IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

AMERICAN ACADEMY OF PEDIATRICS, *et al.*, *Plaintiffs,* v. ROBERT F. KENNEDY, JR., in his official capacity as Secretary of the Department of Health and Human Services; *et al.*, *Defendants.*	Case No. 1:25-cv-11916 (BEM)

DECLARATION OF JAMES J. OH IN SUPPORT OF
PLAINTIFFS' MOTION TO COMPLETE THE ADMINISTRATIVE RECORDS

Pursuant to 28 U.S.C. § 1746, I declare under penalty of perjury that the following is true and correct:

1. I am an attorney at the law firm Epstein Becker & Green and lead trial counsel for Plaintiffs in the above-titled action.

2. I submit this declaration in support of Plaintiffs' Motion to Complete the Administrative Records.

3. Attached hereto as **Exhibit 1** is a true and correct copy of a memorandum to the Secretary recommending an "informed consent process" for COVID-19 vaccinations, designated as HHS_AAP 000255-000263 in AR 1.

4. Attached hereto as **Exhibit 2** is a true and correct copy of a memorandum to the Secretary regarding COVID-19 vaccinations for pregnant women, designated as HHS_AAP 000094-000097 in AR 1.

5. Attached hereto as **Exhibit 3** is a true and correct copy of the final agenda for the June 25-26, 2025, meeting of the Advisory Committee on Immunization Practices ("ACIP"), designated as HHS_AAP 003349-003350 in AR 2.

6. Attached hereto as **Exhibit 4** is a true and correct copy of the summary of anticipated votes at the September 2025 ACIP meeting, designated as HHS_AAP 002361-002362 in AR 2.

7. Attached hereto as **Exhibit 5** is a true and correct copy of correspondence between [redacted], "[redacted]", and [redacted], designated as HHS_AAP 015991 in AR 3.

8. Attached hereto as **Exhibit 6** is a true and correct copy of correspondence between [redacted] and [redacted], designated as HHS_AAP 016028 – 016029 in AR 3.

9. Attached hereto as **Exhibit 7** is a true and correct copy of correspondence between [redacted], [redacted], [redacted], and [redacted], designated as HHS_AAP 015578 – 015583 in AR 3.

10. Attached hereto as **Exhibit 8** is a true and correct copy of correspondence between "[redacted]", [redacted], and [redacted], designated as HHS_AAP 015557 in AR 3.

11. Attached hereto as **Exhibit 9** is a true and correct copy of correspondence between [redacted], [redacted], "[redacted], "[redacted]", and [redacted], designated as HHS_AAP 015587 in AR 3.

12. Attached hereto as **Exhibit 10** is a true and correct copy of correspondence between [redacted] and [redacted] designated as HHS_AAP 015684 in AR 3.

13. Attached hereto as **Exhibit 11** is a true and correct copy of correspondence between [redacted] to [redacted], designated as HHS_AAP 015777-015778 in AR 3.

14. Attached hereto as **Exhibit 12** is a copy of correspondence between [redacted] to "R Kennedy" and "[redacted]", designated as HHS_AAP 016036-016037 in AR 3.

15. Attached hereto as **Exhibit 13** is a true and correct copy of an email dated May 19, 2025, from Hannah Anderson to William Archer and Matthew Thompson regarding ACIP membership that was provided to Senator Bernie Sanders by Dr. Debra Houry, the former chief medical office at the CDC.

16. Attached hereto as **Exhibit 14** is a true and correct copy of an email dated May 19, 2025, from Dr. Demetre Daskalakis, the former director of the National Center for Immunization and Respiratory Diseases to Dr. Debra Houry that was provided to Senator Bernie Sanders by Dr. Debra Houry, the former chief medical office at the CDC.

17. Attached hereto as **Exhibit 15** is a true and correct copy of an email dated May 21, 2025, from Dr. Debra Houry to Dr. Demetre Daskalakis that was provided to Senator Bernie Sanders by Dr. Debra Houry, the former chief medical office at the CDC.

18. Attached hereto as **Exhibit 16** is a true and correct copy of an email dated June 16, 2025, from Stuart Burns to Debra Houry, Rebecca Greco Kone, Nita Witkofsky, and Mina Zadeh that was provided to Senator Bernie Sanders by Dr. Debra Houry, the former chief medical office at the CDC.

19. Attached as **Exhibit 17** are true and correct copies of email exchanges between counsel during their meet and confer discussions.

I declare under penalty of perjury and under the laws of the State of Illinois and the law of the United States that the foregoing is true and correct.

Executed on July 17, 2026.

/s/ James J. Oh
James J. Oh

EXHIBIT 1

MEMORANDUM TO THE SECRETARY

THROUGH: HEATHER MELANSON, CHIEF OF STAFF
CORTNEY MCCORMICK, EXECUTIVE SECRETARY

FROM: MATTHEW MEMOLI, M.D., M.S., PRINCIPAL DEPUTY DIRECTOR, NIH

SARA BRENNER, M.D., M.P.H., PRINCIPAL DEPUTY COMMISSIONER, FDA

SUBJECT: Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age

DATE: May 12, 2025

On June 18 and June 24, 2022, Secretary of Health and Human Services Becerra issued "Secretarial Directives" recommending that children between the ages of 6 months and 17 years receive the COVID-19 vaccine. At this time, after a review of relevant existing data, including new studies unavailable to Secretary Becerra when he issued his Directives on June 18, 2022, and June 24, 2022, there is no clear evidence that the benefits of vaccination for COVID-19 outweigh the risk of harm in children under 18 years of age.

Vaccines are products designed to be given to individuals to stimulate immunity against a certain pathogen thereby preventing disease and its sequelae. A departmental recommendation of any vaccination should be based on a careful evaluation of probable benefits weighed against risks and potential harms. The benefits and risks of vaccination should be clearly established using randomized controlled trials prior to a recommendation. Vaccination of any population should only be recommended when it is clear, based on the best available evidence from these trials, that the benefits are likely to outweigh the known and potential risks of the vaccines. Once a recommendation is made, reevaluation of the recommendation is regularly required, as new data will continue to emerge as a vaccine is used in a population and as a pathogen evolves.

Risks of COVID-19 to Children

Mortality

The risks associated with SARS-COV-2 infection, and subsequent clinical disease known as COVID-19, in children under 18 has been extremely low since the novel virus emerged in 2019. A review using death certificates in countries with widespread COVID-19 testing found that deaths were over-attributed to COVID-19 by as much as 40-50% early in the pandemic and possibly as high as 60-70% after the emergence of Omicron (Friis, 2023). This type of over-attribution led to widespread misunderstanding among the U.S. population about the mortality attributable to COVID-19 in children due to CDC's public dashboard on COVID-19 deaths, COVID Data Tracker, which consistently overstated the number of deaths attributed to COVID-19 in children by 20% or more compared with the CDC's standard and more carefully adjudicated National Center for Healthcare Statistics database (Krohnert, 2023). A clearer picture of the low risk in children emerged in multiple studies, including a landmark study from 2020-2021 of over 750,000 healthy children ages 5-17 infected with SARS-CoV-2. This study identified no deaths due to the virus in their cohort (Sorg, 2022). This study was performed early in the pandemic when death rates were highest from COVID-19 and prior to the current widespread immunity and evolution of milder SARS-COV-2 variants. A subsequent study found the omicron subvariants later in the pandemic posed even lower risk to children with an over 3-fold reduction in infection mortality rate in children and young people compared to early in the pandemic (Hani, 2023), while some of the few overall deaths observed occurred in vaccinated children. By the end of 2023, CDC reported a death rate in children under 18 of 0.5 per million cases (https://data.cdc.gov/Public-Health-Surveillance/Rates-of-COVID-19-Cases-or-Deaths-by-Age-Group-and/54ys-qyzm) with that number likely an over-estimate given unreliable denominators (total number of actual infections was higher than captured in the data) and has been decreasing even further since. These data together suggest that the mortality from SARS-CoV-2 infection among children without underlying health conditions is much less than one per million, which is significantly less than from RSV or influenza. Furthermore, there is no clear evidence that vaccination plays a role in preventing these exceedingly rare deaths.

Hospitalization

Hospitalization rates of children from COVID-19 are also extremely low and have decreased since 2019; they are now substantially lower than for influenza and RSV in the United States. Similar to COVID-19 deaths, starting early in the pandemic, hospitalization rates of children due to SARS-CoV-2 in the U.S. were likely overestimated by at least 40% (Beck, 2021). This suggests that nearly half or more of the children who had been reported to be hospitalized from COVID-19 were hospitalized either due to other illness or injury, or unnecessarily hospitalized due to fear of COVID-19. This again gave the public an inaccurate sense that hospitalization due to

severe COVID-19 was common in children. This also likely led to an inflated perceived effect of vaccination on hospitalization, as the vaccine availability calmed some of these fears.

Multi-Inflammatory Syndrome in Children (MIS-C)

An additional condition of potential risk related to COVID-19 in children is a post-infection inflammatory condition, named Multi-Inflammatory Syndrome in Children (MIS-C). This condition was rare, but is now exceedingly rare with less than 80 total cases nationwide in 2024. To date, no randomized controlled trials have demonstrated a reduction in risk of this condition due to vaccination. Observational data assessing effectiveness of COVID-19 vaccines against MIS-C are likely unreliable due to underlying biases (Høeg, 2024).

Long COVID

Long COVID is a diagnosis which suffers from broad and imprecise case definitions (Høeg, 2024). However, the most well-conducted studies indicate that infection-related lasting symptoms in children are exceedingly rare (Selvakumar, 2023; Høeg, 2023). Randomized studies have also not assessed the efficacy of vaccination against Long COVID (Munro, et al.). One study among Norwegian children found vaccination to be an independent risk factor for more severe fatigue following SARS-CoV-2 infection (Selvakumar, 2025) suggesting a possible worsening of Long COVID associated symptoms, but observational studies have been mixed and prone to multiple biases when evaluating the relationship between vaccination and Long COVID. (Høeg, 2023; Høeg, 2024).

Vaccination Risks

Post-Vaccination Myocarditis and Pericarditis, Including Sudden Cardiac Death and Sequelae

Post-vaccination myo- and pericarditis are well-established side effects of COVID-19 vaccination identified in adolescent boys and girls (Krug, 2022; Kracalik, 2023). About 1 in 2,700 boys vaccinated with a second dose of Pfizer were hospitalized with myo- and/or pericarditis according to a prospective study from Hong Kong (Chua, 2022). Post-vaccination myocarditis can be severe and may have lasting consequences in children and young adults (Kracalik, 2023). In that study, about 1 in 5 children were admitted to intensive care for the condition. At 90 days follow up, over 30% had still not been cleared for physical activity and about 25% were still being prescribed medications. Rates of subclinical myo- and pericarditis, and associated long term health outcomes, have yet to be fully characterized.

Deaths post-vaccination due to myocarditis appear to be rare but have been reported in young people (Mevorach, 2021). A nationwide Korean study (Cho, 2023) attributed 21 total deaths to vaccination-induced myocarditis, corresponding to a death rate of 1-2 per million primary series mRNA vaccinations given in the 12–44-year-old age group, consistent with a nationwide study from Qatar (Butt, 2023). In these two studies together, there was one death and three

fulminant cases in those under 21, highlighting a serious risk of vaccination that should be weighed with a lack of certainty of vaccination benefit and an exceedingly low rate of death among children—well below 1 per million infections in healthy children.

While myocarditis can be a consequence of SARS-CoV-2 infection in children and young people, the risk from vaccination appears to be significantly higher. A study performed in 2021 (Karlstad, 2022) that included 23 million residents of Norway, Sweden, Denmark, and Finland ages 12 and older found no cases of post-COVID myocarditis in children between 12-15 years of age, but did find cases in 16–24-year-olds. However post-vaccination myocarditis was at least six times more common than myocarditis post-COVID infection among both males and females (details in supplement). Furthermore, no robust evidence has shown vaccination to reduce post-COVID-19 myocarditis risks.

