appended herewith as Exhibit “A”.

Furthermore, the Violating CDC Guidelines influence domestic public and private sector policies as can be inferred from similar changes in the California’s Department of Public Health January 9, 2024 update to the COVID-19 Isolation Guidance that influenced worker regulations and therefore workplace policies, as well as school policies, among others. Complainant notes that the concept of a guidance is often juxtaposed against a regulation, but it is apparent from the implementation of the CDPH Guidance that it was implemented through its impact on Cal/OSHA also as a regulation for workers and as a policy of schools. The CDPH Guidance is similar to the new guidance of the CDC in reducing the recommended duration of isolation while infected so that individuals can return to work, school and other public activities after only 24 hours and while infected and infectious. Equally, on the same date of January 9, 2024, the CDPH Guidance was named and incorporated into a regulation by Cal/OSHA, a division of the State of California Department of Public Relations. This Cal/OSHA regulation explicitly states that it

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<sup>5</sup> SHIVARAM, Deepa. « Delta’s CEO asked the CDC for a 5-day isolation. Some flight attendants feel at risk”, December 29, 2021, *NPR*, <https://www.npr.org/2021/12/29/1068731487/delta-ceo-asks-cdc-to-cut-quarantine> (consulted on April 1, 2024)

applies to most workers in California who are not covered by the Aerosol Transmissible Diseases standard.

The CDPH Guidance, through its influence on the regulation of Cal/OSHA and through its influence on school and other local policies, determines when individuals can return to work, school, or other public settings, which in turn affects the spread of infectious diseases within communities. This information is relied upon by employers, schools, and individuals themselves to make decisions about when it is safe to resume normal activities.

Moreover, the impact of isolation guidance on corporate policies regarding sick leave is significant, as it influences how employers handle employee absences due to illness. If the guidance is inaccurate or unclear, it could lead to employees returning to work too soon and potentially spreading illness in the workplace. On the other hand, if the guidance is overly cautious, it could result in unnecessary absences and productivity losses for companies. Therefore, the accuracy and clarity of isolation guidance directly impact corporate policies and practices related to sick leave.

The influence of the isolation guidance in California and more generally was directly reflected in concerns raised by Secretary of HHS Becerra. Secretary Becerra has expressed concern about the deviation from the CDC isolation guidance and opposition to the California guidelines. As reported in an article entitled "Health Secretary Becerra defends CDC's COVID isolation guidance that California shortened,"<sup>6</sup> Secretary Becerra emphasized the importance of adhering to the CDC guidance and stated that those who downplay the COVID threat are "playing with fire." This further highlights the importance and influence of CDC's guidance on the public and other state-enacted policies.

Therefore, the accuracy and reliability of this isolation guidance are crucial for policies and actions adopted, as well as maintaining public health and safety. Overall, considering the far-reaching consequences of isolation guidance on public health, corporate policies, and individual behavior, it is crucial to ensure that this information meets the standards of quality, objectivity, utility, and integrity, for instance as required by the Information Quality Act and the OMB Guidelines adopted thereunder. Ensuring that isolation guidance is accurate, reliable, and timely is essential for protecting public health and safety and for informing sound decision-making at both the individual and organizational levels.

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<sup>6</sup> The Mercury News, "Health Secretary Becerra defends CDC's COVID isolation guidance that California shortened", *The Mercury News*, January 29, 2024, <https://www.mercurynews.com/2024/01/29/health-secretary-becerra-defends-cdcs-covid-isolation-guidance-that-california-shortened/>, consulted on April 24, 2024.

Section II of the Peer Review Quality Bulletin, applying to “Influential Scientific Information”, requires peer review of the disseminated influential scientific information.

Moreover, Section II further requires “for agency-sponsored peer review conducted under Sections II and III, this Bulletin strikes a compromise by **requiring disclosure of the identity of the reviewers**, but not public attribution of specific comments to specific reviewers.” (Emphasis ours.) As such, this portion of Section II uses the term “requires”, which means that this requirement for an agency to disclose the identity of the peer reviewers is a must, as is the case for the CDC. Furthermore, it is of note that the agency must also disclose to the public the comments that have followed the peer review process, even though these comments do not have to be attributed to specific peer reviews.

With regard to the Violating CDC Guidelines, it is unclear if a peer review of the Violating CDC Guidelines had been conducted by the CDC prior to the dissemination of its Violating CDC Guidelines. No mention is made on the CDC’s website or on the Federal Register. Complainant would respectfully invite the IG to verify that the CDC had in fact performed peer review of its Violating CDC Guidelines and met its obligations under Section II of the Peer Review Quality Bulletin. However, regardless of if the CDC had performed peer review, the CDC has failed to meet the following peer review obligations tied to its Violating CDC Guidelines under Section II of the Peer Review Quality Bulletin:

- disclose the identities of the peer reviewers of the Violating CDC Guidelines; and
- publish the comments following the peer review by the peer reviewers of the Violating CDC Guidelines.

Complainant further stresses that, per the Peer Review Quality Bulletin, agencies should strive to ensure that their peer review practices are characterized by scientific integrity. “Scientific integrity” is defined in the Peer Review Quality Bulletin as including “the rationale and supportability of the panel's findings”. First, here, a peer review does not appear to have been conducted for the Violating CDC Guidelines. As such, it is no surprise that the Violating CDC Guidelines fail to meet this definition of scientific integrity. Namely, the Violating CDC Guidelines use the symptom of “fever” as a tool to quantify transmissibility of an individual contaminated with SARS-CoV-2. The individual, under the Violating CDC Guidelines, is permitted to circulate amongst the public 24 hours after the subsiding of the fever. However, a peer review process would rightfully challenge, in order to meet the definition of “scientific integrity”, that the scientific literature does not support that fever is a proper indicator of COVID 19 infectiousness, as illustrated by the examples provided in Exhibit “B”, appended herewith. In fact, Complainant



would request that the CDC, for full transparency, identify the basis of their conclusion that the presence or absence of fever can be tied to SARS-CoV-2 transmissibility.

Therefore, Complainant respectfully requests that the IG require the CDC to assemble a peer review panel meeting the necessary requirements under the Peer Review Quality Bulletin, namely by constituting a panel with experts having a background in COVID-19 transmission and risk assessment, to produce COVID-19 isolation guidelines that follow the necessary peer review process. Relevant expertise for the peer review of COVID-19 is detailed in Exhibit “C”, appended herewith.

Complainant notes that these peer reviewers cannot be employees of the CDC, the public agency performing the peer review, due to a lack of the necessary independence as required under the Peer Review Quality Bulletin.

**2. The CDC is in violation of Section III of the Peer Review Quality Bulletin by failing to disclose the identities of the peer reviewers, failing to provide the opportunity for public participation and neglecting to generate a peer review report:**

The IG will recognize that the Violating CDC Guidelines, relating to guiding human behavior following exposure to a virus that is the cause of a global pandemic and that remains prominently in circulation throughout the American population and the world falls under the definition of “highly influential scientific assessments” per Section III of the Peer Review Quality Bulletin. The IG will appreciate that COVID-19, and resultingly the Violating CDC Guidelines which dictate the behavior of the American population when faced with this pandemic-causing virus, could have a potential impact of more than \$500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest.

