

## **ANALYSIS AND EVIDENCE SUPPORTING A COMPLAINT OF GROSS MISCONDUCT**

**October 29, 2023**

This *Analysis and Evidence Supporting a Complaint of Gross Misconduct* (Analysis) 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). It accompanies the *Complaint of Gross Misconduct* (the Complaint) submitted on even date herewith via that same Hotline. The Complaint has, in fact, been excerpted from this Analysis, which sets forth a more detailed discussion of the points in the Complaint and the evidence associated with them.

The Complaint alleges a charge of Gross Misconduct against the following HHS employees:

**Hon. Xavier Bacerra**, Secretary, HHS (the Secretary)

**Dr. Mandy Cohen**, Director, U.S. Centers for Disease Control (CDC) (the Director)

**Dr. Alexander Kallen**, Designated Federal Officer, Healthcare Infection Control Practices Advisory Committee (HICPAC) (the Federal Officer)

We respectfully request the HHS Office of Inspector General to investigate these charges, and we would very much appreciate acknowledgment by the IG of receipt of this complaint and notice of what action the IG intends to take.

**NOTE REGARDING “START DATE”:** The on-line filing form has a required field entitled “Start Date”. Given the nature of this Complaint, this field has been confusing for us to respond to. No falseness whatsoever has been intended, but for purposes of being able to proceed with the electronic filing, the date of June 3, 2021 was used to fill out the on-line form.

As best as we have been able to determine from the less than perfect information HICPAC makes available regarding its activities, this is the first mention in the HICPAC meeting minutes of the subcommittee which was working on developing the Draft Guidelines

As is discussed below, however, according to the CDC website page entitled Healthcare Infection Control Practices Advisory Committee **Roster**, HICPAC has failed to have the required number of members mandated by its Charter since 2017, and it has failed to have a legally required balanced membership since at least the onset of the Covid-19 pandemic (which appears to have begun in 2020) where aerosols have been a significant mode of transmission for a pandemic level infectious pathogen.

If the IG thinks that one of those dates is more appropriate to properly respond to the requirement of “Start Date”, please use whatever date you consider more proper, and accept our apologies for any confusion.

## **Background:**

As proven below, the membership composition of The Healthcare Infection Control Advisory Committee (HICPAC, the Committee) currently stands in violation of the Federal Advisory Committees Act (FACA) and the Committee's own Charter and has been in such violation for a number of years. The Committee has also failed under FACA and its own Charter to be properly transparent to the public. As such, HICPAC is simply not a legally constituted advisory committee. Its recommendations have no legal standing and no place in the CDC's process of updating the Agency's guidance.

The Secretary, Director and Federal Officer are ultimately responsible for ensuring that the organizations under their authority comply with the law. It is a gross dereliction of duty to allow such organizations to conduct their business, in this case year after year as we shall show, in clear violation of the law. For this reason, we hereby file this Complaint with the HHS Office of Inspector General for the charge of Gross Misconduct.

HICPAC advises the CDC on guidelines for infection control in healthcare settings, and in its June 2023 meeting, a HICPAC subcommittee presented draft updates to the CDC's guidance, *Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (the Draft Guidelines), which was last updated in 2007. These Draft Guidelines must be approved by the full committee before being transmitted as formal HICPAC recommendations for updating the CDC guidance in this area.

The CDC's Isolation Precautions guidance is consequential. It is THE guidance that directs infection control practices in healthcare settings in the United States and is frequently referenced by employers and other government agencies both in the US and around the world.

HICPAC's Draft Guidelines would dangerously weaken the current CDC guidance on infection control precautions, particularly for aerosol transmission. Such a watering down of CDC's guidance would create a real and present risk in healthcare facilities of increased exposures to, infections by, and possible death from Covid-19. Such risk would fall not only on healthcare workers, but on anyone who accesses healthcare.

As we specify in more detail below under **Remedies Sought**, the process of CDC's accepting such legally flawed and potentially dangerous Draft Guidelines must immediately be paused. The Secretary must also immediately move to correct the illegal composition of HICPAC's membership. Once the Committee's membership has been reformed, a legally constituted Committee employing a legally transparent process may then propose new Guidelines for Isolation Precautions guidance to the CDC.

**Points:**

1. HICPAC fails to have the requisite number of members as required by the mandatory language in its Charter that “The Committee shall (emphasis added) consist of 14 non-Federal members.” “Shall” is a legal term of art. It creates a mandatory duty with no wiggle room. It does not mean “maybe” or “if circumstances allow.”

HICPAC has only 64% of its required members, and the Committee has failed to have 14 non-Federal members since 2017, thus placing it in violation of its Charter. This means that HICPAC is not a legally constituted advisory committee, and the Draft Guidelines it is proposing to serve as the basis for CDC’s formal guidance regarding “Preventing Transmission of Infectious Agents in Healthcare Settings” cannot be considered legally legitimate.

Were they to be adopted, and were later challenged in court, the CDC would face the very real risk that guidance based on such Guidelines, arising from an illegally constituted advisory committee, would be declared reversible error.

HICPAC’s Charter reads “**Membership and Designation.** The Committee shall (emphasis added) consist of 14 non-Federal members, including the Chair or Co-Chairs.”

HICPAC’s Charter thus clearly and unambiguously states that the Committee must contain 14 non-Federal members – not 15, not 13, but specifically 14. The Committee, however, fails to contain 14 non-Federal members as required by its Charter. It contains only 9 (and the terms of 4 of them expire on 12/31/2023).

On October 17, 2023, the CDC website page entitled Healthcare Infection Control Practices Advisory Committee **Roster 2023** (the Roster) listed 9 members only: Sharon Wright (Co-Chair, who was designated Chair in the HICPAC 8/22/23 public meeting), Elain Dekker (term expires 2023), Mohamad Fakih (term expires 2023), Judith Guzman-Cottrill (term expires 2023), JoAnne Reifsnnyder (term expires 2023), Erica Shenoy, David Jay Weber, Colleen Kraft, and Jennie H. Kwon.