Additional Safety Signals and Potential Risks of Vaccination in Children

Additional risks that have been associated with mRNA vaccination include but are not limited to seizures, Bell's palsy, transverse myelitis, clotting disorders, strokes, heart attacks, and acute kidney injury (Faskova, 2024; Dag Berild, 2022; Lim 2025; Hu, 2024; Hwang, 2025). Analysis of the randomized trials in children suggests there may be an increased risk of non-COVID-19 lower respiratory tract infection (Hoffman, 2023). The potential benefit in healthy children of vaccination is very small given the low risk of severe disease and, based on existing data, may not outweigh the risks of vaccination. This is most likely the reason why, as mentioned during the 2025 ACIP meeting on April 15, 2025, the U.S. is currently a global outlier in recommending yearly routine vaccination of children under 18 for COVID-19. The WHO European Nations, Australia, Canada, and the UK do not currently recommend routine vaccination of non-high-risk children. Denmark notably does not offer the COVID-19 vaccine to anyone under the age of 65 unless they have certain underlying medical conditions and children <18 may not receive a COVID-19 vaccine unless they have a chronic illness and have been assessed by a pediatrician who recommends vaccination for them. Notably, the Director General of the Danish Health Authority, Søren Brostrøm, stated in the summer of 2022 that "it was a mistake" (det var in fejl) to vaccinate children for COVID-19. Furthermore, updated versions of COVID-19 vaccines, which claim to provide protection against severe illness due to infection with new subvariants, may have additional, new, and/or unknown risks. The clinical efficacy of updated vaccines has also not been established on the basis of randomized controlled trials and health outcomes data; and similarly, comprehensive adverse event data has yet to be captured and fully analyzed for these new products, leading to an incomplete benefit/risk analysis. An example of this in another setting was the 2009 inactivated influenza vaccine, Pandemrix, manufactured by Glaxo Smith Klein which caused narcolepsy in children (Buonocore, 2022). Well over 1,000 children were affected by the time this link was made with the vaccine the following year (Doshi, 2018) as well as additional serious safety concerns. This is a good example of why continued consideration and evaluation of vaccine recommendations must be done regularly.

Lack of Clear Evidence of Vaccination Benefit

As described above, there is insufficient evidence based on clinical outcomes data to render a positive benefit risk assessment for vaccinating children at this time. The initial clinical trials in children and adolescents included less than 2,500 children and were unable to determine efficacy against severe COVID-19 (Frenck, 2021; Ali, 2021; Walter, 2022; Creech, 2022; Anderson, 2022; Muñoz, 2023). Any purported protection against symptomatic disease identified in epidemiological data appears modest and wanes rapidly (Munro, 2024; Chemaitelly, 2022). More recent randomized placebo-controlled trials of original and/or updated vaccine formulations have *not* been conducted to evaluate the safety or efficacy of any COVID-19 vaccines. This is especially relevant and necessary in the setting of current widespread population immunity (as understood from seroprevalence studies) or against the new subvariants in children or adults. What makes this even more concerning is that by the time a new formulation is manufactured and released based on currently circulating variants, the virus has evolved away from the variant the vaccine was designed against, likely reducing efficacy and again altering the benefit/risk calculation

To estimate efficacy, randomized placebo-controlled trials of boosters and updated vaccination formulas have thus far measured neutralizing antibody response to re-vaccination. However, the clinical correlate of protection to this response among children and adults who have previously had SARS-CoV-2 infection one or multiple times has not been established (Zhang, 2025). Further the ever-changing nature of the SARS-COV-2 viral antigens makes it unlikely that the current vaccination strategy will provide durable immunity against COVID-19. Observational data are largely unreliable to assess vaccine efficacy due to multiple biases; one of the most significant being the "Health Vaccinee Bias" that reflects better underlaying health among vaccinated populations (Høeg, 2023, Fürst, 2024, Chemeitelly, 2024). For this reason, the past and current true efficacy of the COVID-19 vaccines remains unclear.

Conclusions

In conclusion, currently available data and published studies do not provide sufficient clinical and scientific evidence to broadly recommend COVID-19 vaccination for those under 18 years of age. No clear benefit of vaccination in children under 18 has been established with current formulations of COVID-19 vaccines against current circulating variants, especially given the widespread immunity from prior infection(s) that currently exists in the population. Given the low risk of infection to those under the age of 18, the known risks of vaccination outweigh any small potential benefit. It is HHS's priority to ensure the health and safety of this vulnerable population—whether risk comes from a disease or a treatment/vaccine. We have a duty to set a gold standard for scientific review of products that are recommended to Americans and that those products, including vaccines, must have clearly defined benefits that outweigh the risks. Ultimately, decisions regarding risk and benefit must be tailored to the individual and made through shared decision making between patients and their physicians.

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EXHIBIT 2

Memorandum

Date: May 12th, 2025

To: Secretary Robert F. Kennedy, Jr.

From: Tracy Beth Høeg, MD, PhD (FDA)

Subject: COVID-19 vaccine safety in pregnant women

A lack of high-quality data on the safety of mRNA Vaccines during pregnancy

The initial randomized clinical trials of Pfizer, Modern and Novavax excluded pregnant women; for this reason, safety could not be determined from these initial trials. In March of 2021, Pfizer stated that " Available data on Pfizer-BioNTech COVID-19 Vaccine administered to pregnant women are insufficient to inform vaccine-associated risks in pregnancy." Pfizer announced in February of 2021 that they would enroll 4,000 women in a randomized controlled trial to evaluate safety, tolerability and immunogenicity in healthy pregnant women. However, Pfizer ended up substantially reducing the size of the study to only include only 173 women vaccinated late in pregnancy (between 24 and 34 weeks). Not only was this study underpowered to detect safety issues during pregnancy, it could not provide *any data at all* on the safety of vaccination early in pregnancy up until week 24. Importantly, the risk of toxicity leading to miscarriage or developmental defect is the highest in the early phase of pregnancy, during the first and early second trimester.

Notably, Novavax has thus far not sought authorization of their vaccine in pregnancy as they lacked safety data. However, Pfizer and Moderna also lack high quality, randomized trial safety data – specifically, there was one insufficiently powered (very small) randomized study of the Pfizer COVID-19 vaccine and no randomized trial pregnant women has been done of the Moderna COVID-19 vaccine.

Limitations of observational data to evaluate safety of vaccines in pregnancy

Because of the above issues, our knowledge about the safety of COVID vaccination during pregnancy relies on lower quality data including findings from pharmacovigilance systems and

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on retrospective observational studies. There are numerous issues with relying on these datasets and analyses.

First, pharmacovigilance data tends to be vastly underreported. (Shumabukuro, 2015) Pregnant women or their obstetricians may not consider the vaccine as a cause of common or non-rate pregnancy outcomes such as miscarriage or fetal abnormality. Also, even if reported to a phamacovigilance database, small percentage increases (such as a couple of percentage points) in conditions such as fetal loss may not be found to be statistically significant from baseline rate but may still impact many women.

Second, observational studies are prone to multiple potential biases, of which *healthy vaccinee bias* (where people who get vaccinated tend to be healthier at baseline than those who do not get vaccinated) is potentially the most important. This bias has been thoroughly documented for the COVID-19 and the influenza vaccine in numerous countries across the world(Høeg, 2023; Fürst, 2024; Chemeitelly, 2024; Reidmann, 2025 Remschmidt, 2015). Women who have better underlying health are also less likely to have pregnancy complications. This may cause us to miss real safety issues if the unvaccinated are more prone to pregnancy complications.

Furthermore, another important bias, selection bias, stems of the fact only a few observational studies have looked at COVID vaccination during early stages of pregnancy, when the risk of toxicity leading to miscarriage or developmental defect is the highest. Most observational studies have not found a significant association between vaccination and adverse outcomes in pregnancy.

Potential safety concerns

However, a large study from Ontario did find a higher rate of fetal loss among women vaccinated prior to week 20. (Velez, 2023) This associations disappeared when excluding induced abortions. However, it is unclear if these were truly elective or recommended due to impending fetal loss. Furthermore, this study adjusted for time of year, which was likely to be inappropriate given the rapid timing of the vaccination rollout in Ontario in this age group.

Memorandum

Another study from Israel (Dick, 2022), where the population was almost exclusively vaccinated with the Pfizer mRNA vaccine found that women vaccinated in the second trimester had a 1.9% higher rate of preterm birth and this was highly significant. This signal persisted after adjusting for multiple potential confounders.

Additionally, another small study of women who underwent *in vitro* fertilization found a 50% higher clinical pregnancy loss rate among COVID-19 vaccinated women compared with unvaccinated (Aharon, et al. 2022), however this was not found to be statistically significant and again, observational studies are subject to multiple biases.

Importantly, the COVID-19 mRNA vaccines have been shown in a study in the American Journal of Obstetrics and Gynecology to cross the placenta (Lin, 2024). mRNA vaccination has also been linked to multiple types of blood clots (Faskova, 2024). Placental blood clots can decrease oxygen to the fetus, cause birth defects, growth restriction, miscarriage and other pregnancy complications.

Uncertainty about vaccine efficacy

In the setting of widespread immunity from prior infection and a lack of randomized placebo control trials looking at clinical outcomes in this setting, the current benefit of mRNA COVID-19 vaccination against severe disease is uncertain. This is because vaccine efficacy in our current circumstances has been deduced from observational data and immunobridging data and the applicability of the initial randomized controlled trials to today's epidemiological circumstances and in a non-immune naïve population is not well defined.

Conclusion

Due to a lack of high-quality data demonstrating safety of the mRNA vaccines during pregnancy and some basis for concern, it would be wise to err on the side of caution and recommend against during vaccination in pregnancy until there is certainty the benefits of vaccination are likely to outweigh potential risks to the mother and developing baby.

References

Memorandum

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EXHIBIT 3

Final Agenda

MEETING OF THE ADVISORY COMMITTEE ON IMMUNIZATION PRACTICES (ACIP)

Centers for Disease Control and Prevention

Atlanta, Georgia 30329

Wednesday, June 25, 2025

10:00	**Opening Remarks**	Dr. Martin Kulldorff (ACIP Chair)
10:15	**Welcome and Roll Call**	Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
10:35	**Update on Work Groups**	Dr. Martin Kulldorff (ACIP Chair)
11:00	**COVID-19 Vaccines**	
	Introduction	Dr. Adam MacNeil (CDC/NCIRD)
	COVID-19 epidemiology	Dr. Adam MacNeil (CDC/NCIRD)
	COVID-19 vaccine effectiveness update	Dr. Adam MacNeil (CDC/NCIRD)
	COVID-19 safety update	Dr. Sarah Meyer (CDC/NCEZID)
	COVID-19 vaccine coverage and implementation	Dr. Georgina Peacock (CDC/NCIRD)
	Evidence to recommendations (partial)	Dr. Adam MacNeil (CDC/NCIRD)
1:00	***Lunch***	
1:30	**Agency Updates**	*CDC, CMS, FDA, HRSA, IHS, NIH*
2:00	**RSV Vaccines- Maternal/Pediatric**	
	Introduction	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on uptake of maternal vaccine and nirsevimab	Dr. Georgina Peacock (CDC/NCIRD)
	Effectiveness and impact of RSV prevention products in infants during the 2024-2025 season	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on safety of maternal vaccine and nirsevimab	Dr. Malini DeSilva (HealthPartners), Dr. Matthew Daley (Kaiser Permanente Colorado)
	Updates and summary of the Evidence to Recommendation Framework for clesrovimab	Dr. Adam MacNeil (CDC/NCIRD)
	Updates on clinical considerations for clesrovimab	Dr. Adam MacNeil (CDC/NCIRD)
	Proposed Recommendations	Dr. Adam MacNeil (CDC/NCIRD)
	Updates to RSV vaccines VFC resolution	Dr. Georgina Peacock (CDC/NCIRD)
4:00	***Break***	
4:15	Public Comment	
5:00	**Votes**	
	RSV Vaccines- Pediatric	Dr. Adam MacNeil (CDC/NCIRD)
	RSV Vaccines- VFC	Dr. Georgina Peacock (CDC/NCIRD)
5:30	**Adjourn**	

Thursday, June 26, 2025

8:00	**Welcome and Roll Call**	Dr. Mina Zadeh (ACIP Executive Secretary, CDC)
8:15	**Influenza Vaccines**	
	Introduction	Dr. Vivien Dugan (CDC/NCIRD)
	Flublok in older children and adolescents: immunogenicity and safety	Dr. Pedro Folegatti (Sanofi Pasteur)
	Estimates of influenza burden and burden averted through vaccination	Dr. Vivien Dugan (CDC/NCIRD)
	Proposed recommendations for 2025-26	Dr. Vivien Dugan (CDC/NCIRD)
	Presentation regarding thimerosal in vaccines	Lyn Redwood, RN, MSN
	Proposed recommendations regarding thimerosal containing influenza vaccine	Dr. Martin Kulldorff (ACIP Chair)
10:15	***Break***	
10:30	**Chikungunya Vaccines**	
	Introduction	Dr. Lyle Petersen (CDC/NCEZID)
	EtR (partial) for use of live attenuated and virus-like particle chikungunya vaccines in U.S territories	Dr. Lyle Petersen (CDC/NCEZID)
	Safety update on live attenuated chikungunya vaccine and use among older persons	Dr. Lyle Petersen (CDC/NCEZID)
10:45	**Anthrax Vaccine**	Dr. Brendan Jackson (CDC/NCEZID)
10:50	**MMRV Vaccine**	
	Presentation on MMRV vaccine in children under under 4 years of age	Dr. Martin Kulldorff (ACIP Chair)
	Proposed recommendations regarding MMRV in children under 4 years of age	Dr. Martin Kulldorff (ACIP Chair)
11:20	***Break***	
11:30	Public Comment	
12:15	***Break***	
12:30	**Votes**	
	Influenza Vaccines	Dr. Vivien Dugan
	Thimerosal containing influenza vaccine recommendations	Dr. Martin Kulldorff (ACIP Chair)
1:00	**Adjourn**	

Acronyms

CDC	Centers for Disease Control and Prevention
CMS	Centers for Medicare & Medicaid Services
COVID-19	Coronavirus disease 2019
EtR	Evidence to Recommendations Framework
FDA	Food and Drug Administration
HRSA	Health Resources and Services Administration
IHS	Indian Health Service
MMRV	Measles, Mumps, Rubella, Varicella Vaccine
NCIRD	National Center for Immunization & Respiratory Diseases
NCEZID	National Center for Emerging and Zoonotic Diseases
NIH	National Institutes of Health
RSV	Respiratory Syncytial Virus
VFC	Vaccines for Children

EXHIBIT 4

Advisory Committee on Immunization Practices (ACIP)

Next ACIP Meeting: Anticipated Votes

For Everyone
SEPT. 19, 2025

WHAT TO KNOW

- ACIP's next meeting will be held on September 18-19, 2025.
- Get meeting information and read draft vote language below.