With respect to the Violating CDC Guidelines being precedent-setting, this is the first time that the human population is facing a widely circulating SARS virus, and the first time that the CDC has reduced so drastically its isolation policy with respect to this virus.

With respect to controversy tied with the Violating CDC Guidelines, the IG is invited to observe the numerous groups and scientists who have voiced their opposition to the Violating CDC Guidelines.

For instance, the CDC’s release of its Isolation guidance led to two highly cited experts to comment strongly on the guidance.

Dr. Eric Topol, Executive VP, Scripps Research, Professor, Molecular Medicine, who has published over 1300 peer-reviewed articles, with more than 300,000 citations, elected to the

National Academy of Medicine, and is one of the top 10 most cited researchers in medicine, stated on March 2, in response to the Violating CDC Guidelines (see <https://twitter.com/EricTopol/status/1763981007773155413>):

“The new CDC Covid "no isolation" guideline promotes people shedding virus to infect others” Citing Puhach, O., Meyer, B. & Eckerle, I. SARS-CoV-2 viral load and shedding kinetics. *Nat Rev Microbiol* 21, 147–161 (2023). <https://doi.org/10.1038/s41579-022-00822-w>

And continuing: “Most people will still be infectious, as assessed from rapid antigen tests (and the new recommendation ignores the use of rapid tests)” Citing the reference:

Marquez C, Kerkhoff AD, Schrom J, et al. COVID-19 Symptoms and Duration of Rapid Antigen Test Positivity at a Community Testing and Surveillance Site During Pre-Delta, Delta, and Omicron BA.1 Periods. *JAMA Netw Open*. 2022;5(10):e2235844. doi:10.1001/jamanetworkopen.2022.35844

And continuing: "Rapid antigen test positivity remained high 5 days after symptom onset, supporting guidelines requiring a negative test to inform the length of the isolation period."

On February 29, 2024, Dr. Eric Feigl-Ding, Epidemiologist and Public Health Economist with over 130,000 citations, sixth most cited in public health economics, and fifth in public health policy, chair of the public health department at the New England Complex Systems Institute, wrote (see <https://twitter.com/DrEricDing/status/1763402220668658163?s=20>): “I am devastated—I saw with my eyes what’s coming from CDC tomorrow. My sources told me on what their rationale is based. And based on what I know (epidemiologist for 20 years)—it is crafted on thin flimsy data. What the CDC is doing is relaxing the guidelines of isolation to effectively ‘you can go out and have fun as long as you’re improving since yesterday’. Yes it’s ridiculous. Others have written on it. And it is totally public health abdication.”

These represent only a few of the comments of highly regarded scientific experts, a larger compilation of comments is listed in Exhibit “D”, appended herewith.

Moreover, the Union “National Nurses United”, composed of more than 225,000 nurses, condemns the CDC’s decision to shorten the five-day isolation guidance for COVID-19<sup>7</sup>.

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<sup>7</sup> National Nurses United, “NNU condemns CDC’s decision to shorten the five-day isolation guidance for Covid-19”, March 6, 2024, [https://www.nationalnursesunited.org/press/nnu-condemns-cdc-decision-to-shorten-isolation-guidance#:~:text=Press%20Release-,NNU%20condemns%20CDC's%20decision%20to%20shorten%20the%20five,isolation%20guidance%20for%20Covid%2D19&text=National%20Nurses%20United%20\(NNU\)%20condemns,its%20isolation%20guidance%20for%20Covid.](https://www.nationalnursesunited.org/press/nnu-condemns-cdc-decision-to-shorten-isolation-guidance#:~:text=Press%20Release-,NNU%20condemns%20CDC's%20decision%20to%20shorten%20the%20five,isolation%20guidance%20for%20Covid%2D19&text=National%20Nurses%20United%20(NNU)%20condemns,its%20isolation%20guidance%20for%20Covid.) (consulted on April 7, 2024)

A modified Delphi Consensus process performed by 494 panel members of previous CDC communications was described by a team led by Dr. Lara Jirmanus, a family physician at the Cambridge Health Alliance, a Fellow at the FXB Center for Health & Human Rights at Harvard University, and a Clinical Instructor at Harvard Medical School and colleagues in a publication entitled "Too Many Deaths, Too Many Left Behind: A People's External Review of the U.S. Centers for Disease Control and Prevention's COVID-19 Pandemic Response"<sup>8</sup>. They state "[T]heir analysis yields 3 overarching shortcomings of the Centers for Disease Control and Prevention's pandemic management: (1) Centers for Disease Control and Prevention leadership downplays the serious impacts and aerosol transmission risks of COVID-19, (2) Centers for Disease Control and Prevention leadership has aligned public guidance with commercial and political interests over scientific evidence, and (3) Centers for Disease Control and Prevention guidance focuses on individual choice rather than emphasizing prevention and equity."

The Violating CDC Guidelines satisfy the definition of "highly influential scientific assessments" under the OMB "Final Information Quality Bulletin for Peer Review" because of its health and economic impacts. It manifestly exceeds the threshold of "a potential impact of more than \$500 million in any one year on either the public or private sector" as economic assessments of the harm from long COVID exceeds \$3 Trillion<sup>9</sup>.

This assessment of the economic impacts of harm from long COVID was done by David Cutler, Otto Eckstein Professor of Applied Economics in the Department of Economics with appointments at the Kennedy School of Government and the School of Public Health and previously senior health care advisor to Barack Obama. An assessment of the overall impact of COVID of \$16 trillion dollars was evaluated by both David Cutler and Larry Summers, an economist who served as the 71st United States Secretary of the Treasury from 1999 to 2001 and as director of the National Economic Council from 2009 to 2010. He also served as president of Harvard University from 2001 to 2006, where he is the Charles W. Eliot University Professor and director of the Mossavar-Rahmani Center for Business and Government at Harvard Kennedy School.<sup>10</sup>

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<sup>8</sup> Jirmanus LZ, Valenti RM, Griest Schwartzman EA, Simon-Ortiz SA, Frey LI, Friedman SR, Fullilove MT. "Too Many Deaths, Too Many Left Behind: A People's External Review of the U.S. Centers for Disease Control and Prevention's COVID-19 Pandemic Response". *AJPM Focus*. 2024 Feb 25;3(4):100207. doi: 10.1016/j.focus.2024.100207. PMID: 38770235; PMCID: PMC11103433.

<sup>9</sup> Cutler, David M. "The costs of long COVID." *JAMA Health Forum*. Vol. 3. No. 5. American Medical Association, 2022

<sup>10</sup> Cutler DM, Summers LH. The COVID-19 Pandemic and the \$16 Trillion Virus. *JAMA*. 2020;324(15):1495–1496. doi:10.1001/jama.2020.19759

Moreover, the very nature of isolation guidance as one of the key responsibilities of HHS which has been delegated to the CDC, and scientific information that influences this guidance, is highly influential information as it can and does influence the actions and the risks of infecting population at large. The influential nature of such scientific information to influence domestic or private sector policy or other consequences is what makes it important enough for this delegation.