With only 9 non-Federal members when 14 are required by mandatory language, HICPAC thus stands in clear violation of its Charter. It is thus not a legally constituted advisory committee, and the Draft Guidelines it is considering simply have no place in the CDC’s process of updating its guidance regarding *Preventing Transmission of Infectious Agents in Healthcare Settings*.

It is clear, furthermore, that the legislative intention in drafting the HICPAC Charter was to create an absolute requirement that the voting membership of the Committee be comprised of “14 non-Federal members.” Nowhere in the HICPAC Charter does there appear any of the sort of non-mandatory language that is specifically recited in relation

to other agencies, such as in the Federal Communications Commission’s authorizing statute. That statute, for example, specifies that the FCC shall have five members – but then provides: “No vacancy on the Commission shall impair the right of the remaining commissioners to exercise the powers of the Commission.”

The HICPAC Charter contains not the slightest hint of any such attenuating language. The Charter’s legislative intent to create an absolute requirement for 14 members is thus clear and unequivocal. Had there been any intent to provide “wiggle room” in this requirement, the Charter’s framers would have done that, as was done with the FCC. HICPAC’s framers specifically chose not to do so. They chose instead to create an unequivocal duty to have 14 members on the Committee, a duty with which HICPAC has clearly failed to comply.

There can also be no legitimate claim that the Committee is operating in some sort of unusual or emergency situation, which in some way might allow a mere quorum to conduct its business. HICPAC has been operating in violation of its membership requirement since 2017, which was the last year it had the required 14 members. According to the Roster, HICPAC’s membership numbers have, in fact, almost steadily decreased since 2017 – standing at 12 in 2018, 13 in 2019 and 2020, 11 in 2021, and only 9 in 2022 and 2023.

The illegality here is plain, but regardless of the legal deficiency to recommendations adopted by this Advisory Committee with only 9 members when 14 are mandatory pursuant to its Charter, there is a serious policy argument to be made that HICPAC should stay its hand in such circumstances – because these Draft Guidelines are a matter of such importance and controversy, and in light of the fact that this is not the only serious flaw in the Committee’s membership, which is discussed further in No. 2 below.

The HHS Secretaries, CDC Directors and HICPAC Designated Federal Officers should never have allowed a federal advisory committee under their authority to operate at all without its mandated number of members, much less to allow such a situation to exist for what is now its sixth year. This is not a minor infraction. It is a serious violation of HICPAC’s Charter that deprives the committee of its legal legitimacy. It is a level of dereliction of duty that supports a charge of Gross Misconduct.

- 2. Even if there is disagreement about whether aerosols are the only, or even the primary mode of transmission of the infectious agent Covid-19, aerosol transmission is undeniably a significant mode of such transmission – and a point of view held by a significant number of experts in the scientific community. Since aerosols are a significant mode of infectious transmission of Covid-19, providing guidance on preventing such transmission is an important function of HICPAC.**

**In order to reasonably and accurately provide such guidance, the Committee must have in its membership a significant number of experts in fields such as aerosol science, industrial hygiene, UV and HEPA filtration, ventilation engineering, respiratory protection and occupational health and safety. Yet, the Committee does not have even one such member.**

**This failure places HICPAC in violation of both the Federal Advisory Committee Act (FACA) which requires “... the membership of the advisory committee to be fairly balanced in terms of the points of view represented,” and the Committee’s obligatory Membership Balance Plan which requires that “in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, interested, and qualified.”**

**Because its membership fails to be fairly balanced in relation to the points of view related to its function, as legally required by FACA and its Membership Balance Plan, HICPAC is not a legally constituted advisory committee and has no legal standing to propose the Draft Guidelines to the CDC.**

To show that the HICPAC membership is not fairly balanced in its points of view and is therefore in violation of FACA, it is not necessary to show that aerosols are the only mode of transmission for the infectious pathogen Covid-19 – or even that they are the primary mode of transmission. It is only necessary to show that aerosols are a significant mode of such transmission.

Dr. Jose-Luis Jimenez, Distinguished Professor and Institute Fellow at the University of Colorado, Boulder is a well-published and well-recognized expert in aerosol science. He is one of the top 10 cited scientists on aerosols. In 2022, in the publication *Indoor Air*, Vol. 32 Issue 5, he wrote:

The COVID-19 pandemic has brought a new appreciation of the importance of airborne disease transmission. Airborne transmission is caused by the inhalation of pathogen-containing aerosols that are produced by an infected person. At the start of the pandemic, WHO concluded that Covid-19 was a contact/ droplet/ fomite disease, understood to mean either direct physical contact, or spray of ballistic larger particles that impact on eyes, nostrils, or mouth, or are picked up by hands and delivered to the same body parts. However, it has become clear that COVID-19 is a predominately airborne disease (emphasis added).

Britannica defines an aerosol as “a system of liquid or solid particles uniformly distributed in a finely divided state through a gas, usually air.” Through aerosol transmission, Covid-19 will fill a closed room or creep into a hall if a door is left ajar. It will penetrate a church where the choir is singing and infect people in the pews. It will fill a bus where someone in the front is breathing it out, and infect people sitting in the back. It will infect multiple people gathered in a close crowd, even if they are outside.

These examples of aerosol transmission of Covid-19, and many other examples, have been documented, both in the laboratory and in the real world, as many expert witnesses will attest. We have included in this complaint the following Exhibits from just three of them. (The authors of these three Exhibits have also been listed as expert witnesses in support of the Complaint).

**Exhibit 1** attached is by Dr. Stephané Bilodeau, Adjunct Professor at McGill University, with over 25 years of practice that combines academic, regulatory and entrepreneurial experience who has served as an Independent Expert for International Organizations. It sets forth some of the extensive documentary and expert evidence supporting the significance of aerosol transmission of Covid-19. **Exhibits 2 and 3** set forth such evidence in video format by Dr. Jose-Louis Jimenez (mentioned above) and Dr. Lisa Brousseau, Research Consultant at the Center for Infectious Disease Research and Policy at the University of Minnesota who has authored more than 100 peer-reviewed publications and book chapters. Dr. Jimenez and Dr. Brousseau made these presentations on October 25, 2023 in a webinar sponsored by the World Health Network.