Summary of anticipated votes

Several votes are planned during the September 18-19, 2025 ACIP meeting.

The vote language shown below is considered draft. All vote language is subject to change and will continue to be updated in advance of the ACIP meeting.

Anticipated votes

Measles, Mumps, Rubella, and Varicella (MMRV) Vaccines

VOTE: The pediatric vaccine schedule should be updated to reflect the following change:

- For measles, mumps, rubella and varicella vaccines given before age 4 years, the combined MMRV vaccine is not recommended.
- Children in this age group should receive separate measles, mumps, and rubella vaccine and varicella vaccine (MMR+V).

Hepatitis B Vaccines

VOTE: All pregnant women should be tested for hepatitis B infection.

VOTE: The pediatric vaccine schedule should be updated to reflect the following change:

- If a mother tests HBsAG-negative:
  - The first dose of the Hepatitis B vaccine is not given until the child is at least one month old.
  - Infants may receive a dose of hepatitis B vaccine before one month according to individual based decision-making.*

**Also referred to as shared clinical decision-making.*

COVID-19 Vaccines

VOTE: It is the sense of the committee that the CDC engages in an effort to promote more consistent and comprehensive informed consent processes, and as part of that considers adding language accessible to patients and medical providers to describe at least the six risks and uncertainties included in the WG chair presentation.

VOTE: It is the sense of the committee that state and local jurisdictions should require a prescription for the administration of a COVID-19 vaccination.

VOTE: It is the sense of the committee that in conversations with patients before COVID-19 vaccination, authorized healthcare providers discuss the risks and benefits of the vaccination for the individual patient. The discussion should consider known risk factors for severe outcomes from COVID-19, such as age, prior infections, immunosuppression, and certain comorbidities identified by the CDC, and include a discussion of the

potential benefits and risks of vaccination and related uncertainties, especially those outlined in the vaccine information statement, as part of informed consent.

VOTE: The pediatric and adult immunization schedules for administration of FDA-approved COVID-19 vaccines should be updated as follows:

- **Adults 65 and older:** Vaccination based on individual-based decision-making*
- **Individuals 6 months to 64 years:** Vaccination based on individual-based decision-making—with an emphasis that the risk-benefit of vaccination is most favorable for individuals who are at an increased risk for severe COVID-19 disease and lowest for individuals who are not at an increased risk, according to the CDC list of COVID-19 risk factors.

**Also known as shared clinical decision making.*

SOURCES

CONTENT SOURCE:
National Center for Immunization and Respiratory Diseases (NCIRD)

EXHIBIT 13

Houry, Debra E. (CDC/IOD)

From: Reczek, Jeffrey (CDC/OD/CDCWO)
Sent: Monday, May 19, 2025 9:03 AM
To: Houry, Debra E. (CDC/IOD)
Subject: Fw: DRAFT DELIBERATIVE

Categories: 4

As discussed. I think this was also meant for Buzzelli.

Jeff Reczek
Director
CDC Washington
[redacted]

From: Anderson, Hannah (HHS/IOS) <[redacted]>
Sent: Monday, May 19, 2025 8:28 AM
To: Archer, William (HHS/IOS) <[redacted]>; Thompson, Matthew (HHS/ASL) <[redacted]>
Cc: Reczek, Jeffrey (CDC/OD/CDCWO) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>
Subject: DRAFT DELIBERATIVE

Reyn-

Bobby has asked for the following changes to be made for the next ACIP meeting:

1. Replace the members with the ten identified
2. Add votes on "joint decision making" for Hep B (for healthy children and potentially others) and multi-dose flu for pregnant women and children
3. Announce that we are bringing back the 7 year review and the biannual report on vaccines
4. Review of the definition of vaccine

Feel free to loop with Jeff and Stuart and then come check in with me.

Hannah

Hannah Anderson
Deputy Chief of Staff, Policy
U.S. Department of Health and Human Services (HHS)

EXHIBIT 14

Monday, May 19, 2025
9:29 AM

Secretary Request on Members.

Members:
Secretary wants to replace 10 members on the ACIP committee. He has a bench of 10 ready to replace. He doesn't care which members. They think last minute appointments were a way to block. Didn't ask us for help. They know who they want to put on. They want us to remove the newest people on whether they are newly appointed. Who is first on, who is first off, and what is their area that they bring to the table.

Agenda Items:
If they are going to bring 10 new members, there are several issues to be discussed. One item that is included:

- Hepatitis B for healthy infants-eliminating
- Multidose vial- Thimerisol Free recommendation
- Vitamin K dose in kids???
- 7 year review of the childhood immunization schedule- announcement

Is there a hep B workgroup? What's time sensitive on the current agenda?

The new members may have trouble voting because they have not been on for long. Some of the members may be

HPV voting plan?

Created with OneNote.

5.19.2025 ACIP w iOD, 4pm

Monday, May 19, 2025
4:02 PM
Meeting to discuss iOS plan for change in membership of ACIP

From Stuart Burns:
Option 1: Remove all members and replace with new members reflecting the priorities of the administration
Option 2: Roll off enough to have new members as voting majority on the committee to reflect new admin perspective.

Stuart Burns will be writing a new memo to support this plan. Stated objective was to "depoliticize" the committee by installing people more aligned to the Secretary's agenda.

One topic discussed was removal of thimerisol from flu vaccines. Dr. H and I encouraged this change to come from FDA that has dominion over ingredients of vaccines. Stuart commented that this was Dr. Weldon's plan 2o years ago. We highlighted that the ACIP may not support a change given the lack of evidence that this ingredient causes adverse events but that FDA could decide to do this as a matter of principal to avoid the criticism that this generates despite the lack of a safety signal.

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

EXHIBIT 15

1) Regular workgroup reconstituted and question presented with full data review and Evidence to Recommendation (EtR) Framework completed to be presented to the committee at regular pace, may take a couple of months.
2) Accelerated workgroup review, ad hoc ACIP meeting with ETR presented- less optimal in a non-public health emergency
3) Present the data directly to the committee without a workgroup and no ETR (strongly not recommended) since this may be a 2-3 day meeting covering ONLY this topic and the critical discussions that happen in the workgroup to guide recommendations will not inform the process.

Hope that helps!

Demetre Costas Daskalakis
Director, National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Wednesday, May 21, 2025 8:14 AM
To: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: RE: 5.19.2025 ACIP w iOD, 9:30am and 4pm

Thanks for sending notes- two other things:
You and I mentioned that you can't just do votes on things at a meeting like Hep B- they need to reconstitute a workgroup to look at the data and evidence and then present at a subsequent ACIP meeting

Of note, Stuart had said all the people had been cleared by WH for ethics and were good to go, but when I asked to make sure all had done 450 forms and to connect with our FACA and SBI teams to ensure rest of paperwork done too it appears none of the ethics/ COI process has been started yet so it is not clear to me if these 10 members are "ready" as they need to go through FACA process before they would be confirmed. This is on my list to discuss with the SBI and OGC teams that review candidates

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Sent: Wednesday, May 21, 2025 8:07 AM
To: Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: 5.19.2025 ACIP w iOD, 9:30am and 4pm

Deb- Just sending my notes to make sure I haven't missed anything. Let me know.

5.19.2025 ACIP w iOD, 9:30am

EXHIBIT 16

Get Outlook for iOS

From: Burns, Stuart (CDC/IOD) <[redacted]>
Sent: Monday, June 16, 2025 1:46 PM
To: Houry, Debra E. (CDC/IOD) <[redacted]>; Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: Re: ACIP UPDATE: Draft vote language and agenda

Based on discussions and what I'm hearing from the secretary's office They are very interested In having ACIP Vote to recommend only thimerosal free flu vaccine to pregnant women and children 12 and under. What steps need to be take to consider this on the agenda?

Stuart

predecisional preliminary draft

Get Outlook for iOS

From: Houry, Debra E. (CDC/IOD) <[redacted]>
Sent: Monday, June 16, 2025 1:34:56 PM
To: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>; Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>
Subject: RE: ACIP UPDATE: Draft vote language and agenda

Thanks Rebecca
I mentioned this morning, that things like strength of rec, shared decision making, etc usually come from workgroup discussions

Debra Houry
Chief Medical Officer & Deputy Director for Program and Science
Centers for Disease Control and Prevention (CDC)
Department of Health and Human Services (HHS)
[redacted]

From: Greco Kone, Rebecca (CDC/NCIRD/OD) <[redacted]>
Sent: Monday, June 16, 2025 12:12 PM
To: Witkofsky, Nina (CDC/IOD) <[redacted]>; Burns, Stuart (CDC/IOD) <[redacted]>; Zadeh, Mina (CDC/OD/OCS) <[redacted]>
Cc: Daskalakis, Demetre (CDC/NCIRD/OD) <[redacted]>; Houry, Debra E. (CDC/IOD) <[redacted]>
Subject: ACIP UPDATE: Draft vote language and agenda

Good morning, Stuart,

I just spoke with Nina who mentioned that you had requested more specific information related to the anticipated vote language for the upcoming ACIP meeting. Please see bottom of this email for the draft

EXHIBIT 17

From: James J. Oh
Sent: Friday, July 10, 2026 1:46 PM
To: Harlow, James W. (CIV); Belfer, Isaac C.
Cc: Richard H. Hughes IV; Kathleen Barrett; Daniella R. Lee; Elizabeth McEvoy; Robert Wanerman; Jennifer Cross
Subject: RE: Meet and Confer on Supplemental Administrative Records

Thank you and likewise.

James J. Oh
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From: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Sent: Friday, July 10, 2026 1:38 PM
To: James J. Oh <JOh@ebglaw.com>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>; Jennifer Cross <JCross@ebglaw.com>
Subject: RE: Meet and Confer on Supplemental Administrative Records

---

Yes, you may add my signature and file.

I hope you and your colleagues have a nice weekend.

James

From: James J. Oh <JOh@ebglaw.com>
Sent: Friday, July 10, 2026 2:28 PM
To: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>; Jennifer Cross <JCross@ebglaw.com>
Subject: [EXTERNAL] RE: Meet and Confer on Supplemental Administrative Records

James,

I have no edits. Attached is Exhibit A that I intend to attach to the JSR. Please advise if we have your approval to affix your e-signature and get on file.

Thanks.

Jimmy

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From: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Sent: Friday, July 10, 2026 11:08 AM
To: James J. Oh <JOh@ebglaw.com>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>; Jennifer Cross <JCross@ebglaw.com>
Subject: RE: Meet and Confer on Supplemental Administrative Records

As promised, attached is a draft of the JSR that includes our respective positions. Please let me know if you have any further edits in response to our position.

Also, I realize that, given your attaching an exhibit, it may make more sense for you to file.

From: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Sent: Friday, July 10, 2026 10:40 AM
To: James J. Oh <JOh@ebglaw.com>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>; Jennifer Cross <JCross@ebglaw.com>
Subject: RE: Meet and Confer on Supplemental Administrative Records

Thanks, Jimmy. I'll put that into a draft filing, add our position, and send back to you for review.