This is the reason that the authority is given to HHS and the CDC to impose isolation and quarantine measures in the face of infectious diseases in the *Public Health Service Act*, specifically from sections 361 and 264 of the Act. These provisions grant the HHS the authority to issue and enforce regulations aimed at preventing the introduction, spread, and transmission of communicable diseases across state lines. This authority has been delegated to the CDC <https://www.cdc.gov/quarantine/aboutlawsregulationsquarantineisolation.html>

Moreover, as HHS and CDC have federal responsibility for isolation and quarantine guidance, and this is fundamental to public health, the removal of isolation is precedent setting. The dropping of isolation guidance for a widely transmitting infectious disease is unprecedented. This action also has significant interagency interest as manifest in the Cal/OSHA regulation as it influences worker and workplace safety, and school safety, a fact well established both historically and not altered to the present.

Moreover, in support of the IG determining that the Violating CDC Guidelines would qualify as a highly influential scientific assessment, the Complainant asks if it would be in the best interest for a federal agency, such as the CDC, whose credibility amongst the U.S. population is dropping as explained above, to first announce the opportunity for public comment and an adoption in May for this change in guidelines, but then proceeds with adopting the change in isolation policy at least a month prior to its announced date and without providing the promised opportunity for public comment.

We respectfully request the IG to recognize that this behavior by the CDC fails to comply with

1. both the spirit and the goals promoted by the Peer Review Quality Bulletin of “process integrity” (defined as “transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement”) and
2. “scientific integrity” (defined as “expertise and balance of the panel members; the identification of the scientific issues and clarity of the charge to the panel; the quality, focus and depth of the discussion of the issues by the panel; the rationale and supportability of the panel's findings; and the accuracy and clarity of the panel report”).

The IG must prevent such behavior by the CDC, which fails to promote transparency and openness, per the spirit of the Peer Review Quality Bulletin, from setting a precedent for the agencies under the supervision of the HHS.

Since the Violating CDC Guidelines constitute a “highly influential scientific assessment”, the CDC has failed to meet its obligations set under Section III of the Peer Review Quality Bulletin, namely they failed to:

- disclose the identities of the peer reviewers;
- provide the opportunity for public participation (Paragraph III(5)) despite making what appears to be a material false representation that public comment would be considered prior to the adoption of the Violating CDC Guidelines, per the CDC’s February 13, 2024 announcement, as referred to herein; and
- generate a peer review report (Paragraph III(6)).

Again, as with Section II of the Peer Review Quality Bulletin, the Complainant first questions if the CDC ever did conduct peer review of the Violating CDC Guidelines in the first place, as required under the Peer Review Quality Bulletin, and respectfully invites the IG to investigate same.

**3. The CDC has violated your HHS Guidelines by failing to disclose in its Violating CDC Guidelines, at least with respect to Long COVID, each appropriate upper-bound or lower-bound estimate of risk regarding long COVID, each significant uncertainty identified in the process of the assessment of public health effects, and peer-reviewed studies known to the Administrator that support, are directly relevant to, or fail to support the estimate of public health effects:**

At Section VII of your HHS Guidelines, “influential scientific, financial or statistical information” is defined by the HHS as disseminated information that results from or is used in support of agency actions that are expected to have an annual effect on the economy of \$100 million or more ***or*** will adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local or tribal governments or communities.” (Emphasis ours.)

We note here that, in accordance with this definition, the word “or” is used. This means that disseminated information that adversely affects “public health”, on its own, would be considered “influential information” under your HHS Guidelines.

For instance, your HHS Guidelines go on, in Section VII, to provide two examples of information which are considered, by the FDA, to be “influential information” :

- Quality Mammography Standards; and
- Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice.

As such, guidelines that would affect isolation of Americans that have been infected with COVID-19, a virus that has caused and continues to cause a pandemic, and therefore impact transmission of the virus amongst the population, would have at least the same impact on public health as “Quality Mammography Standards” and “Hazard Analysis and Critical Control Point (HACCP); Procedures for the Safe and Sanitary Processing and Importing of Juice”. It would be apparent that guidelines which direct a population’s behavior when faced with a pandemic-causing virus falls under the definition of “disseminated information that adversely affects “public health”, and is therefore “influential information”.

Furthermore, the economic assessments regarding the impacts of COVID-19, particularly long COVID, exceed the financial threshold for highly influential information set by OMB guidelines by a factor of 10,000, i.e. if the impact were only 0.1% of the estimated actual impacts it would still exceed that legally established threshold. This is like comparing a football field to the width of a paperclip. The impact on workers through workplace sick leave and to children through requirements by school policies to return to classes while infectious impacts their health choices as well as the risks for others in workplaces and schools. The authority for enforcing isolation and quarantine measures is granted to HHS and the CDC under sections 361 and 264 of the *Public Health Service Act* as central to public health. The removal of isolation guidance for a widely transmitting infectious disease like COVID-19 is unprecedented and has significant implications for public health, worker safety, and school safety.

Therefore, Complainant respectfully submits that the Violating CDC Guidelines are considered influential information per your HHS Guidelines.

As such, and per your HHS Guidelines, the Violating CDC Guidelines has to comport with paragraphs 42 U.S.C. 300 g-1(b)(3)(B)(iii), (iv) and (v) of the 1996 amendments to the *Safe Drinking Water Act* (42 U.S.C. 300g-1(b)(3)(A) & (B) ) by adopting or adapting same. It is of note that the OMB Guidelines which are the basis for your HHS Guidelines, state the following: “With regard to analysis of risks to human health, safety, and the environment maintained or disseminated by the agencies, agencies **shall** either adopt or adapt the quality principles applied by Congress to risk information used and disseminated pursuant to the *Safe Drinking Water Act Amendments of 1996* (SDWA) (42 U.S.C. 300g-1(b)(3)(A) and (B))”(hereinafter the

“SDWA”). Complainant notes here that the language “shall” is used here with respect to “adopting or adapting” these standards. This requirement is therefore a “must” for agencies.

The HHS has permitted the CDC to modify its requirements under the SDWA depending on if the assessment is “qualitative” or “quantitative”. First, Complainant raises the concern that this distinction is insufficient to meet the requirements under the OMB Guidelines listed above, as the OMB Guidelines do not provide such scenarios where an agency may adapt its requirements by implementing a laxer standard.

Second, the Complainant submits that, notwithstanding if the CDC’s adaptation of the SDWA requirements is sufficient to meet its duties under the OMB Guidelines, the CDC has nonetheless failed to meet the lower standard that it has set for itself for qualitative assessments by disseminating its Violating CDC Guidelines. The CDC has set the following requirements for itself under the SDWA for qualitative assessments (as reproduced in your HHS Guidelines):

The agency will use

the **best** available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer-reviewed science and supporting studies when available

data collected by accepted methods (if reliability of the method and the nature of the decision justify use of the data)

In the dissemination of public information about risks, the agency will ensure that the presentation of information about risk effects is **comprehensive, informative, and understandable**.

(Emphasis ours.)

Complainant notes her that the CDC has chosen to use the word “best” here when qualifying the “available science”.

If the Complainant were to entertain that the Violating CDC Guidelines are considered a “qualitative assessment”, which is not the Complainant’s position, the CDC has nonetheless failed to meet its own standard under the SDWA through the adoption of the Violating CDC Guidelines, by failing to use “the best available science” and by failing to “present information about risk effects” in a “comprehensive, informative, and understandable” manner.

This failure is best exemplified in the statements made by the CDC in the Violating CDC Guidelines with respect to Long Covid, one of the conclusions on which rests the CDC’s decision to adapt the isolation guidelines with respect to COVID-19.