(Immediately below is an electronic link to **Exhibits 2 and 3**. Please copy the link address into your browser and when it opens, scroll down slightly to see the two video presentations).

<https://whn.global/airborne-transmission-and-infection-prevention/>

These Exhibits clearly prove that aerosols are, at the very least, a significant mode of transmission for Covid-19. That is the point we wish to emphasize here. We do not attempt to prove that aerosols are the only, or even the primary, mode of Covid-19's transmission – but these Exhibits clearly prove that aerosol transmission of Covid-19 is significant.

Providing guidance to the CDC on preventing transmission of infectious agents in healthcare settings, furthermore, is an important function of HICPAC. The very title of the Draft Guidelines is, after all, "Isolation Precautions: Preventing Transmission (emphasis added) of Infectious Agents in Healthcare Settings." Providing expert guidance to the CDC on limiting aerosol transmission in healthcare settings is thus an important function of the Committee, because HICPAC is charged with addressing the issue of preventing transmission of infectious agents in healthcare, and aerosols are a significant mode of transmission for the infectious agent, Covid-19.

The Federal Advisory Committee Act Section 5(b)(2) requires "... the membership of the advisory committee to be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." The corresponding FACA regulations reiterate this requirement at 41 CFR Section 102-3.30(c).

For discretionary committees being established, renewed, or reestablished (which includes HICPAC), FACA regulations also require under 41 CFR 102-3.60(b)(3) a Membership Balance Plan. The Membership Balance Plan requires “A description of the agency’s plan to attain fairly balanced membership. The plan will ensure that, in the selection of members for the advisory committee, the agency will consider a cross-section of those directly affected, interested, and qualified, as appropriate to the nature and functions of the advisory committee.”

FACA, its corresponding regulations, and an advisory committee’s Membership Balance Plan all thus exist to ensure that the membership of committees like HICPAC are fairly balanced, by including in their membership people who have different interests and different views in relation to the committee’s functions. In order to properly represent the view that aerosols are a significant mode of transmission for Covid-19, therefore, HICPAC would have to include in its membership a significant number of experts in areas such as aerosol science, industrial hygiene, UV and HEPA filtration, ventilation engineering, respiratory protection and occupational health and safety.

The Committee contains not even one such expert member. **Exhibit 4** attached sets forth a review of the current HICPAC members and their expertise. This review clearly shows that the composition of the Committee fails to include a significant number of members with aerosol expertise and is therefore not fairly balanced.

HICPAC’s membership thus violates FACA and the provisions of its own Membership Balance Plan, because it fails to include a significant number of experts in the area of an important committee function, i.e., providing guidance to the CDC on preventing aerosol transmission of the infectious pathogen Covid-19.

This is fatal flaw number two in the composition of HICPAC’s membership (along with fatal flaw number one of failing to have the mandated number of members pursuant to the Committee’s Charter). Like flaw number one this second flaw in HICPAC’s membership also means that it is not a legally constituted advisory committee.

As with the first membership flaw, we say once again that the Draft Guidelines proposed by this illegally constituted Committee cannot be considered legally legitimate. They simply have no place in the CDC’s process of updating its guidance regarding *Preventing Transmission of Infectious Agents in Healthcare Settings*. Were they to be incorporated into CDC guidance that is later challenged in court, the Agency would face the very real risk that guidance based on such Guidelines, arising from an illegally constituted advisory committee, would be declared reversible error.

Again as above, regardless of whether there is any legal deficiency arising from recommendations adopted by a Committee which fails to be fairly balanced as required by FACA and its Membership Balance Plan, there is a serious policy argument to be

made that HICPAC should stay its hand in such circumstances – especially on matters of such importance and controversy as the Draft Guidelines, and in light of the fact that this is not the only fatal flaw in the Committee’s membership, as was discussed in No. 1 above.

Lastly, and as with No. 1 above, the HHS Secretary should never have allowed a federal advisory committee under his authority to operate without its legally required fairly balanced membership. That infraction certainly applies to the membership composition of the current HICPAC, and arguably has applied since 2020 when Covid-19 reared its ugly head.

Again, this is not a minor infraction. It is a serious violation of FACA and HICPAC’s Membership Balance Plan that deprives the committee of its legal legitimacy. It is a level of dereliction of duty that supports a charge of Gross Misconduct.

**3. HICPAC has refused to provide records to the public in violation of FACA and its Charter, and obscured its process of making updates.**

The Federal Advisory Committee Act Section 11 requires that “advisory committees shall make available to any person, at actual cost of duplication, copies of transcripts of... advisory committee meetings.” HICPAC’S Charter, furthermore, under **Recordkeeping** requires that “The records of the Committee, established subcommittees, or other subgroups of the committee.... shall be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C Section 552.”

Debora Gold of the California’s Occupational Safety and Health Administration State Plan (Cal OSHA) testified in the HICPAC meeting of August 22, 2023 that “Cal OSHA is seriously concerned about the lack of transparency and openness in this process. Despite repeated requests we have not seen a draft of the proposed guidelines, we have not seen the minutes of working groups or even of the previous meeting and working group meetings have not been advertised or open to the public.”

In an August 23, 2023 press release, National Nurses United president Zenei Triunfo-Cortez said, “When we tried to get information about these meetings via FACA, our request was denied. We submitted a FOIA request to the CDC and received 279 pages of redacted documents.”

National Nurses United has reported in a web based publication entitled *Urge the CDC and HICPAC to fully recognize aerosol transmission and protect health care workers and patients* that: (1) HICPAC working group meetings regarding guidance updates are closed and not open to the public; (2) HICPAC committee votes have been held before public comment and meeting presentations have not been publicly posted; (3) Updates



from the working group to HICPAC are not publicly posted; and (4) meeting summaries are posted months after the fact.

The public may make short comment during each HICPAC meeting, but there is no other mechanism for the committee or its working groups to garner input from frontline healthcare workers or the unions that represent them, or patients who will be impacted by an updated Guidance.