From: James J. Oh <JOh@ebglaw.com>
Sent: Friday, July 10, 2026 10:29 AM
To: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>; Jennifer Cross <JCross@ebglaw.com>
Subject: [EXTERNAL] RE: Meet and Confer on Supplemental Administrative Records

James,

Here is what Plaintiffs' Report will say:

Plaintiffs' Report

The government has made rolling productions of the Administrative Records ("ARs") in this case, with the first AR produced on March 12, 2026, regarding the May 2025 Secretarial Directive regarding the Covid-19 vaccine (AR #1). The government made supplemental productions on AR #1, #3 (ACIP reconstitution), and #4 (childhood schedule) on June 8. Since June 8, the parties have met and conferred on multiple occasions by video and email. Those efforts have been exhausted, and disputes remain on whether all ARs are complete as set forth in Plaintiffs' counsel's email to defense counsel on July 8. (See Exhibit A, attached hereto). Accordingly, Plaintiffs intend to file a Motion to Complete Administrative Records by Friday, July 17.

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From: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Sent: Friday, July 10, 2026 9:11 AM
To: James J. Oh <JOh@ebglaw.com>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: RE: Meet and Confer on Supplemental Administrative Records

***** EXTERNAL EMAIL *****

Purely for my planning purposes today, when might you circulate a draft of the JSR notifying the court of your forthcoming motion to complete the record?

James

From: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Sent: Thursday, July 9, 2026 3:50 PM
To: James J. Oh <JOh@ebglaw.com>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: RE: Meet and Confer on Supplemental Administrative Records

Defendants' position remains that ARs 1-6 all are complete.

For purposes of the JSR due tomorrow, Defendants will reiterate our view that record disputes should be tabled until after the renewed stay motion. But recognizing that the Court may disagree, I'm happy to discuss a proposed briefing schedule for your motion to complete the record. Do you have a desired date for filing the motion?

James

From: James J. Oh <JOh@ebglaw.com>
Sent: Wednesday, July 8, 2026 11:54 PM
To: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: [EXTERNAL] RE: Meet and Confer on Supplemental Administrative Records

James,

Thank you for your responses today to my July 7 email, which followed-up on our July 6 meet and confer. With regard to your #4, below, we do not agree that a motion to complete the record should be tabled until after the Court resolves the stay motion. With regard to your request for plaintiffs to specifically identify documents that plaintiffs believe are properly part of the Administrative Records in this case but were excluded, please allow me to remind you that I have sent correspondence to you and Isaac detailing with specificity categories of documents that Plaintiffs believe are missing from ARs ## 1, 3, and 4. For your convenience, I identify the correspondence I have previously sent on ARs 1, 3, and 4, as well as address the other ARs:

AR #1 (May 27, 2025 Secretarial Directive): the government produced AR #1 on March 12. I sent a letter to you and Isaac on March 31, 2026, letter listing 32 categories of documents that Plaintiffs contend are missing from AR #1. I re-sent my March 31 letter as an attachment to a May 18, 2026, email. On June 8, Defendants supplemented ARs ## 3-5, but, since my March 31 letter, Defendants have not supplemented AR #1. In your email below, you confirmed that AR #1, "as certified, is complete." Plaintiffs have satisfied their meet and confer obligation on AR #1.

AR #2 (September 2025 ACIP vote on the Covid vaccine): Defendants produced this AR on April 13. Since then, Defendants have made no supplemental production and have represented that AR #2, as certified, is complete. Plaintiffs believe that this AR is not complete. Defendants produced in this AR the agenda for the June 25, 2025, ACIP meeting (3349-50). At that meeting, six presentations were made on COVID-19, none of which focused on an informed consent process for the Covid vaccine. Yet, in document 2361-62, titled "Next ACIP Meeting: Anticipated Votes," the document states that a vote at the September 18-19 ACIP meeting was anticipated on COVID-19 Vaccines as follows: "It is the sense of the committee that the CDC engages in an effort to promote more consistent and comprehensive informed consent processes, and as part of that considers adding language accessible to patients and medical providers to describe at least the six risks and uncertainties included in the WG chair presentation." There are no documents in this AR that predate September 18 that explain why the ACIP voted on September 19, 2025, to make the Covid vaccine SCDM for everyone 6 months and older. In spite of Defendants' certification that this AR is complete, please advise by close of business on Monday, July 13, whether Defendants will search for and produce documents that predate September 19, 2025, that explain how and why the ACIP voted on September 19 to make the Covid vaccine SCDM for all, who was involved in that decision, and what evidence, data, and documents were relied upon, or, alternatively, advise whether Defendants stand on their position that this AR is complete.

AR #3 (ACIP Reconstitution): an AR on the ACIP Reconstitution was produced on April 17, 2026. In an email on April 18, 2026, I listed six categories of documents missing from this AR.

In response to my meet and confer efforts on this AR, Isaac sent an email on April 22, 2025, in which he stated that Defendants intended to file a motion to stay proceedings. On May 1, the Court denied the motion to stay, and on June 8, Defendants made a supplemental production of documents (which I agree contains emails that indicate how individuals other than [redacted] were first identified as a candidate for the ACIP). You have confirmed that this AR "is complete, including as to emails involving Aaron Siri (or his law firm) and conflicts vetting." Plaintiffs have satisfied their meet and confer obligation on AR #3.

AR #4 (Childhood Schedule): this AR (less Confidential documents) was produced on May 1. Attached to an email that I sent to you and Isaac on May 21 was a document titled CATEGORIES OF DOCUMENTS MISSING FROM AR #4 (CHILDHOOD IMMUNIZATION SCHEDULE) that listed 10 categories of documents that Plaintiffs contended were missing from this AR. Defendants made a supplemental production to this AR on June 8, 2026. You have stated that Defendants' "position remains that, as certified, the records are complete." Plaintiffs have satisfied their meet and confer obligation on AR #4.

AR #5 (December 2025 ACIP vote on Hep B): Defendants made an initial production of this AR on May 5, 2026, and a supplemental production on June 8, 2026. At the June, 2025 ACIP meeting, the Hepatitis B vaccine was not on the agenda. The Hep B vaccine was, however, on the agenda at the ACIP meeting on both September 18 and 19. There are no documents in this AR that predate the September 18-19 ACIP meeting that explain how and why the Hep B vaccine wound up on the agenda for the September 18-19 ACIP meeting, nor any documents dated between the September 18-19 ACIP meeting and the December ACIP meeting that explain why the ACIP voted at the December 4-5 meeting to eliminate the recommendation that newborns receive the Hep B vaccine. Although Defendants just served on July 2 a revised Certification of Supplemental Administrative Record representing that this AR is "complete," please advise by COB on Monday, July 13, whether Defendants will search for and produce the documents specified in this paragraph or whether they stand on their position that this AR is complete.

AR #6 (ACIP June 2025 Thimerosal vote): Defendants produced this AR on May 13, 2026, and have not made a supplemental production. The topic of thimerosal in vaccines was not on the agenda for the April 15-16, 2025, ACIP meeting, but then appears on the agenda for the June 25-26 meeting of the newly-constituted ACIP. There are no documents in this AR that explain how and why thimerosal was on the agenda for the June 25-26 meeting, why there was a vote, or why [redacted] was designated to make a presentation on thimerosal on June 26, 2025, at the ACIP meeting. Please advise by COB on Monday, July 13, whether Defendants will search for and produce the documents specified in this paragraph or whether they stand on their representation that this AR is complete.

If you would like to discuss, please advise.

Thank you.

Jimmy

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From: Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Sent: Wednesday, July 8, 2026 10:49 AM
To: James J. Oh <JOh@ebglaw.com>; Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: RE: Meet and Confer on Supplemental Administrative Records

***** EXTERNAL EMAIL *****

Jimmy,

In the interest of efficiency, we thought it would be helpful to provide written responses to your points before our next call. Our responses track your numbering.

1. Although we appreciate plaintiffs' offer to propose redactions now for all the documents designated as Confidential, as a practical matter, this does not lessen the burden on the government. Only the government has designated information Confidential in this matter. And only the government bears ultimate statutory and regulatory responsibility for safeguarding this information. For any document where plaintiffs propose redactions, the government must undertake a complete, de novo review to ensure the accuracy and

completeness of redactions.

We continue to believe that adhering to the protocol set forth in the protective order is the best course. As we explained on Monday's call, the briefing process itself reveals which Confidential record documents are actually relevant to the disposition of this matter. By contrast, a front-end redaction of all Confidential documents necessarily wastes time and effort on the likely significant quantity of documents that neither side will rely on.

As to publicly referencing the names of candidates suggested for ACIP, those candidates who were actually appointed to ACIP by the Secretary may, of course, be named in a public filing. But at this point, we cannot agree to the public naming of individuals who were merely suggested for ACIP (either formally or informally) but never appointed. Indeed, some of these individuals may not even know that a third party had suggested them for ACIP. We, however, are continuing to consult with the relevant Privacy Act experts and will let you know if our position changes.

2. We disagree with your contention that AR #3 about ACIP "contains no other emails that indicate how any others who were selected for the ACIP in 2025" were identified and selected. See, for example, HHS_AAP 015999-016006, 016036-016096, 016182-016189, 015369, and 015477.

   We otherwise confirm that AR #3 is complete, including as to emails involving Aaron Siri (or his law firm) and conflicts vetting.

3. For AR #1 (May 2025 directive) and AR #4 (January 2026 action), our position remains that, as certified, the records are complete.

4. Consistent with the government's renewed stay motion, we maintain that any motion practice regarding the record should wait until the Court resolves the stay motion. However, if plaintiffs intend to proceed with a motion to *complete* the administrative record, as part of the meet-and-confer process, we ask that plaintiffs specifically identify to us the documents that plaintiffs believe are "properly part of the record but [were] excluded" and the "non-speculative grounds for [plaintiffs'] belief that the documents were considered by the agency and not included in the record." *Oceana, Inc. v. Ross*, 290 F. Supp. 3d 73, 78–79 (D.D.C. 2018). The government can then respond for the specific documents you identify, thereby clarifying the precise nature of the dispute.

Finally, I wanted to follow up about HHS_AAP 015777, which we also discussed on Monday. The earliest emails in the chain are also from Becca Claassen to Reyn Archer. That is reflected in the vertical lines on the left side of the message, which is a Gmail formatting feature (ex. https://support.google.com/mail/thread/180223993/how-to-avoid-auto-indent-vertical-lines-on-mail-replys?hl=en).

I look forward to speaking at 3. Or if you'd like more time to digest these responses, I'm happy to chat tomorrow instead.

James

From: James J. Oh <JOh@ebglaw.com>
Sent: Tuesday, July 7, 2026 5:56 PM
To: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>; Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: [EXTERNAL] RE: Meet and Confer on Supplemental Administrative Records

Isaac, James, and Katrina,

I appreciate that you spent an hour and a half on a call with me, Kathleen, and Richard yesterday to meet and confer about the Administrative Records ("ARs") that the government has produced in this case. I will send an invite to James tomorrow for 10 am CT/11 am ET, since Isaac and Katrina are both out of the office tomorrow, to discuss the items that Isaac promised to follow-up on in our call. If, James, you have nothing to report other than "we're still working on it," please let me know, and we can cancel the call. I would, however, ask for an ETA on when answers will be provided to the following on which Isaac agreed to follow-up:

1. Confidential designations and names of individuals who appear in the ARs who were suggested for the ACIP. In our call, I proposed that Plaintiffs would do redactions of any PII or PHI on any of the documents designated Confidential and then run the redactions by you so that we could spare the parties the work of having to file documents under seal that contain minimal PII or PHI. This would also spare the Court the hassle of having to deal with documents filed under seal and potentially have to make rulings on those documents. You rejected my proposal because it would be too much work for the government at this point in time. Instead, you insisted on following the protocol set forth in the Protective Order that documents that Defendants have designated as Confidential must first be filed with the Court under seal, and thereafter, the parties will "confer about whether it is reasonably feasible and not unduly burdensome to redact the Confidential Information contained in the documents filed under seal." My proposal for Plaintiffs to do the redactions now of the small number of Confidential documents in the ARs relieves most of the burden on the government and on the Court, and, therefore, I do not understand why you won't agree to my proposal. Alternatively, I proposed being able to use just the names that appear on the CVs in the ARs of suggested candidates for the ACIP with everything else on the CVs redacted.