In the Violating CDC Guidelines, the decision to reduce the isolation period following a COVID-19 infection is at least in part predicated on a drop in the danger presented by the virus to the human population. However, one of the growing concerns surrounding COVID-19 infection, further crystallized in the scientific literature as studies continue to confirm the virus' long-term impacts on the health of the American population, is that associated with long term health effects to the American population following a COVID infection. One of these manifestations of long-term health effects is coined Long Covid. In the words of the CDC, CDC admits that the risk posed by long COVID is still ill-defined, by stating "CDC and partners are working to understand more about who experiences Long COVID and why, including whether groups disproportionately impacted by COVID-19 are at higher risk"<sup>11</sup>. As such, the CDC admits that it is currently uncertain regarding the extent of the risk of long COVID. As such, any entity attempting to qualify the risk of an ill-defined threat to a population cannot do so, as the parameters of such a threat remain ill-defined. Moreover, the CDC goes on to state "Long COVID can include a wide range of ongoing health problems; these conditions can last weeks, months, or years", and "[p]eople can be reinfected with SARS-CoV-2, the virus that causes COVID-19, multiple times. Each time a person is infected or reinfected with SARS-CoV-2, they have a risk of developing Long COVID"<sup>12</sup>. As such, the risk of Long COVID appears to be tied to infection and re-infection (as most Americans are currently experiencing re-infection at this stage). As stated by the CDC, "The best way to prevent Long COVID is to protect yourself and others from becoming infected."<sup>13</sup>

In the Violating CDC Guidelines, the CDC bases its decision to reduce the isolation period for COVID-19, on the following (cited from the Violating CDC Guidelines):

- **Due to the effectiveness of protective tools and high degree of population immunity, there are now fewer hospitalizations and deaths due to COVID-19.** Weekly hospital admissions for COVID-19 have decreased by more than 75% and deaths by more than 90% compared to January 2022, the peak of the initial Omicron wave. Complications like multisystem inflammatory syndrome in children (MIS-C) are now also less common, and prevalence of Long COVID also appears to be decreasing. These reductions in disease severity and death have persisted through a full respiratory virus season following the expiration of the federal Public Health Emergency for COVID-19 and its associated special measures on May 11, 2023.

As such, the conclusion that the CDC has reached in the March 1, 2024 Violating CDC Guidelines, is that "the prevalence of Long Covid also appears to be decreasing", thereby supporting a drop in the threat of COVID-19 infection for the American population. However, in

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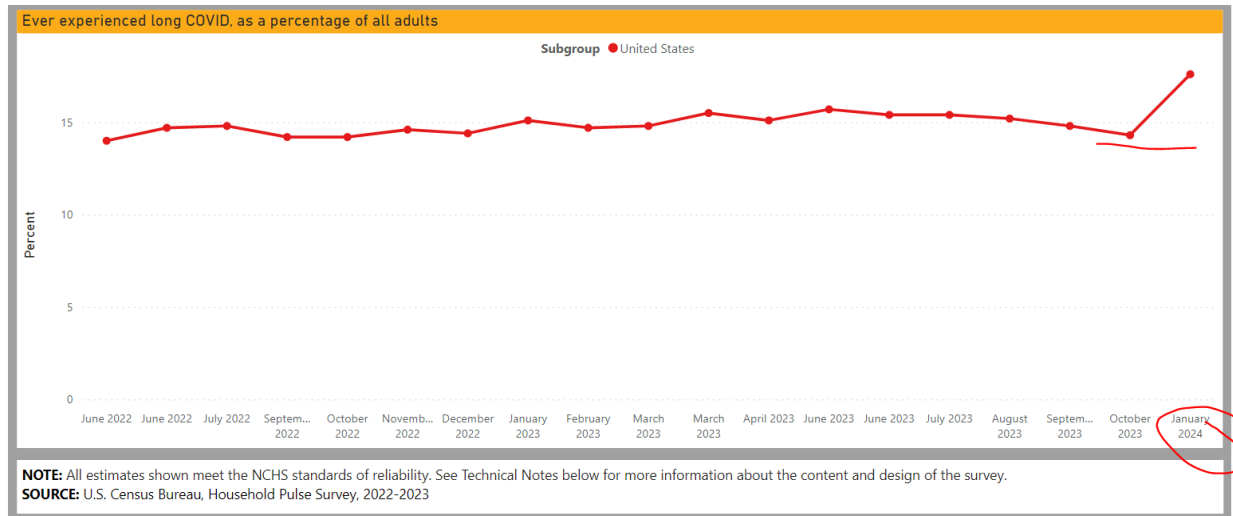
<sup>11</sup> CDC, Long Covid, Centers for Disease Control and Prevention, Updated on March 14, 2024, <https://www.cdc.gov/coronavirus/2019-ncov/long-term-effects/index.html> (consulted on April 1, 2024)

<sup>12</sup> *Ibid.*

<sup>13</sup> *Ibid.*



the CDC's own Long Covid report, published only three days after the Violating CDC Guidelines, a sharp rise in Long Covid amongst the American population is observed<sup>14</sup>:



It would be surprising to conclude that the CDC did not benefit from the March 4, 2024 Long COVID data when publishing its conclusions regarding Long COVID in its March 1, 2024 Violating CDC Guidelines, published only a mere 3 days prior. In fact, the CDC does not present any support in its Violating CDC Guidelines showing that the “prevalence of Long Covid appears to be decreasing”. Its own data supports a contrary conclusion.

As such, because the CDC's conclusions presented in the Violating CDC Guidelines appear to contradict its own most recent data, it cannot be said that the CDC has met its requirement under the SDWA, as published in your HHS Guidelines, to use “the **best** available science and supporting studies” because the report it has issued does not address or account for its own data. CDC cannot scientifically maintain that the “prevalence of Long COVID also appears to be decreasing” when this statement contradicts its own data.

Conclusions on risk assessment that contradict an agency's own data is not” **comprehensive, informative, and understandable**”, in the words of the CDC's self-establishment requirements under the SDWA for qualitative assessments.

As such, Complainant respectfully submits that the Violating CDC Guidelines fall short of the requirements under the SDWA and your HHS Guidelines by failing to use the best available science (unless the CDC considers that its own science is not “the best available science”, and

<sup>14</sup> Household Pulse Survey on Long COVID, CDC, Centers for Disease Control and Prevention, updated on March 4, 2024 (<https://www.cdc.gov/nchs/covid19/pulse/long-covid.htm>, consulted on March 17, 2024

if so, they should clarify this point in their guidance) and to present its information in a manner that is “**comprehensive, informative, and understandable**” by not contradicting its own findings. It is of note that this alarming increasing in Long COVID, and the contrasting conclusions reached by the CDC in its Violating CDC Guidelines, did not go unnoticed by the media<sup>15</sup>. Such an egregious departure from its obligations under the SDWA seriously weakens the CDC’s credibility with the American population.