HICPAC's lack of transparency has been roundly criticized by experts, healthcare workers and patient advocates. Just one of many examples of such criticism is from Peg Seminario, former director of occupational safety and health for the AFL-CIO in *The Daily Beast* July 1, 2023, "The minutes for the past meetings are only bare bones. They have no transcripts. No presenters. There's nothing. It's just outrageous. It's a federal advisory committee."

HICPAC's lack of transparency violates FACA and the committee's Charter.

**4. By requiring a specific number of members, a committee fairly balanced in points of view, and a transparent committee process, FACA, its associated regulations and HICPAC's own Charter seek to prevent precisely what has happened at HICPAC:**

The Draft Guidelines HICPAC has produced have been met with what Judy Stone described in *Forbes* as "a firestorm in the public health community" for failing to properly incorporate the significance of aerosol transmission of Covid-19.

More than 900 experts, for example, joined by more than 1,000 members of the public signed a July 20, 2023 letter to CDC Director Mandy Cohen opposing the Draft Guidelines, and as Dr. Kevin Kavanaugh wrote in the August 28, 2023 issue of *Infection Control Today*, "the most worrisome detrimental outcome of the CDC's possible rollback of guidance is the loss of credibility."

(Immediately below is an electronic link to this letter. Please copy the link address into your browser).

[https://www.nationalnursesunited.org/sites/default/files/nnu/documents/0723\\_HICPAC\\_experts\\_letter\\_background\\_combined\\_FINAL.pdf](https://www.nationalnursesunited.org/sites/default/files/nnu/documents/0723_HICPAC_experts_letter_background_combined_FINAL.pdf)

The informational slide deck outlining the Draft Guidelines makes little mention of aerosol transmission of infectious pathogens, uses evidentiary support studies that do not account for aerosol transmission or asymptomatic spread and fails to include guidance related to ventilation, UV disinfection and HEPA filtration, all essential tools against an airborne pathogen.

The Draft Guidelines neglect the role of asymptomatic transmission of Covid-19, which makes it highly likely that without adequate respiratory protection, healthcare workers will infect patients. Asymptomatic transmission, furthermore, makes it impossible for health care workers to accurately assess their own risk, which the Draft Guidelines state is the responsibility of the healthcare worker. These Guidelines also fail to account for patient healthcare-acquired infections and adverse outcomes, and strikingly, vulnerable patients are not even mentioned.

The firestorm of criticism over the Draft Guidelines 'should never have arisen. By requiring fairly balanced committee membership and a transparent process, FACA and its associated regulations seek to prevent precisely what has happened at HICPAC.

The Committee's illegal lack of sufficient members and its failure to have a fairly balanced membership composition, coupled with its communications insularity seems to have created a mental and ideological inbreeding at HICPAC. It is hard to imagine that a set of Draft Guidelines so at odds with respected science and expert opinion would have been proposed by a fairly balanced committee, with the proper representation of aerosol scientists, industrial hygienists, UV and HEPA filtration specialists, ventilation engineers, and respiratory protection and occupational health and safety experts.

This is not merely an academic concern. The adoption of Draft Guidelines such as these, which fail to ensure adequate respiratory protection toward a dangerous infectious aerosol, would virtually guarantee that people will sicken and die as a result of this faulty guidance.

- 5. HICPAC could have known and should have known that the composition of its membership violated FACA and its own Charter, but instead closed its eyes to these legally fatal flaws. It thus seems to be guilty of what the law terms "Willful Blindness." In the application of this principle, the law is not concerned with *why* one remains ignorant when one could and should have known better, only that one *does* remain ignorant. It is a principle for imputing intent to someone's actions.**

**Looked at from this point of view, HIPCAC had the intention to do precisely what it has done: limit the number of its members on the Committee, excluded from membership experts with divergent points of view, and develop its Draft Guidelines virtually in the shadows with as little transparency as possible.**

**In this vein, it is also worth noting that over 20% of the Committee members (two of nine), including the Chair, appear to have demonstrated at least prejudice and possibly bias by going on record in the *Annals of Internal Medicine*, June 2023 arguing that the time for universal masking in healthcare settings has passed, essentially resolving well before the fact the very question the Committee is supposed to be considering.**

Willful Blindness is a legal concept first developed in English law in the nineteenth century in *Regina v. Sleep*. It has been applied in American law in proceedings such as *United States of America v. Kenneth L. Lay* where, as Margaret Heffernan quotes in the book *Willful Blindness*, Judge Simeon Lake instructed the jury, “Knowledge can be inferred if the *defendant deliberately blinded himself to the existence of a fact* (emphasis hers).” Willful Blindness, in other words, is a legal principle for imputing constructive intent.

In HICPAC’s slide presentation associated with the Draft Guidelines, there was just enough mention of airborne transmission to avoid the accusation that the committee was totally ignoring it. Both the presentation and its associated Guidelines, however, utterly failed to give aerosol transmission the weight its level of science and expert opinion deserve.

It is difficult to believe that HICPAC has been unaware of the sheer weight of science and expert opinion regarding the significance of aerosol transmission of Covid-19. Even if the committee were so unaware, however, it has nevertheless been Willfully Blind to such significance. HICPAC could have known, and should have known, of this significance. The committee chose instead to turn a blind eye to it, and to propose instead Draft Guidelines which refuse to adequately recognize the significance of aerosol transmission of Covid-19.

Advisory committee members are supposed to be experts within their fields of expertise. When over 20% of the Committee’s membership including the Chair, however, go on record in a publication essentially resolving the very question the Committee is supposed to be deciding, and when the full record in the Committee has not yet been fully presented, it raises questions about their objectivity and openness to evidence that contradicts their already expressed positions.

### **Remedies Sought:**

1. The CDC must immediately pause the process of updating its guidance, *Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* (the CDC Guidance). The process of developing and approving the Draft Guidelines currently underway in HICPAC must immediately cease.

HICPAC is not a legally constituted advisory committee, and its lack of legal standing deprives it of any authority to recommend changes to CDC guidance. Too much scientific evidence, furthermore, calls the Draft Guidelines into serious question and too many experts in the field have severely criticized them as dangerous to healthcare workers and patients alike.