2. Documents showing how ACIP members appointed in 2025 entered the pipeline of candidates for the ACIP. In our call, I shared my screen and showed an email produced in the AR from [redacted] to [redacted] dated January 2, 2025, with the subject "ACIP Nominee – [redacted] was announced as one of eight new members of the ACIP on June 11, 2025. The January 2, 2025, email shows when he entered the ACIP candidate pipeline. The rest of the AR on the ACIP Reconstitution, however, contains no other emails that indicate how any others who were selected for the ACIP in 2025 ([redacted] entered the pipeline for consideration, who recommended them, when they were first identified, the vetting done, conflict reviews, and communications concerning these appointments (including whether additional emails involving [redacted] and his law firm about the ACIP reconstitution exist). You indicated that you would check on this and get back to me. With regard to conflicts, you reiterated your position that OGE Form 450s are not part of the AR because they traditionally are completed after an individual is appointed but before they begin work on the ACIP. But what about documents regarding conflicts vetting that was done before their appointments were announced, if any?

3. Completeness of all of the Records. In our call, I questioned the completeness of all of the records. By way of example, I brought up AR #1 re the May 27, 2025, Secretarial Directive on the Covid vaccine and why nothing was produced in the record about the video that was posted on X on May 27, 2025, announcing the changes to the CDC's immunization schedules for children and pregnant women. I also questioned why nothing was produced between December 5, 2025 – when [redacted] did a presentation on Denmark's childhood schedule and Aaron Siri did a presentation on the U.S. childhood schedule at the ACIP meeting, and the Presidential Memo on aligning the US childhood schedule with peer countries was released – through the January 6, 2026, Decision Memo, such as documents on the aborted announcement that was scheduled for December 18 on children's health. Your response to my

questions about whether these ARs were complete was to point to the certifications that represented that these ARs were all complete. You also again refused my request to file the certifications on the record or have them signed under penalty of perjury.

4. Briefing schedule on motion to supplement/complete the record. I indicated that I intended to file a motion to complete the record by this Friday. You objected to that, stating that a Joint Status Report was due this Friday in which we were to apprise the Court of issues that remained on the AR and to propose a briefing schedule on a discovery motion in the JSR. In light of your objection, I intend to state in the JSR that Plaintiffs intend to file a Motion to Complete/Supplement the Administrative Records by no later than July 24 and reserve the right to file that motion before that date. That should give you ample time to produce any additional documents in response to # 2, above.

Best,

Jimmy

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From: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Sent: Thursday, July 2, 2026 5:32 PM
To: James J. Oh <JOh@ebglaw.com>; Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: RE: Meet and Confer on Supplemental Administrative Records

***** EXTERNAL EMAIL *****

Jimmy,

Thanks for your email. Attached are revised certified indices for AR nos. 3–5, which certify that the ARs are "true, correct, and complete." There is no requirement that AR certifications be sworn under penalty of perjury or filed on the docket.

As stated in my prior email, we have agreed to remove the confidentiality designation from HHS_AAP014712–15. A version of that document without the confidentiality designation is attached. We also agree to remove the confidentiality designations from HHS_AAP015771–72 and HHS_AAP014636–40 and will produce versions of those documents without the confidentiality designations next week.

We appreciate your proposing redactions to certain documents. However, any discussion of redactions is premature at this point. Paragraph 4 of the Stipulated Protective Order provides that the parties will discuss redactions *after* any documents containing Confidential Information are submitted to the Court under seal. After such a filing, the parties will "confer about whether it is reasonably feasible and not unduly burdensome to redact the Confidential Information contained in the documents filed under seal," and "[t]o the extent such redactions are reasonably feasible and not unduly burdensome, the filing parties shall file on the public docket versions of the documents that redact any Confidential Information." ECF No. 320 at 4. Preparing redactions for only those documents filed under seal is "more efficient and expeditious" than redacting all confidential documents in the ARs on the front end, given that many of those documents may never be filed on the docket. ECF No. 318 at 2.

We disagree with your suggestion that redacting the confidential documents is a quick and simple process. Although we appreciate that you spent an evening preparing proposed redactions of those documents, the redactions you proposed contain errors. For example, your proposed redacted version of HHS_AAP015073–77 does not redact individuals' place of birth, which is PII. Additionally, preparing redactions of resumes/CVs/bios would require more than simply redacting email addresses and phone numbers (e.g., your proposed redactions to HHS_AAP015276–84). Some resumes/CVs contain additional confidential information, including date of birth, date of marriage, place of birth, children's names and birthdays, and professional license numbers. *E.g.*, [redacted], HHS_AAP015037–72; [redacted], HHS_AAP014954–5012. Even for individuals' professional and educational history, it could be very time-consuming to confirm that all such information in a resume/CV/bio is publicly available. For example, even if a person has a publicly available resume/CV/bio, it might not include all the information in the version of the resume/CV/bio in the ARs.

Given our legal obligations to protect confidential information, *see, e.g.*, 5 U.S.C. § 552a; 18 U.S.C. § 1905; 21 U.S.C. § 331(j), we need to be very careful to ensure that all confidential information is redacted in any document to be disclosed publicly. That process takes time and may not be reasonably feasible for certain documents with extensive confidential information (e.g., CVs with voluminous information protected by the Privacy Act, where it is not clear that the version of the CV in the AR has been publicly disclosed). Defendants will comply with the Stipulated Protective Order: after any documents containing Confidential Information are filed under seal, Defendants will confer with Plaintiffs about whether it is reasonably feasible and not unduly burdensome to redact the Confidential Information in such documents. ECF No. 320 at 4. Before that time, it is premature to discuss redactions. Moreover, there is no prejudice to Plaintiffs because Plaintiffs' outside counsel and the other individuals identified in paragraph 5 of the Stipulated Protective Order already have access to the documents designated as confidential.

Finally, as stated in my prior email, we redacted information protected by the deliberative process privilege in HHS_AAP015578–80 and HHS_AAP015588. The redacted information consists of predecisional and deliberative communications between HHS employees regarding potential ACIP nominees. *See Town of Norfolk v. U.S. Army Corps of Eng'rs*, 968 F.2d 1438, 1458 (1st Cir. 1992). Because the basis for the deliberative process privilege is apparent from the unredacted portions of the documents (e.g., the sender, recipients, dates, and subjects of the redacted emails and the text of other emails in the chains), there is no need for *in camera* review.

If you have any questions or concerns, we remain available on Monday, July 6, at 11:00 a.m. ET/10:00 a.m. CT.

Thanks,

Isaac

Isaac C. Belfer
U.S. Department of Justice
Civil Division | Federal Programs Branch
(202) 305-7134 | Isaac.C.Belfer@usdoj.gov

From: James J. Oh <JOh@ebglaw.com>
Sent: Monday, June 29, 2026 12:42 AM
To: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>; Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: [EXTERNAL] RE: Meet and Confer on Supplemental Administrative Records

Isaac,

I have replied in green below to the responses you made in red in your email of Friday, June 26, 2026.

As you know, Defendants would not agree to produce documents they designated as Confidential without a protective order in place. Further, you would not agree to make redactions of PII because that approach allegedly "would require significant additional time and resources." In supplemental productions of documents designated Confidential in ARs ## 3-5, in the AR # 3 supplemental production, the government produced only 228 documents designated Confidential consisting of 1,490 pages; in the AR #4 supplemental production, the government produced only 17 documents designated Confidential consisting of 95 pages; and in the AR #5 supplemental production, the government produced only one (1), one-page document. The total number of documents produced that were designated Confidential in these three ARs was 246 consisting of 1,586 pages. This is a trifle in litigation these days and hardly required "significant additional time and resources" to make redactions. Indeed, I got through all of them and made redactions myself in the attached in an evening. I believe that you overstated and misled me when we were negotiating the Protective Order about the volume of documents that were Confidential and/or required redaction. Moreover, the Confidential designations on many of the documents stamped Confidential are spurious at best. Accordingly, I sincerely hope that you and your clients respond in good faith to my comments below.

In your June 23, 2026, email to me responding to my question about whether ARs ## 3-5 were complete after supplemental productions, you stated: "In response to your question, AR ## 3, 4, and 5 are complete." In your June 24, 2026, email at 4:07 PM (CT), you stated "Defendants agree to produce revised certifications stating that AR ## 3-5 are 'complete.'" Please produce revised certifications by close of business on Thursday, July 2. Please also ensure both that the revised certifications are signed under penalty of perjury and that you file those revised

certifications on the docket. In other APA cases in this district, it has been the government's practice in APA cases to sign Certifications of Administrative Record under penalty of perjury and to file the Certifications on the record. *See, e.g., AAU, et al., v. DOD, et al.*, Case No. 1:25-cv-11740-BEM, Dkt. No. 72-1 (attached hereto); *Commonwealth of Massachusetts, et al. v. Robert F. Kennedy, Jr., et al.*, Case No. 1:25-DF-10814-WGY, Dkt. No. 118-1 (attached hereto); *APHA, et al., v. NIH, et al.*, Case No. 1:25-cv-10787-WGY, Dkt No. 85, Designation and Certification of Administrative Record (attached hereto).

I will send an invite for a videoconference at 11 am ET on Monday, July 6. Whether we need to go ahead with that call depends on how you respond by close of business on July 2.

Thank you.

Jimmy

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From: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Sent: Friday, June 26, 2026 4:03 PM
To: James J. Oh <JOh@ebglaw.com>; Harlow, James W. (CIV) <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: RE: Meet and Confer on Supplemental Administrative Records

From: James J. Oh
Sent: Friday, June 19, 2026 12:16 AM
To: Belfer, Isaac C. <isaac.c.belfer@usdoj.gov>; Harlow, James W. <james.w.harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <rwanerman@ebglaw.com>
Subject: Meet and Confer on Supplemental Administrative Records

Isaac,

We would like to meet and confer with you on Monday (6/22) or Tuesday (6/23) about the Confidential designations made in the supplemental productions for Administrative Records ##3, 4, and 5, since we have a status report due on June 24. We believe that most, if not all, of the documents that the government designated as Confidential are not Confidential under the Protective Order, especially if personal identifying information (PII) such as email addresses, addresses, and phone numbers are redacted.

We also have concerns about the Certifications of Supplemental Administrative Record produced with each of these ARs, which I address first:

Certifications of Supplemental Administrative Record

Defendants served by email on June 8, 2026, a "Certification of Supplemental Administrative Record" ("Supplemental Certification") for each of the supplemental AR productions for ARs ## 3-5. The second sentence of each of these Certifications were the same except for the identification of the final agency action to which the Certification applied: "I hereby certify that the documents listed on the attached Revised Administrative Record Index, which include the

partial administrative record certified on April 17, 2026, are to the best of my knowledge a true and correct copy of the non-privileged information that was directly or indirectly considered in connection with [final agency action]." Conspicuously missing from each of the Supplemental Certifications is the word "**complete**." In other Administrative Procedure Act cases filed in the District of Massachusetts last year, when the government filed a Certification of Administrative Record, the signer of the Certification represented that the AR produced was "complete." *See, e.g., AAU, et al., v. DOD, et al.*, Case No. 1:25-cv-11740-BEM, Dkt. No. 72-1, Designation and Certification of Administrative Record, ¶ 3 ("To the best of my knowledge, information, and belief, the document that have been labeled with Bates range … constitute the **complete** administrative record for the analysis and rationale that supported the 15 percent indirect cost rates, as reflected in the Policy.") (emphasis added); *APHA, et al., v. NIH, et al.,* Case No. 1:25-cv-10787-WGY, Dkt No. 85-1, Designation and Certification of Administrative Record, ¶ 2 ("To the best of my knowledge, information, and belief, the records described below and shared with plaintiffs on June 2, 2025 constitute the true, accurate, and **complete** administrative records for the grant terminations challenged in this case … the true, accurate, and **complete** administrative records for plaintiffs' 'Challenged Directives.'") (emphasis added).

Please confirm that ARs ## 3, 4, and 5 are **complete** and provide Amended Certifications of Supplemental Administrative Record for these ARs so stating.

Supplemental AR # 3

Plaintiffs would appreciate an explanation as to why these documents have been designated Confidential:

1. Decision Memoranda and other HHS memoranda.
    a. 6.9.25 Memo recommending termination of ACIP members (014712-15)
    b. 4.9.25 Memo requesting designation of FDA representative to the ACIP (14739-40)
    c. 4.9.25 Memo requesting designation of NIH representative to the ACIP (14741-42)
    d. 6.25.25 Memos requesting appointments of ACIP members (14743-58)
    e. 6.13.25 Memo requesting approval of 2025 ACIP nomination slate (14759-63)
    f. 9.8.25 Memo requesting approval of 2025 ACIP nomination slate (14925-28)
    g. 11.25.25 Memo requesting approval of 2025 ACIP nomination slate (15078-80)
    h. 12.2.25 Memo requesting approval of 2025 ACIP nomination slate (15162-64)
    i. 12.18.25 Memo requesting approval of new members for the ACIP (15222-25)

2. Documents re terminations of the 17 ACIP members (14716-38)

3. Department of Health and Human Services Request for Approval of Nominees for Public Advisory Committees
    a. 15073, 15109, 15218-21, 15267, 15268, 15269, 15270,

4. Resumes, CVs, bios, emails, spreadsheets re candidates nominated for the ACIP
    a. The public should be able to see who was nominated and not appointed to be able to compare to those who were appointed.
    b. Plaintiffs would agree to redact PII such as addresses, phone numbers, and email addresses.
    c. I noted in my email to you of May 18, 2026, that "subsection (b)(11) of 5 U.S.C. § 552a 'permits a court of competent jurisdiction to order disclosure of Privacy Act protected information that would otherwise be prohibited from disclosure without prior written consent of the individual to whom the record pertains.' United States Department of Justice Overview of the Privacy Act of 1974, p. 119 (2020 edition)."

