

World Health Network

MEMORANDUM

TO: **Hon. Xavier Bacerra**, Secretary, Department of Health and Human Services (HHS)

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

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

CC: Hon. Christi Grimm, Inspector General, HHS

FROM: Dr. Yaneer Bar-Yam, New England Complex Systems Institute, World Health Network

Kevin Bell, J.D., World Health Network

FURTHER CC, HICPAC MEMBERS:

Dr. Sharon Wright

Elaine Dekker

Dr. David Jay Weber

Dr. Mohamad Fakih

Dr. Judith Guzman-Cottrill

Dr. JoAnne Reifsnyder

Dr. Erica Shenoy

Dr. Colleen Kraft

Dr. Jennie Kwon

DATE: October, 30, 2023

RE: COMPLAINT FILED WITH THE HHS OFFICE OF INSPECTOR GENERAL (IG)

Please Note: This Memorandum is being sent to Hon. Xavier Bacerra, Dr. Mandy Cohen, Dr. Alexander Kallen and Hon. Christi Grimm both via email as a PDF attachment and physically in paper form via Federal Express. It is being sent by email only to HICPAC members.

We write to inform you that for the reasons discussed below, as Department of Health and Human Services employees and pursuant to the instructions set forth on the HHS Office of Inspector General website entitled "Submit a Hotline Complaint," a complaint was filed on October 29, 2023 with the IG by Yaneer Bar-Yam, New England Complex Systems Institute, World Health Network against Xavier Bacerra, Secretary, HHS (the Secretary), Mandy Cohen, Director U.S. Centers for Disease Control (the Director), and Alexander Kallen, Designated Federal Officer, Healthcare Infection Control Practices Advisory Committee (the Federal Officer) for the charge of Gross Misconduct.

We have received confirmation of this filing which is appended at the end of this document. We further inform you that whether or not the IG chooses to conduct its own investigation of these matters, the facts set forth in that complaint and discussed in this Memorandum still stand. 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, in clear violation of the law. For this reason, we have filed a complaint with the Inspector General for a charge of Gross Misconduct.

CDC guidance based on Guidelines from an Advisory Committee which is itself illegally constituted, whose very membership composition stands in violation of FACA and its own Charter, cannot be considered legitimate. As the product arising from an illegally constituted advisory committee, in the face of a court challenge, such guidance would face a serious risk of being declared reversable error – especially after HHS and CDC have by this memorandum been served clear notice of the illegal composition of HICPAC's membership.

Such a court challenge might be brought, for example, by an organization representing disabled persons, a union representing healthcare workers, a group of retired physicians who believe the

oath of "Do No Harm" is being violated, a motivated individual with private means whose mother dies of a hospital-acquired Covid-19 infection, a couple with crowd sourced funding whose child is crippled in the same way, an individual or group disturbed by CDC's actions who organize around a PR campaign, etc.

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.

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 HIPCAC'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 in the Complaint and Associated Evidentiary Filing:

The following sets forth the points in the Complaint filed with the HHS Office of Inspector General.

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 "<u>Membership and Designation</u>. The Committee <u>shall</u> (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 (HICPAC) 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 Reifsnyder (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 HIPCAC 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 statue. 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 Secretary, CDC Director and HICPAC Designated Federal Officer 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 infections 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 <u>significant</u> 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 the publication *Indoor Air*, Vol. 32 Issue 5 in 2022, 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.

Exhibit 1 is by Dr. Stephane 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.

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: <u>Preventing Transmission</u> (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, HIPCAC 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 and when it opens, scroll down slightly to see the two video presentations).

 $https://www.nationalnursesunited.org/sites/default/files/nnu/documents/0723_HICPAC_experts_letter_background_combined_FINAL.pdf$

The informational slide deck outlining the Draft Guidelines makes little mention of aerosol transmission of infectious pathogens, uses for 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 points of view focusing on aerosol transmission, 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 prejudgment 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 *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 serving.

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: The page immediately following contains confirmation of the filing of the Complaint from the U.S. Department of Health and Human Services Office of Inspector General.



Confirmation

You have successfully submitted your complaint.

Thank you for your submission. Hotline tips are incredibly valuable, and we appreciate your efforts to help us stamp out fraud, waste, and abuse.

We will review your complaint for relevance and completeness. If you have identified yourself, a reviewing official may contact you for further information. It is important to note that you may not be contacted by an investigator but that does not mean your complaint is not being investigated. Due to the high volume of complaints we receive, it is not possible to contact every complainant. The Hotline will not be able to confirm receipt of your complaint or respond to any inquiries about action taken on your complaint.

You may request information about your complaint through the <u>OIG Freedom of Information Act</u> office. Remember to phrase your request in terms of a search for records pertinent to your complaint, not status. You should wait at least six months before filing such a request.

Return to HHS-OIG Hotline

Share your feedback, help us improve

We have launched our new complaint forms, and would appreciate your feedback. Please tell us about your experience and provide any recommendations on how we can improve the website. Thank you for taking the time to help us improve our complaint process.