2. The Secretary must promptly correct the illegal composition of HICPAC's membership to bring the Committee into compliance with (1) its Charter requirement to have 14 non-Federal members, and (2) its FACA and Membership Balance Plan requirements to have a fairly balanced membership.

In order to create a fairly balanced membership, the Secretary must appoint as voting members, a significant number of experts in aerosol science, industrial hygiene, UV and HEPA filtration, ventilation engineering, respiratory protection and occupational health and safety.

3. HICPAC must immediately adopt measures to increase transparency as required by FACA and its own Charter, such as opening working group meetings to the public, promptly posting meeting presentations and summaries and facilitating broader stakeholder input. The Committee must also establish mechanisms to actively seek and incorporate input from frontline healthcare workers, their representative unions and the patients who will be directly impacted by the guidelines.
4. A new set of Guidelines for the CDC Guidance must be developed by a fairly balanced HICPAC following a transparent process, which acknowledges the overwhelming body of scientific evidence and expert opinion that aerosols are a significant mode of transmission for the infectious agent, Covid-19.

New Guidelines must recognize this significance and fully integrate it into guidance related to control measures for Covid-19, including but not limited to guidance involving ventilation, UV disinfection, HEPA filtration and the utilization of NIOSH-approved respirators.

It is no surprise that these Draft Guidelines have caused such a stir. They are the direct result of the insularity of HICPAC's membership which violates both FACA and its own Charter, coupled with the Committee's choice to develop these Guidelines in the shadows, willfully refusing to share its deliberations with the very people it is supposed to be protecting.

The Draft Guidelines which propose weakening CDC's guidance, *Isolation Precautions: Preventing Transmission of Infectious Agents in Healthcare Settings* are being proposed by an "advisory committee" with no legal standing. They are potentially mortally dangerous to both healthcare workers and patients. Were they to be adopted, and later challenged in court, the CDC would face the very real risk that guidance based on such Guidelines, arising from an illegally constituted advisory committee, would be declared reversible error.

The HHS Secretary should never have allowed a federal advisory committee under his authority to operate without the number of members mandated in its Charter and with a membership composition that fails to be fairly balanced as required by FACA and the Committee's Membership Balance Plan, much less to allow these infractions to continue for years. These are

serious violations which deprive HICPAC of its legal legitimacy. They are a level of dereliction of duty that supports a charge of Gross Misconduct.

**PLEASE NOTE:**

**Exhibit 1**, a review of relevant literature by Dr. Stephané Bilodeau is appended immediately below.

**Exhibits 2 and 3** are video presentations by Dr. Jose-Louis Jimenez and Dr. Lisa Brousseau. The link to these presentations may be found on page 6 under Point No. 2.

**Exhibit 4**, the Roster of the current HICPAC committee is appended below, immediately following the literature review of Exhibit 1.

**Regarding Witnesses:** For simplicity of communication, we have listed one phone number for the complainant, Yaneer Bar-Yam, and the three expert witnesses, Dr. Stephané Bilodeau, Dr. Jose-Louis Jimenez and Dr. Lisa Brousseau. As set forth in the on-line filing form, these witnesses have their own independent affiliations, but to facilitate reaching them, we have listed one central phone number. By contacting that phone number, the IG can be assured of reaching them, but we would be happy to identify and provide separate phone numbers for them if the IG would prefer.

**The 10 pages of Exhibit 1 follow on the next page.**

# EXHIBIT 1

## Is Aerosol transmission a significant part of COVID-19 transmission?

The answer is clear: aerosol transmission of SARS-CoV-2 has been widely recognized as a significant route of infection. When a person exhales, speaks, sings, sneezes, or coughs, they generate respiratory particles that are released into the air. If a person is infected with a virus and has a significant viral load in the fluid lining their respiratory tract, these emitted particles may contain both the virus and the fluid from the lungs, mouth, and nose. Aerosol transmission occurs when these particles travel through the air encounter and infect a second individual. Gravity causes larger particles to drop to the ground, while smaller particles, known as aerosols, remain airborne and move through the air like smoke. Therefore, the term aerosol transmission refers more specifically to the transmission caused by these lighter particles. The term airborne transmission, or airborne route, is used to distinguish this route of transmission. Extensive evidence and numerous scientific articles have emerged since the start of the pandemic, supporting the consideration of an airborne route for COVID-19. It is widely accepted that airborne transmission plays a significant, if not dominant, role as the virus can remain viable in aerosols for a minimum of three hours and travel considerable distances similar to smoke, spanning several meters, based on local conditions.

The interdisciplinary nature of aerosol transmission, which encompasses both physical and biological processes involving the movement of particles through the air, sets it apart from the training of medical professionals who focus on treating infected patients.

The objective of the current collection of scientific literature (articles, reviews, and studies) is to identify and appraise the available evidence (clinical trials and laboratory studies on masks and respirators, epidemiological studies, and air sampling studies) to confirm the significance of aerosol transmission. The importance of aerosol transmission is not unique to the SARS-CoV-2 pandemic. As reported by Mowraska and Milton as early as July 2020, retrospective studies conducted after the SARS-CoV-1 epidemic in 2003 demonstrated that airborne transmission was the most likely mechanism explaining its spatial pattern of infections. Overall, the scientific consensus for the significant role of airborne transmission has profound implications for the control of the COVID-19 pandemic and future pandemic preparedness.