Moreover, the implications of the long COVID condition can be found in an official review by the National Academies of Science, Engineering and Medicine, which is a referent organization for peer review according to the OMB "Final Information Quality Bulletin for Peer Review" which states "Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed," in a recently released a document on the "Long-Term Health Effects of COVID-19: Disability and Function Following SARS-CoV-2 Infection," whose framing states "Since the onset of the coronavirus disease 2019 (COVID-19) pandemic in early 2020, many individuals infected with the virus that causes COVID-19, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), have continued to experience lingering symptoms for months or even years following infection. Some symptoms can affect a person ability to work or attend school for an extended period of time."<sup>16</sup>

Finally, Complainant submits that the Violating CDC Guidelines also constitutes a quantitative risk assessment, similar to assessing the risk of “drinking water”, as the Violating CDC Guidelines instead address the risk posed by inhaling the air for the American population. Complainant notes that the World Health Organization has recently recognized the air-spreading nature of COVID-19 and has produced a manual to quantify, and not simply qualify, the risk of SARS-CoV-2 airborne transmission.<sup>17</sup> Therefore, just like how the risk of pathogens or harmful compounds found in drinking water can be quantified, so can the risk of SARS-CoV-2 airborne transmission be quantified in residential, public and healthcare settings. In the words of the WHO, this risk quantification “is **essential** to inform non-pharmaceutical risk reduction

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<sup>15</sup> SCHREIBER, Melody. « ‘Alarming’ Rise in Americans With Long Covid Symptoms”, *The Guardian*, March 15, 2024, <https://www.theguardian.com/world/2024/mar/15/long-covid-symptoms-cdc#:~:text=A%20total%20of%2017.6%25%20of,such%20as%20myocarditis%2C%20studies%20show.> (consulted on April 1, 2024)

<sup>16</sup> National Academies of Sciences, Engineering, and Medicine. 2024. Long-Term Health Effects of COVID-19: Disability and Function Following SARS-CoV-2 Infection. Washington, DC: *The National Academies Press*. <https://doi.org/10.17226/27756>

<sup>17</sup> World Health Organization, “Indoor airborne risk assessment in the context of SARS-CoV-2”, *World Health Organization* (2024), <https://iris.who.int/bitstream/handle/10665/376346/9789240090576-eng.pdf?sequence=1&isAllowed=y> (consulted on April 7, 2024)

measures, such as increasing ventilation, air cleaning and disinfection, source control interventions, and controlling the occupancy, as well as to communicate the risk and enable informed decisions by the occupants<sup>18</sup>. Moreover, in your HHS Guidelines, examples are provided regarding what is considered a “quantitative risk assessment”, which includes exposure to physical hazards such as toxic substances and to antibiotic resistance bacteria. Here, with regard to the Violating CDC Guidelines, the CDC is tasked to provide a risk assessment following exposure to another physical hazard, that of a virus, and establishing safety protocols to follow subsequent to that exposure to the physical hazard. As such, Complainant respectfully requests that the IG confirm that a set of guidelines for managing SARS-CoV-2 transmission similarly requires a quantitative risk assessment, as performed by the WHO.

Additionally, per the portion of your HHS Guidelines relating to the CDC, relating to the risk assessment practices adopted by the CDC, it states “[I]n each of the areas we regulate, we apply risk assessment practices to the specific task that are widely accepted among relevant domestic and *international public health agencies*” (Emphasis ours.). With respect to SARS-CoV-2 risk assessment, the World Health Organization has adopted a quantitative risk assessment<sup>19</sup>. The WHO is the leading international public health agency for preventing disease. As stated in the report by the WHO for quantifying SARS-CoV-2 airborne transmission, “[Q]uantifying the probability of SARS-CoV-2 infection through the inhalation mechanism is essential to inform the development of risk reduction measures such as indoor risk-based ventilation standards.” This manual produced by the WHO provides “a new, standardized, and validated model for quantifying the risk of airborne transmission of SARS-CoV-2 in indoor settings.”

As such, under the very standard set by the CDC in your HHS Guidelines, as the WHO has adopted a quantitative risk assessment for SARS-CoV-2 airborne transmission, so should the CDC.

As a quantitative assessment, per the SDWA and your HHS Guidelines, the CDC failed to meet the following requirements by disseminating the HHS Guidelines (our comments are in brackets and in **bold** in the text below, reproduced from your HHS Guidelines):

The agency will use

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<sup>18</sup> *Ibid.*

<sup>19</sup> *Ibid.*

the best available science and supporting studies conducted in accordance with sound and objective scientific practices, including peer-reviewed science and supporting studies when available. [***as explained above, the CDC failed to address its most recent Long Covid data in its Violating CDC Guidelines***]

data collected by accepted methods (if reliability of the method and the nature of the decision justifies use of the data).

In the dissemination of public information about health risks, the agency shall ensure that the presentation of information is comprehensive, informative, and understandable, within the context of its intended purpose. [***as submitted above, the CDC's conclusions presented in its Violating CDC Guidelines contradict its own findings on Long Covid, thereby not resulting in information that is comprehensive, informative and understandable***]

In a document made available to the public, the agency shall specify, to the extent practicable-

Each population addressed by any estimate of applicable effects;

The expected or central estimate of risk for the specific populations affected;

Each appropriate upper-bound and/or lower-bound risk estimates; [***the lower-bound and upper-bound risk posed by Long COVID is not sufficiently addressed in the Violating CDC Guidelines***]

Data gaps and other significant uncertainties identified in the process of the risk assessment and the studies that would assist in reducing the uncertainties [syc] [***the CDC does not include in its Violating CDC Guidelines the unknowns regarding Long COVID and COVID infection that it has expressed on other pages of its website, as cited above***]; and

Additional studies not used in the risk assessment that support or fail to support the findings of the assessment and the rationale of why they were not used. [***the CDC does not cite studies, including its own report and data, in its Violating CDC Guidelines, that contradict its conclusions regarding the severity and prevalence of Long Covid***]

At least for the reasons provided above, the CDC has not met its obligations under your HHS Guidelines by disseminating its Violating CDC in its current form.

**4. The CDC is in violation of the Bulletin for Guidance Practices by disseminating its Violating CDC Guidelines and failing to publish a notice to the Federal Register that a draft version of the Violating CDC Guidelines are available, not making the draft document of the Violating CDC Guidelines available to the public, failing to invite public comment on the draft of the Violating CDC Guidelines, and never preparing and posting on the CDC’s website a response-to-comments resulting from the invitation for public comment pertaining to the Violating CDC Guidelines:**

First, in accordance with the definition section of the Bulletin for Guidance Practices, the Violating CDC Guidelines qualify as an *“economically significant guidance document” as the Violating CDC Guidelines may reasonably be anticipated to lead to an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy or a sector of the economy”*.

As stated previously, the economic assessments regarding the impacts of COVID-19, particularly long COVID, exceed the financial threshold for highly influential information set by OMB guidelines by a factor of 10,000, i.e. if the impact were only 0.1% of the estimated actual impacts it would still exceed that legally established threshold. This is like comparing a football field to the width of a paperclip. Complainant notes that there is a level of absurdity in not concluding that isolation guidelines that relate to a virus which is the cause of an ongoing pandemic, based on the WHO’s assessment of the COVID-19 pandemic, and that has resulted in the death of more than one million Americans, would not be considered an “economically significant guidance document”.