5. Emails from outside parties who recommended candidates for the ACIP

    a. [redacted] law firm emails and attachments.
        i. [redacted] letter to the Secretary, 6.5.25, recommending additions of non-voting liaison representatives and the attachments thereto (015771-72)
        ii. Emails from [redacted] attaching a spreadsheet of ACIP candidates and a "preliminary analysis on ACIP Charter and FACA implications that [redacted] team provided us." (15777).
            1. Spreadsheet of candidates from [redacted] law firm (15779-83).
            2. ACIP Charter Analysis (15785-96).
        iii. Email from Elizabeth Brehm attaching "a number of suggested individuals." (15797-99) and attachment
        iv. There are only three emails to/from [redacted] law firm in the supplemental production. Plaintiffs find it hard to believe that only three emails exist between [redacted] law firm and Defendants regarding the ACIP.

    b. [redacted] emails and attachments.
        i. 4.6.25 email (15685-87)
        ii. 6.4.25 email to [redacted] attaching a document "prepared at the request of Mr. Kennedy earlier this year regarding ACIP that outlines the concerns I identified at the time …" (015963-71). Plaintiffs would appreciate an explanation as to why these documents have been designated as Confidential.
        iii. 4.3.25 and 4.4.25 emails to [redacted] with recommendations for the ACIP and other positions.
        iv. 1.2.25 email from [redacted] to [redacted] recommending [redacted] for the ACIP. (15991)
        v. 1.2.25 email from [redacted] to [redacted] ecommending [redacted] for the ACIP. (15994)

vi. 4.6.25 email from [redacted] to [redacted] with ACIP recommendation of [redacted]. (15997)

c. [redacted] emails with ACIP recommendations (15684, 15999, 16007, 16009, 16028, 16030)

6. Redacted documents: why are there redactions on these documents? We request that Defendants submit to the Court for *in camera* review.
   a. 6.26.25 email from [redacted]s entirely redacted. (15778-79)
   b. 6.10.25 email from [redacted] (15588)

Supplemental AR #4

Plaintiffs request an explanation as to why any of the documents in Supplemental AR #4 are designated Confidential.

Supplemental AR #5

Plaintiffs request an explanation as to why the one document produced in Supplemental AR #5 was designated Confidential.

On Monday, June 22, I am available before 2 p.m. CT. On Tuesday, June 23, I am wide open.

Thank you.

Jimmy

James J. Oh
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227 W. Monroe
Suite 4500
Chicago, IL 60606
(312) 499-1470
joh@ebglaw.com

From: James J. Oh <JOh@ebglaw.com>
Sent: Tuesday, May 26, 2026 5:18 PM
To: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>; Harlow, James W. <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: [EXTERNAL] RE: Administrative Records ## 3, 4, and 1

Isaac,

I write in anticipation of our meet and confer tomorrow at 1 p.m. CT about the Joint Status Report due this Friday.

AR #3 (ACIP reconstitution)

As you know, on June 9, 2025, the Secretary published a Commentary in the Wall Street Journal announcing the terminations of all ACIP members due to "persistent conflicts of interest." The article linked here indicates that, on June 18, 2025, only a week after the Secretary announced new ACIP members in a June 11 post on X, an HHS spokesperson stated that "'Before starting work on ACIP, the new members' ethics agreement will be made public. Every ACIP member will be vetted in accordance with their ethics agreement before they are permitted to participate in each meeting agenda item," and "both the ethics agreements and the OGE 450s will be disclosed.'" https://www.statnews.com/2025/07/09/kennedy-conflict-of-interest-radical-transparency-acip-vaccine-experts/#:~:text=WASHINGTON%20%E2%80%94%20The%20Department%20of% On June 12, 2025, Robert Malone posted on X the following: "FYSA- i have already completed three months of ethics vetting and COI training by the appropriate officials." https://x.com/RWMaloneMD/status/1933216806338244828

In our call last week, you took the position that information that postdates announcement of the appointments of the new ACIP members on June 11(and on September 11, 2025) are not properly part of AR #3, apparently in reliance on 5 C.F.R. § 2634/903(b)(1), which provides that a new appointee to a federal advisory committee must "[n]ot later than 30 days after assuming a new position or office" file a confidential financial disclosure." However, 5 C.F.R. § 2634.903(b)(3) provides that "agencies may at their discretion, require that prospective entrants into positions described in § 2634.904(a) file their new entrant confidential financial disclosure reports *prior* to serving in such positions, to ensure that there are no insurmountable ethics concerns." (Emphasis added). Here, given the Secretary's stated reason for terminating the ACIP in June of last year, one would think that the Secretary would have wanted to "ensure that there are no insurmountable ethics concerns" before announcing the eight appointments to the ACIP on June 11, 2025. I would ask that you check whether conflicts disclosures were required of the appointees announced on June 11 and September 11, 2025, *before* their appointments were announced. If they were, then such documents should have been produced as part of AR #3. Indeed, Robert Malone's admission on June 12, 2025, that he already had gone through three months of ethics vetting and COI training indicates that he completed an OGE 450 form before June 11. If Dr. Malone underwent this vetting and training before his appointment was announced, the other appointees announced on the same date and on September 11 must also have gone through such vetting and training before their appointments were announced.

I also note that "a special Government employee who has been appointed to serve on an advisory committee must file the required report before any advice is rendered by the employee to the agency, *or in no event, later than the first committee meeting*." 5 CFR § 2634.903(b)(3) (emphasis added). If your position is that OGE 450 forms exist for all ACIP appointees last year but they are not properly part of AR #3, then the OGE 450 forms are properly part of the administrative records on the September, 2025, Covid vote (AR #2), the December, 2025, HepB vote (AR #5), and the June, 2025, thimerosal vote (AR # 6), as they should have been completed and filed with OGE before those meetings to make them eligible to vote at those meetings.

Finally, I take issue with your hyper-technical interpretation of these ethics regulations and the case law on what is properly considered to be part of an administrative record in an APA case. The intent and spirit of the federal government ethics laws and regulations is to "ensure that there are no insurmountable ethics concerns" with any SGE *before* they begin service on an advisory committee. Consistent with the Secretary's repeated emphasis on "radical transparency," I would ask that you produce all OGE 450 forms and other ethics and conflicts of interest disclosures made by all appointees to the ACIP last year, regardless of whether they were submitted before or after their appointments were announced. Alternatively, I would ask that you confirm that no OGE 450 forms and other conflicts of interest disclosures exist for any of the appointees to the ACIP last year.

I need definitive answers from you on these questions tomorrow so that I know if Plaintiffs need to move to complete the administrative records.

AR #4 (childhood schedule)

The January 5, 2026, Decision Memo re "Adopting Revised Childhood and Adolescent Immunization Schedule" states in the fourth paragraph on the first page that "You also discussed immunizations with CDC and Food and Drug Administration (FDA) officials with duties and responsibilities related to vaccine safety and efficacy, respectively." While meeting notes from conversations with health officials from Denmark, Germany, and Japan were produced in AR #4, no meeting notes were produced from [redacted] discussions with CDC and FDA officials. To be sure, if such meeting notes exist, they should have been produced in AR #4. Accordingly, please either confirm that Defendants will produce meeting notes of [redacted] discussions with CDC and FDA officials that predate the January 5, 2026, Decision Memo; or confirm that AR #4 is complete in this regard and that there is no documentation of what [redacted] discussed with CDC and FDA officials about revising the CDC's childhood schedule.

In addition, I note that the Hoeg/Kulldorff Assessment of the U.S. childhood schedule dated January 2, 2026, states that the assessment was written "in consultation with experts at CDC, FDA, NIH, and CMS." However, there is no mention in the Hoeg/Kulldorff assessment of what consultation CDC, FDA, NIH, and CMS experts provided about aligning the U.S. childhood schedule with that of peer nations. Accordingly, please confirm that Defendants will produce documentation of Hoeg and Kulldorff's consultations with experts at CDC, FDA, NIH, and CMS; or confirm that AR #4 is complete in this regard and that no documentation exists of Hoeg and Kulldorff's consultations with experts at CDC, FDA, NIH, and CMS.

In our call last week, you agreed to check with the agency to see if there were any written communications with countries other than Denmark, Germany, or Japan. I trust that you'll be able to provide confirmation on this tomorrow.

Finally, footnote 2 to the AR #4 index states that "Defendants will provide this document at a later date." Please confirm when that document will be produced.

Protective Order

For convenience, I reattach the redlined protective order I sent to you last week. Assuming that we reach agreement on the P.O. tomorrow, presumably the documents marked with an asterisk on the indexes for AR ## 3 and 4 are ready to be produced immediately. Please confirm tomorrow.

Thank you.

Jimmy

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From: James J. Oh
Sent: Thursday, May 21, 2026 10:55 PM
To: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>; Harlow, James W. <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <rwanerman@ebglaw.com>
Subject: RE: Administrative Records ## 3, 4, and 1

Isaac,

This email follows-up on the meet and confer session you, Daniella, and I had today.

First, I agreed with you that it makes sense to file the ARs on the record once confidentiality issues have been resolved.

Second, attached is a redlined protective order. I'd like to be able to designate up to ten individuals at each of the Plaintiff Organizations who can receive and view documents marked as Confidential – Subject to Protective Order. Each would sign the Confidentiality Agreement. There are likely not to be up to 10 at each of the Plaintiff Organizations, but some of the larger organizations have more than a few who may have a reason to review documents that the government produces. In paragraph 6, to avoid going piecemeal to the Court to resolve disputes, I added a sentence that Plaintiffs may seek Court intervention within five business days after

meet and confer efforts have been exhausted on all disputed documents. I also added a provision in paragraph 6 that once the parties agree on information to be redacted, then that document does not have to be filed under seal after redactions are made. I dated the document Wednesday, May 27. Hopefully, we can reach an agreement on the P.O. in time to inform the Court in the status report due May 29.

Third, in our discussion of AR #3, the ACIP Reconstitution, you took the position that OGE 450 forms are not part of the administrative record for the ACIP Reconstitution claim because they, in your view, are not documents that the Secretary would have considered in making the decision to appoint any of the new ACIP members. You refused to answer whether OGE 450 forms exist for any of the individuals whom the Secretary has appointed to the ACIP. Plaintiffs' position is that, since the Secretary justified terminating the entire ACIP because of conflicts of interest, whether his appointments completed OGE 450 forms or whether his appointments were required to disclose potential conflicts of interest at anytime before they participated in their first ACIP meeting should be part of the AR on this claim. Quite frankly, I am surprised that the government is taking the position that they do not have to produce the OGE 450 forms for the ACIP members appointed last year (assuming that they exist) when the Secretary justified terminating the ACIP in his June 9 WSJ Commentary because of "persistent conflicts of interest." This is inconsistent with the Secretary's alleged commitment to "Radical Transparency." See https://www.hhs.gov/radical-transparency/index.html ("HHS is empowering the public with information on … potential conflicts of interest on committees.").

Fourth, with regard to AR #4, the Childhood Schedule, we discussed the document that I sent to you on May 18 that listed ten categories of documents that Plaintiffs contend are missing from this AR. You disagreed that any documents related to the presentation at the December 5, 2025, ACIP meeting on the childhood schedule, to the Presidential Memo released that same evening, "the event involving children's health" that was scheduled for December 19 that was cancelled, or the off-the-record press conference conducted by HHS and that included the Secretary on the morning of January 5, 2026, should have been part of this AR. You disagreed with Plaintiffs' position that these facts demonstrate a series of events, or a process, that culminated in the January 5, 2026, Decision Memo about the childhood schedule. Accordingly, Defendants are refusing to produce any documents from categories 1-6 in the document titled "Categories of Documents Missing from AR #4 (Childhood Immunization Schedule)."

Fifth, with regard to whether the CDC Director communicated with any peer countries other than Denmark, Germany, and Japan about their childhood schedules, you agreed to check with the agency to see if there were any written communications with countries other than Denmark, Germany, or Japan.