The following list of noteworthy excerpts (and related references) illustrates a fraction of the reported studies confirming the importance of aerosols and their airborne transmission. (The number in bracket **Ref [X]** refers to the references listed in Appendix B)

1. Aerosol particles float in the air like smoke because they are small enough so that gravity doesn't play a major role in their airborne trajectory. The direct measurement of these particles in the breath of infected individuals has been linked to the degree of transmissibility of variants.  
**Ref [2] "Aerosol inhalation is recognized as the dominant mode of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission. Three highly transmissible lineages evolved during the pandemic (...) Alpha, Delta, and Omicron independently evolved high viral aerosol shedding phenotypes, (...) These findings support a dominant role of infectious aerosols in transmission of SARS-CoV-2."**
2. Airborne particles have been shown in multiple studies to contain viable virus, which means that the virus can result in infections; this has been reported in Refs [15, 16, 61, 62, 63].  
**Ref [15] "SARS-CoV-2 remained viable in aerosols throughout the duration of our experiment (3 hours), with a reduction in infectious titer from 103.5 to 102.7 TCID50 per liter of air. This reduction was similar to that observed with SARS-CoV-1."**

**Ref [16] “Viable SARS-CoV-2 was isolated from air samples collected 2 to 4.8 m away from the patients. The genome sequence of the SARS-CoV-2 strain isolated from the material collected by the air samplers was identical to that isolated from the newly admitted patient.”**

3. Early in 2020, researchers already reviewed multiple forms of evidence that SARS-CoV-2 can be spread by the aerosol route.

**Ref [35] “This narrative review makes the case that aerosol transmission is an important mode for COVID-19, through reviewing studies about bioaerosol physiology, detection of infectious SARS-CoV-2 in exhaled bioaerosols, prolonged SARS-CoV-2 infectivity persistence in aerosols created in the laboratory, detection of SARS-CoV-2 in air samples, investigation of outbreaks with manifest involvement of aerosols, and animal model experiments.”**

4. Later in 2020, researchers state that beyond any reasonable doubt, viruses released during exhalation, talking, and coughing in microdroplets (i.e., aerosols) remain aloft in the air and pose a risk of exposure at distances well beyond 2 m from an infected individual— even greater than the scale of a typical room.

**Ref [8] “Studies by the signatories and other scientists have demonstrated beyond any reasonable doubt that viruses are released during exhalation, talking, and coughing in microdroplets small enough to remain aloft in air and pose a risk of exposure at distances beyond 1–2 m from an infected individual”**

**Ref [8] “We appeal to the medical community and to the relevant national and international bodies to recognize the potential for airborne spread of coronavirus disease 2019 (COVID-19). There is significant potential for inhalation exposure to viruses in microscopic respiratory droplets (microdroplets) at short to medium distances (up to several meters, or room scale), and we are advocating for the use of preventive measures to mitigate this route of airborne transmission.”**

5. Since early 2021, multiple forms of evidence have been identified in the scientific literature to support the aerosol transmission of COVID-19

**Ref [3] “Ten streams of evidence collectively support the hypothesis that SARS-CoV-2 is transmitted primarily by the airborne route.”**

6. In 2021, the virus had been detected in the air in various settings, one of the driving features for airborne transmission.

**Ref [4] “SARS-CoV-2 RNA is detected intermittently in the air in various settings. Standardized guidelines for conducting and reporting research on airborne transmission are needed.”**

7. Aerosols (sometimes referred to as “the smaller exhaled droplets”) dominate transmission at large distances compared to larger droplets that fall to the ground but were also found to represent an important part of the short-range airborne transmission route (the large droplet route contributes less than 10% of exposure when the droplets are smaller than 50  $\mu\text{m}$  and when the subjects are more than 0.3 m apart, even while coughing.)

**Ref [12] “The short-range airborne route is found to dominate at most distances studied during both talking and coughing. The large droplet route only dominates when the droplets are larger than 100  $\mu\text{m}$  and when the subjects are within 0.2 m while talking or 0.5 m while coughing.”**

8. Studies have shown regular indoor activities in confined spaces are significant transmission settings. Droplet transmission does not distinguish indoor and outdoor conditions, while the airborne transmission is higher indoors than outdoors because of the accumulation of aerosols (similar to smoke) in indoor spaces and the movement of air outside that dilutes the density of aerosols.

**Ref [13] “While it has been acknowledged that spending time outside has general health benefits, our review posits that there are also benefits in reducing transmission of SARS-CoV-2 by reducing**

***exposure time (substituting time indoors with time outdoors). These results suggest that moving activities to outdoor settings may reduce infections and ultimately save lives."***

9. This study suggests that high attack rates observed in outbreaks, notably in superspreader events, can only be explained by aerosol transmission as the main route of contagion.  
***Ref [29] "(...) the high attack rate values can be justified only assuming the airborne transmission as the main route of contagion. Moreover, we show that such outbreaks are not caused by the rare presence of a superspreader, but can be likely explained by the co-existence of conditions, including emission and exposure parameters, leading to a highly probable event, which can be defined as a superspreading event".***
10. This article in Nature, from February 2021, explains why superspreader events and aerosol transmission are linked and that superspreader events have been observed in many outbreaks where a few people account for "the lion's share of transmission."  
***Ref [65] "Numerous superspreading events have occurred in crowded indoor spaces with poor ventilation. This aligns with other pieces of evidence that airborne transmission through aerosols is an important – if not the main – mode by which SARS-CoV-2 passes from one person to the next."***
11. This study validated that passengers waited for 3 hours in an airport rest area. When they removed masks to eat and drink, they released viral aerosols, which rose to a second level of the airport with hot air, causing an outbreak in that area.  
***Ref [33] "The results showed that the inbound passengers waited for approximately 3 h in the rest area on the first level of the international arrival area (Zone E). During the period, masks were removed for eating and drinking, resulting in the viral aerosols rising from the first level to the second level with hot air."***
12. Studies involving infected caged animals that were connected to separately caged uninfected animals via an air duct have shown transmission. [19, 56]  
***Ref [19] "(...) these results demonstrate that SARS-CoV and SARS-CoV-2 can remain infectious while traveling through the air. Efficient virus transmission between ferrets is in agreement with frequent SARS-CoV-2 outbreaks in mink farms."***  
***Ref [56] "Low-dose ocular-only aerosol exposure or inhalation aerosol exposure of ferrets to IAV similarly led to productive infection of ferrets and shedding of aerosolized virus."***
13. To better understand how airborne SARS-CoV-2 transmission occurs, this study sought to determine viral loads within coarse ( $>5\ \mu\text{m}$ ) and fine ( $\leq 5\ \mu\text{m}$ ) respiratory aerosols produced when breathing, talking, and singing and confirmed that fine aerosols contain more virus particles than coarse ones.  
***Ref [57] "Fine aerosols produced by talking and singing contain more SARS-CoV-2 copies than coarse aerosols and may play a significant role in SARS-CoV-2 transmission. Exposure to fine aerosols, especially indoors, should be mitigated. "***
14. This study found that aerosols are exhaled in various common activities; while sneezing expels the highest volume of aerosols, it is followed by significant volumes and infection risk ratio for coughing, singing, speaking, and breathing.  
***Ref [20] "The expelled volume of aerosols was highest for a sneeze, followed by a cough, singing, speaking, and breathing. (...) After 2 h of exposure, singing became the second highest risk scenario. One air exchange per hour reduced risk of illness by about a factor of 2. Six air exchanges per hour reduced risks of illness by a factor of 8-13 for the sneeze and cough scenarios and by a factor of 4-9 for the other scenarios."***