Moreover, as CDC’s change in isolation policy for COVID-19 presented in the Violating CDC Guidelines stems from their understanding that COVID-19 is no longer an emergency and does not present, in their view, a significant health risk to the population greater than that of other viruses, the CDC cannot benefit from the exception provided at Section V of the “Bulletin for Guidance Practices” for “emergency situations”. In fact, the CDC has been contemplating to change their policy on COVID-19 isolation since at least as early as August 2023<sup>20</sup>, thereby further illustrating that this change in guidance is not an emergency in the eyes of the CDC, the changing having taken at least 6 months, where the CDC has to act more quickly.

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<sup>20</sup> The Guardian, “CDC plans to end five-day Covid isolation guidelines – report”, February 13, 2024, *The Guardian*, <https://www.theguardian.com/world/2024/feb/13/covid-new-cdc-isolation-guidelines-symptoms> (consulted on April 1, 2024)

As the Violating CDC Guidelines meet the definition of an “economically significant guidance document”, the CDC has failed to fulfill its obligations under Section IV(1) of the Bulletin for Guidance Practices, by:

- failing to publish a notice to the Federal Register that a draft version of the Violating CDC Guidelines are available. The draft version of the Violating CDC Guidelines was in fact never published. Moreover, the CDC appears to have mislead the American population in its February 13, 2024 announcement that the Violating CDC Guidelines would be made available to the public, which turned out to be a false representation made by the CDC<sup>21</sup>;
- failing to make the draft document of the Violating CDC Guidelines available to the public: as explained above, the draft document of the Violating CDC Guidelines was never made available to the public, as misrepresented by the CDC during its February 13, 2024 announcement. Moreover, the CDC published its Violating CDC Guidelines at least one month prior to the date at which the guidelines were advertised by the CDC as being public, not allowing American economic sectors to prepare consequently<sup>22</sup>;
- failing to invite public comment on the draft of the Violating CDC Guidelines. Despite the CDC representing falsely to the American population in its February 13, 2024 statement that the Violating CDC Guidelines would be subject to public comment<sup>23</sup>, such never transpired, in violation of paragraph IV(1)(c) of the Bulletin for Guidance Practices; and
- never preparing and posting on the CDC’s website a response-to-comments resulting from the invitation for public comment pertaining to the Violating CDC Guidelines. As public comment was never provided by the CDC for its Violating CDC Guidelines, it is not surprising that the CDC also failed in meeting its obligation to prepare and post an appropriate response-to-comments.

As such, at least for the reasons provided above, and in view of the growing concern regarding the CDC’s evolving loss of credibility amongst the American population, Complainant invites the IG to recognize the CDC’s violations of Section IV of the Bulletin for Guidance Practices.

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<sup>21</sup> *Ibid.*

<sup>22</sup> *Ibid.*

<sup>23</sup> *Ibid.*

Complainant thanks the IG for reviewing the present Supplementary Brief Relating to Information Quality Act Complaint and defers to the remedies sought in the Complaint.

Respectfully submitted,

*World Health Network*

World Health Network

[relations@whn.global](mailto:relations@whn.global)

125 Mt. Auburn St #38031, Cambridge, 02238

Exhibit "A"



December 21, 2021

Rochelle P. Walensky, MD, MPH  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Road, NE  
Atlanta, GA 30333

Dear Dr. Walensky:

We are writing on behalf of Delta Air Lines to the Centers for Disease Control and Prevention (CDC) to reconsider the current guideline for 10 days of isolation in fully vaccinated individuals who experience breakthrough COVID-19 infections.

This guidance was developed in 2020 when the pandemic was in a different phase without effective vaccines and treatments. At Delta, over 90% of our workforce are fully vaccinated, and those rates are increasing daily. Our employees represent an essential workforce to enable Americans who need to travel domestically and internationally. With the rapid spread of the Omicron variant, the 10-day isolation for those who are fully vaccinated may significantly impact our workforce and operations. Similar to healthcare, police, fire, and public transportation workforces, the Omicron surge may exacerbate shortages and create significant disruptions. Further, all airline personnel are required to mask at airports and on airplanes.

Current data suggest that Omicron is 25-50% more contagious, and likely less virulent and associated with more mild disease particularly among individuals who are fully vaccinated. Further, Omicron is associated with a shorter incubation period and infectious period among the fully vaccinated.

To address the potential impact of the current isolation policy safely, we propose a 5-day isolation from symptom onset for those who experience a breakthrough infection. Individuals would be able to end isolation with an appropriate testing protocol. As part of this policy change, we would be interested to partner with CDC and collect empirical data.

We look forward to continuing our partnership with the CDC to protect the health and safety of our people, customers and communities as the pandemic evolves.

All our very best,

A handwritten signature in black ink, appearing to read 'Carlos del Rio'.

Carlos del Rio, MD  
Medical Advisor  
Delta Air Lines

A handwritten signature in black ink, appearing to read 'Henry Ting'.

Henry Ting, MD  
SVP and Chief Health Officer  
Delta Air Lines

A handwritten signature in black ink, appearing to read 'Ed Bastian'.

Ed Bastian  
Chief Executive Officer  
Delta Air Lines

Delta Air Lines, Inc., Post Office Box 20706, Atlanta, GA 30320-6001, U.S.A.



## What experts are needed for a peer review of CDC isolation guidance?

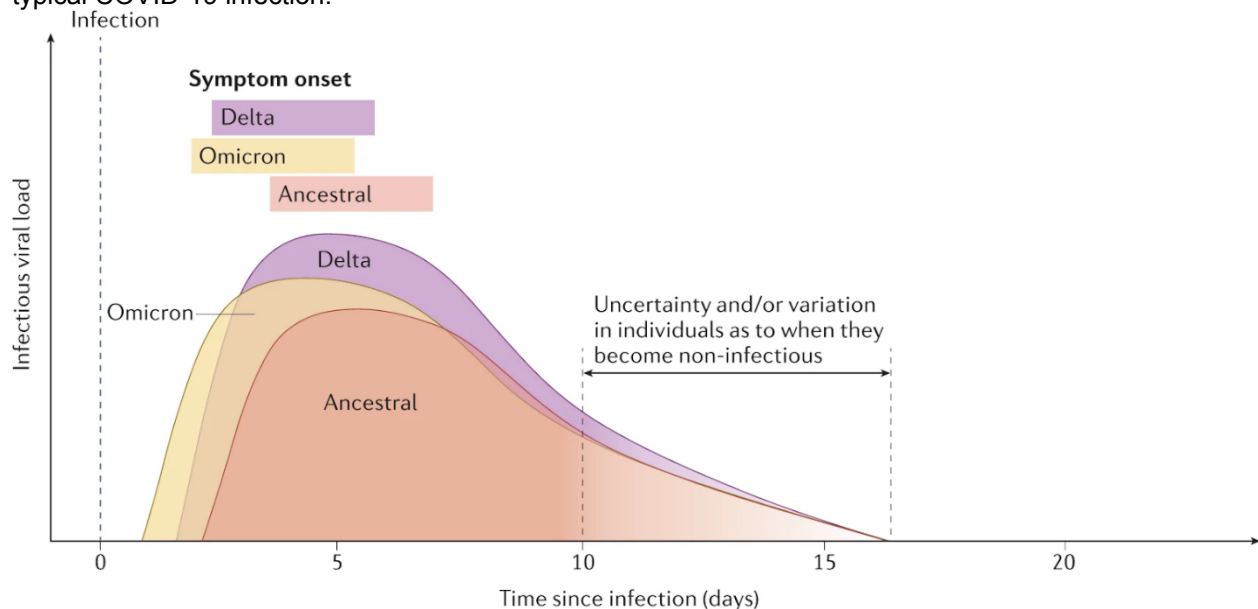
The CDC isolation guidance specifies that the isolation duration can be shortened based upon the observation of symptoms over time to as short as one day if the individual has a reduction of fever. This aspect of the CDC isolation guidance means that experts in the following domains are necessary for peer review of the CDC isolation guidance:

1. Experts in the science of infectious disease transmission measurements over time.
2. Experts in the relationship between symptoms and infectious disease transmission.