Sixth, with regard to item # 10 in the "Categories of Documents Missing from AR #4," you would not agree that the recent reversion of the CDC's childhood schedule to July 2, 2025, which, *inter alia*, confirmed that the Covid-19 vaccine for children was classified as SCDM, removed any question that the May 2025 Secretarial Directive regarding the Covid vaccine for children was a final agency action.

Thank you for sending an invite for Wednesday, May 27, at 1 p.m. CT to continue our conversation.

Hope you have a nice Memorial Day Weekend.

Jimmy

James J. Oh
Epstein Becker Green

227 W. Monroe
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(312) 499-1470
joh@ebglaw.com

From: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Sent: Wednesday, May 20, 2026 4:11 PM
To: James J. Oh <JOh@ebglaw.com>; Harlow, James W. <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: RE: Administrative Records ## 3, 4, and 1

One more point: If the Court would like us to file the ARs on the docket in addition to producing them to Plaintiffs, we would want to file the complete ARs rather than partial ARs. Thus, we think it makes sense to file the ARs on the docket after the confidentiality issues have been resolved and we are able to file complete ARs.

Isaac C. Belfer
U.S. Department of Justice
Civil Division | Federal Programs Branch
(202) 305-7134 | Isaac.C.Belfer@usdoj.gov

From: Belfer, Isaac C.
Sent: Wednesday, May 20, 2026 5:05 PM
To: 'James J. Oh' <JOh@ebglaw.com>; Harlow, James W. <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: RE: Administrative Records ## 3, 4, and 1

Hi Jimmy,

I could talk tomorrow, 5/21, at 1:00 p.m. CT. I will circulate a Teams invite.

We received the Court's order, ECF No. 315, and we plan to ask to be excused from the 5/22 deadline to file the ARs on the docket. Defendants have produced the nonconfidential parts of the ARs to Plaintiffs but have not yet produced documents containing confidential information because the parties are discussing a potential protective order. If the Court would like us to file the ARs on the docket in addition to producing them to Plaintiffs, we'd be happy to do so once we have resolved the confidentiality issue. We can provide an update on that issue in the 5/29 JSR. Additionally, the large size of the ARs could pose logistical challenges to filing them on the docket.

Would Plaintiffs consent to our request to be excused from the 5/22 deadline to file the ARs on the docket?

Thanks,
Isaac

Isaac C. Belfer
U.S. Department of Justice
Civil Division | Federal Programs Branch
(202) 305-7134 | Isaac.C.Belfer@usdoj.gov

From: James J. Oh <JOh@ebglaw.com>
Sent: Wednesday, May 20, 2026 4:27 PM
To: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>; Harlow, James W. <James.W.Harlow@usdoj.gov>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>
Subject: [EXTERNAL] Re: Administrative Records ## 3, 4, and 1

Isaac,

I'm available before 2 pm CT tomorrow. When are you available tomorrow?

EPSTEIN BECKER GREEN

James J. Oh | Bio
t 312.499.1470 | f 312.827.9525
JOh@ebglaw.com

227 W. Monroe Street, Suite 4500 | Chicago, IL 60606
t 312.499.1400 | www.ebglaw.com

> On May 18, 2026, at 10:47 AM, James J. Oh <JOh@ebglaw.com> wrote:
>
> **May 18, 2026**
>
> Isaac,
>
> We appreciate that the government has met the deadlines for producing the six Administrative Records set forth in the Court's March 24, 2026, Order (ECF 296). Plaintiffs, however, do not believe that the ARs produced are complete and, as previously indicated, would like to meet and confer ASAP about the ARs produced. You indicated that you would be ready to talk mid-week this week. I am attending an out-of-town graduation this week, Monday-Wednesday, so can we please schedule a time on Thursday, May 21, to discuss? When we talk, Plaintiffs would like to prioritize discussion and completion of ARs #3, #4, and #1, in that order. For now, we can table discussion of the other ARs until we have reached the point of a resolution between the parties on these ARs or when we have exhausted efforts to meet and confer.
>
> The issues for discussion on Thursday are as follows:

1. **Documents Marked as Confidential in the Administrative Record Index for AR # 3 (ACIP Reconstitution) and Protective Order**

In the Administrative Record Index for AR #3 served on Friday, April 17, footnote 1 states: "Index entries marked with an asterisk (*) indicate that some or all of the documents have been withheld as confidential." In an April 20, 2026, email to me, you indicated that "[w]hen the footnote in AR #3 index said certain documents were 'withheld as confidential,' that meant the documents contain information that would be designated as 'Confidential Information' under the proposed protective order. It did not refer to privileged information."

In an email a few days later, you indicated that the documents marked with an asterisk on AR #3 index were so marked because "The Privacy Act protects 'any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education … and … employment history.' 5. U.S.C. § 552a(a)(4)." (See your email of 4/23/2026 at 7:01 PM). By the title of the documents listed in the AR Index for AR #3, it is unclear how some of the documents could contain information on an individual's employment history. Nor can we readily identify any other category of "Confidential Information" set forth in the proposed P.O. into which any of the documents marked with an asterisk in AR Index #3 might fall. Accordingly, Plaintiffs need to understand how any document marked with an asterisk in AR Index #3 contains information covered by the Privacy Act or falls into a "Confidential Information" category in the proposed P.O.

We also question whether a P.O. is necessary or appropriate in the first place in this case. The Secretary has been operating under the banner of "Radical Transparency" since his nomination and confirmation, and, therefore, we would think that Defendants would welcome all documents produced in the ARs in this case becoming part of the public record. We also are having difficulty understanding how documents such as the "Decision Memo re: Removal of Current and Prospective ACIP Members," or the "June 24, 2025 Decision Memo re: Appointment of New Members to the ACIP, CDC," or a "Financial Operating Plan" could contain either employment history or Confidential information. Furthermore, the Curricula Vitae of nominees to the ACIP have been withheld from production as Confidential, but they are at the very heart of this claim. We note that subsection (b)(11) of 5 U.S.C. § 552a "permits a court of competent jurisdiction to order disclosure of Privacy Act protected information that would otherwise be prohibited from disclosure without prior written consent of the individual to whom the record pertains." United States Department of Justice Overview of the Privacy Act of 1974, p. 119 (2020 edition). When we meet, let's discuss whether the parties can submit an Agreed Order to the Court to produce documents marked with an asterisk in the AR #3 index.

2. **Completeness of AR #3 (ACIP Reconstitution**

Attached hereto is my email of Saturday, April 18, identifying categories of documents that Plaintiffs believe should have been produced in AR #3.

3. **Completeness of AR #4 (Childhood Schedule)**

Attached hereto is a list of categories of documents that Plaintiffs believe should have been produced in AR #4.

4. **Completeness of AR #1 (May 2025 Secretarial Directive)**

Attached hereto is my letter of March 31, 2026, identifying categories of documents that Plaintiffs believe should have been produced in AR #1. In an April 10, 2026, email, you stated that "having considered the issues raised in your letter, we are conducting additional searches to confirm that the administrative record for the May 2025 Secretarial Directive is complete. We will update you after we have finished reviewing the search results." When we meet and confer, please provide an update.

For your convenience, I have attached a .pdf of this email and all attachments.

Please advise on a time we can schedule a call for this Thursday, May 21.

Thank you.

Jimmy

James J. Oh
Epstein Becker Green
227 W. Monroe
Suite 4500
Chicago, IL 60606
(312) 499-1470
joh@ebglaw.com

<mime-attachment>
<2026-03-31 Letter to DOJ re May Directive Administrative Record.pdf>
<Categories of Documents Missing From AR _4 5.18.26.pdf>
<2026-5-18 Correspondence to I. Belfer.pdf>

From: James J. Oh
Sent: Monday, May 18, 2026 10:48 AM
To: Belfer, Isaac C.; Harlow, James W.
Cc: Richard H. Hughes IV; Kathleen Barrett; Daniella R. Lee; Elizabeth McEvoy; Robert Wanerman
Subject: Administrative Records ## 3, 4, and 1
Attachments: RE: AAP AR #3 - Request to Meet and Confer; 2026-03-31 Letter to DOJ re May Directive Administrative Record.pdf; Categories of Documents Missing From AR _4 5.18.26.pdf; 2026-5-18 Correspondence to I. Belfer.pdf

May 18, 2026

Isaac,

We appreciate that the government has met the deadlines for producing the six Administrative Records set forth in the Court's March 24, 2026, Order (ECF 296). Plaintiffs, however, do not believe that the ARs produced are complete and, as previously indicated, would like to meet and confer ASAP about the ARs produced. You indicated that you would be ready to talk mid-week this week. I am attending an out-of-town graduation this week, Monday-Wednesday, so can we please schedule a time on Thursday, May 21, to discuss? When we talk, Plaintiffs would like to prioritize discussion and completion of ARs #3, #4, and #1, in that order. For now, we can table discussion of the other ARs until we have reached the point of a resolution between the parties on these ARs or when we have exhausted efforts to meet and confer.

The issues for discussion on Thursday are as follows:

1. **Documents Marked as Confidential in the Administrative Record Index for AR # 3 (ACIP Reconstitution) and Protective Order**

In the Administrative Record Index for AR #3 served on Friday, April 17, footnote 1 states: "Index entries marked with an asterisk (*) indicate that some or all of the documents have been withheld as confidential." In an April 20, 2026, email to me, you indicated that "[w]hen the footnote in AR #3 index said certain documents were 'withheld as confidential,' that meant the documents contain information that would be designated as 'Confidential Information' under the proposed protective order. It did not refer to privileged information."

In an email a few days later, you indicated that the documents marked with an asterisk on AR #3 index were so marked because "The Privacy Act protects 'any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education … and … employment history.' 5. U.S.C. § 552a(a)(4)." (See your email of 4/23/2026 at 7:01 PM). By the title of the documents listed in the AR Index for AR #3, it is unclear how some of the documents could contain information on an individual's employment history. Nor can we readily identify any other category of "Confidential Information" set forth in the proposed P.O. into which any of the documents marked with an asterisk in AR Index #3 might fall. Accordingly, Plaintiffs need to understand how any document marked with an asterisk in AR Index #3 contains information covered by the Privacy Act or falls into a "Confidential Information" category in the proposed P.O.

We also question whether a P.O. is necessary or appropriate in the first place in this case. The Secretary has been operating under the banner of "Radical Transparency" since his nomination and confirmation, and,

therefore, we would think that Defendants would welcome all documents produced in the ARs in this case becoming part of the public record. We also are having difficulty understanding how documents such as the "Decision Memo re: Removal of Current and Prospective ACIP Members," or the "June 24, 2025 Decision Memo re: Appointment of New Members to the ACIP, CDC," or a "Financial Operating Plan" could contain either employment history or Confidential information. Furthermore, the Curricula Vitae of nominees to the ACIP have been withheld from production as Confidential, but they are at the very heart of this claim. We note that subsection (b)(11) of 5 U.S.C. § 552a "permits a court of competent jurisdiction to order disclosure of Privacy Act protected information that would otherwise be prohibited from disclosure without prior written consent of the individual to whom the record pertains." United States Department of Justice Overview of the Privacy Act of 1974, p. 119 (2020 edition). When we meet, let's discuss whether the parties can submit an Agreed Order to the Court to produce documents marked with an asterisk in the AR #3 index.

2. **Completeness of AR #3 (ACIP Reconstitution**

Attached hereto is my email of Saturday, April 18, identifying categories of documents that Plaintiffs believe should have been produced in AR #3.

3. **Completeness of AR #4 (Childhood Schedule)**

Attached hereto is a list of categories of documents that Plaintiffs believe should have been produced in AR #4.

4. **Completeness of AR #1 (May 2025 Secretarial Directive)**

Attached hereto is my letter of March 31, 2026, identifying categories of documents that Plaintiffs believe should have been produced in AR #1. In an April 10, 2026, email, you stated that "having considered the issues raised in your letter, we are conducting additional searches to confirm that the administrative record for the May 2025 Secretarial Directive is complete. We will update you after we have finished reviewing the search results." When we meet and confer, please provide an update.

For your convenience, I have attached a .pdf of this email and all attachments.

Please advise on a time we can schedule a call for this Thursday, May 21.

Thank you.