15. Transmission between individuals who are more than 6 ft away from each other has been documented, most clearly through the observation of superspreader events.[1, 9, 22, 23, 25]  
**Ref [1] "Airborne transmission of pathogens has been vastly underappreciated, mostly because of an insufficient understanding about the airborne behavior of aerosols and at least partially because of the misattribution of anecdotal observations. Given the lack of evidence for droplet and fomite transmission and the increasingly strong evidence for aerosols in transmitting numerous respiratory viruses,..."**  
**Ref [25] "Our finding of a highly-overdispersed offspring distribution highlights a potential benefit to focusing intervention efforts on superspreading."**
16. Transmission between individuals has been documented between people in adjacent rooms who do not encounter each other directly.  
**Ref [10] "By combining genomic sequence analysis and epidemiologic investigations, we identified a multibranch chain of transmission of this virus, including on international and domestic flights, as well as a probable case of aerosol transmission without direct person-to-person contact."**
17. Infections have been documented in health-care facilities, where there have been strict contact-and-droplet precautions and the use of personal protective equipment (PPE) designed to protect against droplets but not aerosol exposure.  
**Ref [14] "The index case was a symptomatic patient in whom isolation was discontinued after 2 negative results on nasopharyngeal PCR testing. The patient subsequently infected multiple roommates and staff, who then infected others."**
18. Experts from specialties encompassing aerosol studies, ventilation, engineering, physics, virology, and clinical medicine have joined together to produce a review to consolidate the evidence for airborne transmission mechanisms and offer justification for modern strategies for prevention and control of COVID-19 in healthcare and the community.  
**Ref [27] "This article collates and explores some of the most commonly held dogmas on airborne transmission in order to stimulate revision of the science in the light of current evidence. (...) There is little doubt that SARS-CoV-2 is transmitted via a range of airborne particle sizes subject to all the usual ventilation parameters and human behaviour."**
19. This study measured the dispersion of tracer gas in the drainage system of a building, providing circumstantial evidence that the flow of aerosols could account for transmission in a high-rise building.  
**Ref [30] "On the basis of circumstantial evidence, long-range aerosol transmission may have contributed to the community outbreak of COVID-19 in this high-rise building. The vertical transmission of diseases through aerosols in high-rise buildings demands urgent attention."**
20. This review covers the aerodynamics and different modes of transmission, including droplets, droplet nuclei, and aerosol particles, adding that SARS-CoV-2 spreads mainly through the air, and infected people can transmit it when they cough, sneeze, talk, or breathe.  
**Ref [31] "The main transmission route of SARS-CoV-2 is through the air (airborne transmission). This review details the airborne transmission of SARS-CoV-2, the aerodynamics, and different modes of transmission (e.g. droplets, droplet nuclei, and aerosol particles). SARS-CoV-2 can be transmitted by an infected person during activities such as expiration, coughing, sneezing, and talking."**
21. In 2023, Studies confirmed that airborne viruses were ejected and collected in the air in significant amounts, even from individuals not reporting high levels of symptoms.

**Ref [64] “Two individuals emitted 86% of airborne virus, and the majority of airborne virus collected was released on 3 days. Individuals who reported the highest total symptom scores were not those who emitted most virus.”**

22. Reviewing the evidence gathered from numerous articles, this study summarizes the case that the primary mode of transmission of SARS-CoV-2 is exposure to airborne respiratory particles, such as respiratory droplets and aerosols, carrying the virus.

**Ref [34] “COVID-19 disease, caused by the novel SARS-CoV-2 virus, can be transmitted from human to human by multiple means, including respiratory droplets, aerosols, and fomites. According to numerous studies, the principal mode of transmission of SARS-CoV-2 is exposure to airborne respiratory particles (respiratory droplets and aerosols) carrying the virus.”**

23. This study linked the amount of virus individuals produce in exhaled aerosols to conditions in which they are more likely to transmit COVID-19.

**Ref [58] “Coronavirus disease 2019 (COVID-19) transmission via exhaled aerosol particles has been considered an important route for the spread of infection, especially during super-spreading events involving loud talking or singing. However, no study has previously linked measurements of viral aerosol emissions to transmission rates. (...) Aerosol samples were collected using a BioSpot-VIVAS and a NIOSH bc-251 2-stage cyclone (...) COVID-19 cases were more likely to exhale SARS-CoV-2-containing aerosol particles close to symptom onset and during singing or talking as compared to breathing.”**

24. In a recent study, the presence of viruses in different sizes of aerosol particles was measured to be consistent with playing a key role in transmitting SARS-CoV-2 viruses. Particle number concentrations were measured, and multiple samples were collected on gelatin filters in two hospital wards during the alpha and delta variant outbreaks. SARS-CoV-2 RNA was found to exist in particles with aerodynamic diameters of 0.5-4 µm and in ultrafine particles (aerosols).