Below are key scientific questions relevant to the isolation guidance articles on these two subjects. The subsequent summary of the literature is not a comprehensive review, however it represents significant peer reviewed scientific literature, largely from the years 2022-2024. This literature is not cited or discussed relative to the CDC isolation guidance and its implications for the risk of infection. We therefore conclude that there is a significant body of literature that was not accounted for in the existing policy for isolation with COVID-19.

## Question: Does one-day isolation of infected individuals protect others from transmission?

CDC guidance released publicly on March 1 indicates that a person who has tested positive for COVID-19 may return to regular activities when symptoms are improving and fever is absent without medication or at least 24 hours. However, the scientific literature does not support this position as a method of infection prevention. A review published in Nature excellently summarizes the kinetics of a typical COVID-19 infection:



(Puhach, Meyer, and Eckerle 2023)

As the figure indicates, infectious virus, measured by culturing samples from patients, may be present for ten or more days post-symptom onset. There is no single day of isolation that would achieve prevention of infection of others. The relevant literature used to develop the portion of the figure focusing on infectious period post-symptom onset is as follows:

- [\(Puhach et al. 2022\)](#) studied “Infectious viral load in unvaccinated and vaccinated individuals infected with ancestral, Delta or Omicron SARS-CoV-2.” They measured viral load using PCR tests and infectious virus by culturing the virus on cells up to 5 days after the onset of symptoms and found infectious virus in 53.8% of fully vaccinated patients with the Delta variant 5 days after the onset of symptoms.
- [\(Takahashi et al. 2022\)](#) examined vaccinated people with the mild or asymptomatic Omicron and found that the infectious virus was shed 6–9 days after onset or diagnosis, even after symptom resolution.
- [\(Siedner et al. 2022\)](#) found infectious virus for a median of 7 days in people with Delta breakthrough infections.
- [\(Boucau et al. 2022\)](#) found infectious virus in nasal swabs of patients for a median of 8 days post-symptom onset or initial positive PCR assay in people with Omicron.

Other papers cited in this review add context for other aspects of viral shedding.

- [\(Ke et al. 2022\)](#) observed a number of patients with Alpha or ancestral COVID-19 who shed infectious virus for more than 5 days. They also showed significant individual variation in infectious virus shedding.

Since the Nature review was accepted at the end of 2022 online (published March 2023 in print), studies have continued to be published on the topic of infectious virus shedding. Some of these are as follows:

- Papers mentioned in Wu
- [\(Hakki et al. 2022\)](#) measured infectious virus and symptoms over time and found that more than half of cases shed infectious virus 5 days after symptoms began and noted that “under a crude 5-day self-isolation period from symptom onset, two-thirds of cases released into the community would still be infectious, but with reduced infectious viral shedding.”
- [\(Deyoe et al. 2023\)](#) conducted a study of household transmission and observed a median duration of culturable virus of 6 days.
- [\(Jaumdally et al. 2024\)](#) specifically examined infectious virus present in exhaled aerosols and found that half of participants emitted culture-positive aerosols for up to 9 days after symptom onset. They also found that high viral load detected via RT-PCR identified people likely to be highly infectious.
- [\(Drain et al. 2023\)](#) identified infectious virus in 80% of patients in the first 5 days after symptom onset and 41% of patients 6-10 days after symptom onset.

Other studies have used viral RNA present in the respiratory tract measured via PCR as an indication of infectiousness:

- [\(Theaux et al. 2023\)](#) found that “SARS-CoV-2 RNA was detected 10 days post SO [symptom onset] in 57% of the subjects.”
- [\(Lin et al. 2023\)](#) detected SARS-CoV-2 RNA past a certain threshold for 8-10 days.
- [\(Kissler et al. 2023\)](#) measured viral load over multiple infections and found “mean clearance time 9.2 days for a first infection and 6.3 days for a second infection.”

Further studies examined viral RNA or antigens over time as an indication of the effectiveness of different treatments ([Spivak et al. 2023](#); [Cegolon et al. 2022](#); [Pan et al. 2023](#); [Zhong et al. 2022](#)).

## Question: Does fever reduction, from one day to the next indicate a substantial reduction of infectiousness?

A systematic review article ([Dadras et al. 2022](#)) concluded that the evidence for a link between disease severity (including the presence or absence of fever) and viral load (infectiousness) is inconclusive. The

following studies, some of which were cited in Dadras et al, examined symptoms of COVID-19 and their relationship to infectiousness and have not been taken into account by the CDC's current isolation guidelines.

- (Ngoc et al. 2023) noted no definitive association between disease severity and the viral load.
- Several papers have reported no or inconclusive differences in viral load between symptomatic and asymptomatic patients (Mozgovoij et al. 2023; Glenet et al. 2021).
- (Drain et al. 2023) found that “presence of fever, respiratory symptoms, and loss of taste/smell were not statistically significantly associated with infectiousness during the first 14 days after onset of symptoms.”
- (Ke et al. 2022) found that only muscle aches, runny nose and scratchy throat were associated with participants shedding infectious virus. Current guidance indicating that individuals can exit isolation when symptoms are improving would not account for symptoms like runny nose and scratchy throat, which often persist even when an individual is feeling better.
- (Hasanoglu et al. 2021) found higher viral loads in asymptomatic patients than symptomatic patients.
- (Le Borgne et al. 2021) observed no significant difference in viral load based on disease severity or mortality.
- Viral load was not determined to relate to recovery of taste or smell dysfunction (Cho et al. 2020).
- (Jacot et al. 2020) observed viral loads to not be predictive of disease outcome.
- (Jaumdally et al. 2024) observed that “Although respiratory symptoms (cough, sore throat, shortness of breath, chest pain) were associated with infectiousness, almost one-third of aerosol culture positive individuals had no respiratory symptoms or were asymptomatic, making this metric unreliable for guiding public health interventions.”

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## Exhibit “C”

The present exhibit details suggested areas of expertise for the selection of a panel of peer reviewers tied to the peer review of future isolation guidelines for COVID-19:

### A. Mathematical Expertise:

Complainant notes that the Peer Review Quality Bulletin underlines the importance of mathematical expertise as “essential in the review of models”:

*The most important factor in selecting reviewers is expertise: ensuring that the selected reviewer has the knowledge, experience, and skills necessary to perform the review. Agencies shall ensure that, in cases where the document being reviewed spans a variety of scientific disciplines or areas of technical expertise, reviewers who represent the necessary spectrum of knowledge are chosen. For instance, expertise in applied mathematics and statistics is essential in the review of models, thereby allowing an audit of calculations and claims of significance and robustness based on the numeric data.<sup>[19]</sup> For some reviews, evaluation of biological plausibility is as important as statistical modeling. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.*

In order to accurately assess and mitigate the aggregation of risks over time for individuals and society as a whole, as well as events such as black swans and fat tail distributions, it is crucial to have experts in management of real world risk, drawn from the fields of mathematical statistics, statistical physics, and nonlinear dynamics. These experts can provide valuable insights and conduct both qualitative and quantitative risk evaluations for the probabilities and profiles of risk for different groups, including biological and occupational risk profiles. In addition to biological, medical, and epidemiological experts, these individuals play a key role in evaluating the potential harm and impact of infectious diseases such as COVID-19. Interdisciplinary collaboration between these different fields of expertise is essential in order to effectively manage and respond to complex and unpredictable events. This collaboration is also vital to provide clear information about the relationship between policies and societal risk, and individual choices and the consequences for individuals in specific events, over time and into the future.

