

This Complaint is hereby filed with the Health and Human Services (HHS) Office of Inspector General (IG) via the IG'S website entitled "Submit a Hotline Complaint." The accompanying document *Analysis and Evidence Supporting a Complaint of Gross Misconduct* (submitted under the Evidence section of the on-line filing form) expands on the points contained in this Complaint and offers evidence to support them.

This 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: For important comments regarding "Start Date" please see the Analysis

Background:

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.

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).

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.

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.

The Exhibits set forth in the accompanying document *Analysis and Evidence Supporting a Complaint of Gross Misconduct* 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.

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

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."

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:

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.

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 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.

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 process of developing and approving the Draft Guidelines currently underway in HICPAC must immediately cease.
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.
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.