**Ref [60] “Aerosol particles proved to play a key role in airborne transmission of SARS-CoV-2 viruses. Therefore, their size-fractionated collection and analysis is invaluable. (...) Our results revealed that SARS-CoV-2 RNA is most likely to exist in particles with 0.5–4 µm aerodynamic diameter, but also in ultrafine particles.”**

## APPENDIX A

**Table A: Definitions related to the airborne transmission of a respiratory virus**

	<b>Brief Definition</b>
Aerosol	Suspension of particles in a gas carried along with airflow or currents, sometimes referred to as microscopic droplets or microdroplets.
Droplet	Liquid particles that can potentially carry pathogens (the term droplet is now being avoided for smaller particles due to the prefix “drop,” suggesting that it falls due to gravity).
Droplet Nuclei	Small particles (diameter less than 5 µm) that are the result of the desiccation of larger droplets.
Large Droplets	Large liquid particles (diameter larger than approximately 100 µm) that may carry pathogens whose trajectories are dictated by gravity and rapidly fall to the ground after emission.

Microdroplets	Small liquid particles (diameter typically less than approximately 100 $\mu\text{m}$ ) that may contain pathogens and can remain in the air longer and travel farther than the larger droplets while sometimes being the result of the desiccation of larger droplets. They are also referred to as aerosols.
Bioaerosol	A type of aerosol composed of fungi, bacteria, other microorganisms, and other biological matter, usually ranging from 1 nm to 100 $\mu\text{m}$ .
Particulate Matter	The combination of chemical and biogenic compounds of natural and/or anthropogenic origin, whose size varies between 1 nm and 100 $\mu\text{m}$ , and which are found in the air and can be diffused and transported even over long distances.
Aerosol Transmission	Transmission of a pathogen either through large particles of respiratory fluids (droplets) or through smaller particles that can remain aerosolized (droplet nuclei). This transmission mode can occur over larger distances and does not require close contact between the susceptible and infected individuals.
Droplet Transmission	Short-range, direct transmission of a pathogen over short distances (<3 m) through large droplets whose trajectories are dictated by gravitational settling.
Airborne Transmission	The transmission of an infectious disease through small particles suspended in the air, the aerosol. It is also referred to as aerosol transmission.

## APPENDIX B

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**Exhibit 4 follows on the next page:**

## **EXHIBIT 4**

### **Expertise of Voting Members of HICPAC**

There are 9 voting members of HICPAC as follows:

**1. Sharon Wright: As one can see below, Sharon Wright is an expert in medicine. She is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**

Sharon Wright, MD, MPH  
Education: Doctor of Medicine (MD), Master of Public Health (MPH)  
Infectious Disease Physician  
Chief Infection Prevention Officer  
Beth Israel Lahey Health  
Cambridge, MA  
Term: 5/4/2001- 6/30/2024

**2. Elaine Dekker: As one can see below, Elaine Dekker is an expert in medicine. She is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**

Elaine Dekker, RN  
Education: BS in Nursing  
Infection Prevention & Control Program Manager  
Priscilla Chan and Mark Zuckerberg San Francisco  
General Hospital & Trauma Center  
San Francisco, CA  
Term: 10/8/2018-12/31/2023

**3. David Jay Weber: As one can see below, David Jay Weber is an expert in medicine. He is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**

David Jay Weber, MD MPH  
Education: Doctor of Medicine (MD), Master of Public Health (MPH)  
Distinguished Professor of Medicine, Pediatrics and Epidemiology UNC School of Medicine and UNC Gillings School of Global Public Health  
Associate Chief Medical Officer, UNC Medical Center Medical Director, Department of Infection Prevention, UNC Medical Center  
Chapel Hill, NC  
Term: 1/20/23-6/30/2024

**4. Mohamad Fakh: As one can see below, Mohamad Fakh is an expert in medicine. He is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**



Mohamad Fakih, MD, MPH  
Education: Doctor of Medicine (MD), Master of Public Health (MPH)  
Vice President, Quality and Clinical Integration  
Ascension  
Grosse Pointe Woods, MI  
Term: 7/1/2019-12/31/2023

**5. Judith Guzman-Cottrill: As one can see below, Judith Guzman-Cottrill is an expert in medicine. She is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**

Judith Guzman-Cottrill, DO  
Education: Doctor of Osteopathic Medicine (DO)  
Professor of Pediatrics  
Division of Infectious Diseases  
Oregon Health & Science University  
Portland, OR  
Term: 7/1/2019-12/31/2023

**6. JoAnne Reifsnyder: As one can see below, JoAnne Reifsnyder is an expert in medicine and healthcare business administration. She is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**

JoAnne Reifsnyder, PHD, MBA, MSN  
Education: PhD in Nursing, Master of Business Administration (MBA) in Health/Health Care Administration/Management  
Executive Vice President, Clinical Operations  
Genesis HealthCare  
Kennett Square, PA  
Term: 7/1/2019-12/31/2023

**7. Erica Shenoy: As one can see below, Erica Shenoy is an expert in medicine and health economics. She is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**

Erica Shenoy, MD, PhD  
Education: Doctor of Medicine (MD), PhD in Health Policy/Economics  
Chief of Infection Control, Mass General Brigham  
Associate Chief, Infection Control Unit, Massachusetts General Hospital  
Associate Professor, Harvard Medical School  
Boston, MA  
Term: 1/20/2023-6/30/2026

**8. Colleen Kraft: As one can see below, Colleen Kraft is an expert in medicine. She is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**

Colleen Kraft, MD, MSc

Education: Doctor of Medicine (MD), MS in Clinical Research

Associate Professor, Pathology and Laboratory Medicine

Emory University School of Medicine

Atlanta, GA

Term: 5/4/2021-6/30/2024

**9. Jennie H. Kwon: As one can see below, Jennie H. Kwon is an expert in medicine. She is not an expert in aerosol science, industrial hygiene, ventilation engineering, UV and HEPA filtration, respiratory protection, or occupational health and safety.**

Jennie H. Kwon, DO, MSCI

Education: Doctor of Osteopathic Medicine (DO), Masters of Science in Clinical Investigation

Associate Professor

Medical Director of Infection Prevention and Senior Epidemiologist

Washington University

St. Louis, MO

Term: 1/20/23-6/30/2024