An expert on quantitative real world risk including tail risk analysis is Nassim N. Taleb, most cited researcher in risk analysis and the third most cited in applied probability, author of *Skin In the Game*, *Antifragile*, *The Black Swan*, *Foiled by Randomness*, and *The Bed of Procrustes*, a 5-volume work on probability, risk, opacity and decision making under real world uncertainty, Distinguished Professor of Risk Engineering at the New York University Tandon School of Engineering (see <https://scholar.google.com/citations?user=64BtMdsAAAAJ&hl=en&oi=ao>)

- B. As well there is an importance of the charge to peer review, so that it must be made available to the public. In order to satisfy the charge to the agency, such a charge must, in the context of the risk of health harm, include a charge to the scientific review panel to evaluate quantitative risk, its uncertainty, including whether such a quantitative risk and uncertainty can be evaluated. Without such a charge the agency cannot be said to satisfy its requirements under the guidance as the scientific review has not evaluated

which category and information is possible to obtain from the available scientific studies, in order to satisfy its charge under the OMB guidelines.

“In general, an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s).”

As part a review, qualitative words such as “Decrease” “Increase” (and similarly “fewer” “lower” “less” “more” “some degree”) require documentation about whether the decrease or increase is a substantial change in the risk, and whether the decrease or increase is a difference that should change a policy. For example a 1% change may be scientifically verifiable within uncertainty, but such a change in risk may not be of substantial significance in view of the 99% risk remaining. Similarly a 10% risk may be significant but not change the need for mitigation of the 90% risk remaining. Similarly a 90% or even 99% risk reduction may or may not be a change in the need for mitigation due to the remaining 10% or 1% risk. Therefore, both absolute and relative risks must be characterized consistently as part of a comprehensive risk assessment. Uncertainties must be similarly characterized. Moreover if a risk decreases due to the dynamics of the disease incidence or properties, whether that decrease is permanent, temporary or fluctuating is important. If a policy is changed, the expected change of the risk must be evaluated. Moreover, the risk of an individual event does not provide the same policy relevance as the risk over time including multiple events such that the risk may remain or accumulate to be high over months, years, decades or lifetimes, leading to reduced life expectancy, decreased life conditions, or requirements for medical care or support in response to disability, or inability to work and thus impact financial or economic conditions.

The CDC requirements under OMB's guidance lead to a responsibility to charge the review panel to review the practicability and specific responses to questions about risk such as:

1. What is the risk of a person infecting others when they are isolating for a limited time over which they are infectious, how does this depend on the time of isolation?
2. What is the potential risk to an individual in a space due to another person not practicing isolation?
3. How does the risk level increase when more people are present in the space?(see WHO estimation tool).
4. How does the risk level depend on the conditions under which people are meeting? (see WHO estimation tool).
5. What is the potential risk to an individual with high-risk health conditions in a space where someone is not practicing isolation?
6. How can an individual identify if they are at risk due to another person not practicing isolation so that they can adopt precautions measures specified in the guidance, and who holds the responsibility for informing others about this risk?
7. What is the risk over time of individuals in specific occupations contracting an infection due to others not practicing isolation?
8. What are the potential consequences of an individual contracting an infection, and over time from multiple infections? These can include cognitive issues, heart attacks, strokes, immune system dysregulation, reproductive issues, and contracting other diseases.
9. What is the risk over time for an individual to become unable to work due to long-term COVID symptoms including disability?
10. What is the risk for a member of a vulnerable group to become unable to work due to long-term COVID symptoms?

11. What is the risk of an uninfected individual being harmed by an infected person they cross paths with?
12. How does the risk over time of an individual in a specific profession becoming unable to work temporarily or permanently fluctuate due to increases and decreases in infection rates and due to new variants?
13. What is the infection risk over time for an individual required by their employer to follow CDC guidelines?
14. What is the risk over time for an individual to get infected at a workplace that follows different practices?
15. What is the potential loss for an employer due to employees' inability to work during an acute infection?
16. What is the potential loss for an employer due to employees' long-term COVID disability?
17. What is the population-wide risk of disability as a result of increased infection rates?
18. What is the economic impact of the population-wide risk of disability as a result of increased infection rates?
19. What is the overall risk of disability and economic impacts for certain professional groups considering the existing circumstances?
20. How does a policy change impact the risk level?
21. In considering the choices involved in personal safety measures, what are the outcomes of different decisions for risk and harm, including long term disability?
22. How can one person's choice affect others' risks and the decisions they should make?
23. If the CDC's stated goal is prevention, does the lack of prevention equate to an increase in risk? If so, at what level for vulnerable or professional groups?

These questions are central to the role of public communications on risk, and it is a matter of scientific understanding and thus peer review to determine what questions can be answered. Many of these are directly addressed, and some may be addressed by the WHO tool which calculates risk based on the number of infectious versus noninfectious people in a space.

# Public comment on CDC Isolation Guidance

## Twitter/X comments

Eric Topol

<https://x.com/Billius27/status/1763994003949617638?s=20>

Eric Feigl Ding

<https://x.com/DrEricDing/status/1763402220668658163?s=20>

<https://twitter.com/dreicding/status/1764445235155804597>  
<https://twitter.com/DrEricDing/status/1763402220668658163>  
<https://x.com/DrEricDing/status/1763628664434905296?s=20>

Peter Hotez

<https://x.com/PeterHotez/status/1764271958319853741?s=20>

## Examples from Organizations and Press

NNU

<https://www.nationalnursesunited.org/press/nnu-condemns-cdc-decision-to-shorten-isolation-guidance>

WSWS

<https://www.wsws.org/en/articles/2024/03/04/drxv-m04.html>

CDC Drops Five Day Covid-19 Isolation Despite Controversy

<https://www.forbes.com/sites/judystone/2024/03/01/cdc-drops-five-day-covid-19-isolation-despite-controversy/?sh=16258fa719d8>

People's CDC

<https://peoplescdc.org/2024/02/14/press-release-keep-covid-isolation/>

Pan End It

<https://actionnetwork.org/petitions/new-cdc-covid-19-isolation-guidance-weakens-labor-protections-discriminates-against-high-risk-people-and-does-not-match-the-science?source=twitter&>

Atlanta Journal-Constitution

<https://www.msn.com/en-us/health/medical/we-are-in-a-different-place-cdc-lifts-5-day-isolation-guidelines-for-covid/ar-BB1jBFsH>

Medpage

<https://www.medpagetoday.com/opinion/second-opinions/109196>