Jimmy

James J. Oh
Epstein Becker Green
227 W. Monroe
Suite 4500
Chicago, IL 60606
(312) 499-1470
joh@ebglaw.com

From: James J. Oh
Sent: Saturday, April 18, 2026 5:19 PM
To: Belfer, Isaac C.
Cc: Robert Wanerman; Elizabeth McEvoy; Daniella R. Lee; Kathleen Barrett; Harlow, James W.
Subject: RE: AAP AR #3 - Request to Meet and Confer

Isaac,

Following-up on the Certified Administrative Index on AR#3 re the Reconstitution of the ACIP that was produced last evening, the footnote on page 1 of the Certification of the Administrative Record states: "Index entries marked with an asterisk (*) indicate that some or all of the documents have been withheld as confidential." I request a Zoom meet and confer this Monday, April 20, for you to explain what the footnote means. Does this mean that the government will produce the documents marked with an asterisk once a protective order is in place? Or does this footnote mean that the government will not produce them because they are privileged and therefore confidential. I note that there are no corresponding Bates #s next to the documents on the index with an asterisk, and there are no gaps in the Bates numbering of the documents that were produced that are not marked with an asterisk, indicating that the government has no intention of producing the documents marked with an asterisk unless compelled by a court order. I could be wrong about this, which is why I think it best that we talk about this in a call.

AR#3 Documents Marked with an Asterisk

By the title of the documents on the certified index, I don't see how most, if not all, of the documents marked with an asterisk could be "Confidential," whatever that means in this context. Questions about the documents marked with an asterisk include the following:

1. Decision Memos:
    a. June 9, 2025 Decision Memo re: Removal of Current and Prospective ACIP Members
    b. June 24, 2025 Decision Memos re: Appointment of New Members to the ACIP, CDC
    c. June 24, 2025 Decision Memo re: Nominations to ACIP
    d. November 26, 2025 Decision Memo re: Nomination to the ACIP
    e. December 3, 3025 Decision Memo re: Chair and Vice Chair Nominations to the ACIP
    f. December 23, 2025 Decision Memo re: Nominations to the ACIP
    g. I don't understand how these Decision Memos could be Confidential where the government has produced other Decision Memos that have not been marked Confidential. See May 27, 2025 Decision Memo re: Recission of CDC Recommendations for COVID-19 Vaccines for Healthy Children and Pregnant Women," HHS_AAP 000092-93; and October 3, 2025 Decision Memo re ACIP Recommendation for COVID-19 Vaccination," HHS_AAP 1914-17.
2. June 9, 2025 Notification Letters of ACIP Termination.
    a. Assuming that these are the letters sent to the terminated ACIP Members on June 9 (which I understand actually were short emails), I don't understand how a letter sent to a fired ACIP Member and third party could be considered Confidential.
3. Attachment D – Financial Operating Plan attached to the September 10, 2025 Decision Memo and December 3, 2025 Decision Memo re: Chair and Vice Chair Nominations to the ACIP.

   a. Please explain why the Financial Operating Plan presumably for the ACIP, a federal advisory committee, is Confidential and not knowledge the public is entitled to know.
4. Attachment E – Curricula Vitae of Nominees attached to September 10, 2025 Decision Memo, November 26, 206 Decision Memo.
   a. I am having difficult understanding why anyone's curriculum vitae is Confidential, where the CVs were submitted to the federal government for a position on a public federal advisory committee.
5. HS-532 Requests for Approval of Nominees for Public Advisory Committees attached to:
   a. June 24, 2025 Decision Memo
   b. September 10, 2025 Decision Memo
   c. November 26, 2025 Decision Memo re Nomination to the ACIP
   d. December 3, 2025 Decision Memo re: Chair and Vice Chair Nominations to the ACIP
   e. December 23, 2025 Decision Memo re Nominations to the ACIP
   f. Please explain why these Requests for Approval are confidential.
6. Biographies of ACIP Candidates
   a. I don't understand how these possibly could be Confidential.
7. HHS Correspondence with **External** Stakeholders re: ACIP Reform and Committee Nominations (emphasis added)
   a. Correspondence with external stakeholders cannot be privileged, since it is correspondence with a third party.
   b. The description of this correspondence indicates that this correspondence goes to the heart of Plaintiffs' FACA claim re inappropriate influence by special interests and, therefore, should be produced.
8. Communications between HHS and Potential ACIP Nominees.
   a. I need to hear an explanation as to why these communications are considered Confidential and have not been produced.
9. ACIP Nominations Submitted to the CDC Website and Resource Mailbox
   a. I need to hear an explanation as to why these documents are considered Confidential and have not been produced.
10. HHS Meeting re: Potential ACIP Nominees
   a. I need to hear an explanation as to whether this is one document or many, why the document(s) is/are Confidential, and whether Defendants will identify at least how many meetings occurred and who attended. At a minimum, the information on the identities of who participated in these meetings cannot be protected from disclosure.
11. Public and Congressional Comments on ACIP Reconstitution.
   a. If these are public documents, how can they be Confidential?

<u>Missing from AR#3</u>

When we meet and confer, we also need to discuss what is missing from AR#3, including, but not limited to, the following:

1. In his June 9, 2025, WSJ Commentary announcing the firing of the ACIP, RFK justified the terminations because "[t]he committee has been plagued with persistent conflicts of interest." Presumably, the Secretary has documentation of the then 17 members' conflicts of interest that justified their terminations. Please produce such documents. Alternatively, please confirm that the Secretary did not review and/or does not possess any such documents.
2. The CDC's website currently states: "Upon appointment, each voting member is required to file an Office of Government Ethics 450 form (OGE450), a Confidential Financial Disclosure Report, which is

reviewed by the ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC." https://www.cdc.gov/acip/apply-for-membership/index.html (visited on 4/18/26).

   a. Please produce the OGE450s for every new ACIP member appointed by the Secretary or confirm that they do not exist.
   b. For example, [redacted] Please produce such disclosures or confirm that he did not make them before, during, or after his appointment to the ACIP.

3. AR#3 includes no documents that ACIP candidates are supposed to submit for selection to the ACIP, including at least two letters of recommendation and a cover letter that includes a statement of interest. See https://www.cdc.gov/acip/apply-for-membership/index.html. Please produce such documents or confirm that they do not exist.
4. In a June 12, 2025, post on X, Robert Malone stated: "i have already completed three months of ethics vetting and COI training by appropriate HHS officials.'" No documents were produced in AR#3 on the ethics vetting and training Dr. Malone claims he completed or that any other ACIP member appointed by the Secretary completed. Please produce those documents.
5. In her Declaration filed on the record on February 17, 2026 (ECF 242), Diana Zuckerman attested that she was vetted for a position on the ACIP by a partner at Aaron Siri's law firm. Nothing was produced in AR#3 regarding Siri's law firm's involvement in the nomination and/or vetting process for Dr. Zuckerman or any other candidate. Please produce those documents.
6. As you know, a new ACIP Charter was published on April 9, 2026. Plaintiffs find the new Charter to be suspect and problematic. The facts indicate that Defendants, prompted by [redacted] and the Informed Consent Action Network, adopted the new Charter specifically to do an end-run around Judge Murphy's March 16, 2026, preliminary injunction order. See https://www.facebook.com/del.bigtree/posts/huge-news-after-a-court-ruling-wiped-out-recent-vaccine-program-changes-made-by-/10162096421190964/ . The new Charter is thus related and relevant to Plaintiffs' ACIP Reconstitution claim. Accordingly, it is Plaintiffs' position that any and all documents related to the new ACIP Charter should be produced as part of AR#3.

If you decline to meet and confer on Monday, or if Defendants take the position that none of the documents marked with an asterisk will be produced, please let me know whether you agree that this email satisfies Plaintiffs' obligation under the local rules to meet and confer before filing a motion.

Thank you.

Jimmy

James J. Oh
Epstein Becker Green
227 W. Monroe
Suite 4500
Chicago, IL 60606

(312) 499-1470
joh@ebglaw.com

From: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Sent: Friday, April 17, 2026 8:27 PM
To: James J. Oh <JOh@ebglaw.com>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Gianna Costello <GCostello@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Harlow, James W. <James.W.Harlow@usdoj.gov>
Subject: AAP AR #3

Jimmy,

Attached is the certified index for the administrative record due today. I will send you a link to download the nonconfidential documents in the record.

Thanks,
Isaac

Isaac C. Belfer
U.S. Department of Justice
Civil Division | Federal Programs Branch
(202) 305-7134 | Isaac.C.Belfer@usdoj.gov

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March 31, 2026

VIA EMAIL

Isaac C. Belfer
United States Department of Justice
Isaac.C.Belfer@usdoj.gov

Re: ***American Academy of Pediatrics, et al. v. Kennedy, et al.:***
Administrative Record On The May 27 Directive

Dear Isaac:

On March 12, 2026, Defendants produced what they claim in a "Certification of Administrative Record" of that same date to be "a true, correct, and *complete* copy of the non-privileged information that was directly or indirectly considered in connection with the May 27 Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women and the implementation of that directive." ("May 2025 Directive") (emphasis added). Plaintiffs believe that the Administrative Record ("AR") that Defendants produced on the May 2025 Directive is far from complete. Plaintiffs expected, but did not see, multiple categories of documents that should exist and should have been produced in the AR on the May 2025 Directive but were not. In this letter, Plaintiffs itemize those categories of documents that they contend are missing from the AR on the May 2025 Directive.

As you know, "[t]he administrative record is that which was before the agency at the time the decision being reviewed was made, and it consists of *all* documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Towns of Norfolk & Walpole v. U.S. Army Corps of Engineers*, 137 F.R.D. 183, 185 (D. Mass. 1991), *aff'd*, 968 F.2d 1438 (1st Cir. 1992) (emphasis added). In addition, when an agency's decision-making process is the central issue in a case brought pursuant to the Administrative Procedure Act, as in this case, then the government cannot shield documents from disclosure under the deliberative process privilege. *See New York v. Salazar*, 701 F.Supp.2d 224, 237 (N.D.N.Y. 2010) (emphasis added) (holding documents could not be withheld on basis of deliberative process privilege because the "central theme of many of plaintiffs' claims" was that the "deliberative process itself was fatally flawed"); *see also Texaco Puerto Rico, Inc. v. Dep't of Consumer Affairs*, 60 F.3d 867, 885 (1st Cir. 1995) (acknowledging that the deliberate process privilege is a qualified privilege—not an absolute one—and that courts consider various factors when determining whether to permit the privilege, including "the interests of the litigants, society's interest in the

accuracy and integrity of factfinding, and the public's interest in honest, effective government"). Finally, as Plaintiffs previously noted in our letter dated November 7, 2025, we expect that there are emails and text messages that influenced the decision makers on the May 2025 Directive. Currently, the AR on the May 2025 Directive is largely devoid of emails or other electronic communications. Plaintiffs are entitled to know with whom the Secretary consulted about the May 2025 Directive and the evidence relied upon—whether directly or indirectly—to issue the May 2025 Directive. *See Bimini Superfast Operations LLC v. Winkowski*, 994 F.Supp.2d 103, 106 (D.D.C. 2014) (holding emails were properly included in administrative record as documents that were directly or indirectly considered in decision making); *see also Towns of Norfolk & Walpole*, 137 F.R.D. at 185.

Before I list the categories of documents that Plaintiffs contend should have been produced in the May 2025 Directive AR but were not, a brief summary of the facts regarding the May 2025 Directive is in order to provide context for Plaintiffs' contentions.

On May 27, 2025, the Department of Health and Human Services ("HHS") posted a video on X in which Secretary Kennedy, with Food and Drug Administration ("FDA") Commissioner Marty Makary, and National Institutes of Health ("NIH") Director Jay Bhattacharya, at his side, announced that he had directed the Centers for Disease Control and Prevention ("CDC") to remove the recommendations that pregnant women and "healthy children" receive a Covid-19 booster. To be sure, the words spoken in the video were scripted. On that same day, HHS released the May 2025 Directive that instructed the CDC to remove the recommendations that pregnant women and healthy children receive the Covid-19 vaccine. However, two days later, the CDC did not remove from the childhood schedule the routine recommendation that children receive the Covid-19 vaccine but instead reclassified the Covid-19 vaccine for children to Shared Clinical Decision-Making ("SCDM"). To date, neither HHS nor the CDC nor the Secretary have provided any explanation why the instruction to remove the childhood recommendation was instead changed to SCDM.

On February 27, 2026, when Defendants filed their second opposition to Plaintiffs' preliminary injunction motion, Defendants for the first time produced three memos regarding the May 2025 Directive: (1) a "Decision Memo" dated May 27, 2025, from [redacted], Acting General Counsel that apparently was delivered to Secretary Kennedy "THROUGH: [redacted], Executive Secretary," the subject of which was: "DECISION – Recission of CDC Recommendations for COVID-19 Vaccines for Healthy Children and Pregnant Women" (the "Covid Decision Memo"); (2) a "Memorandum To The Secretary," "THROUGH: [redacted], Chief of Staff and [redacted], Executive Secretary," from [redacted], Principal Deputy Director, NIH, and [redacted], Principal Deputy Commissioner, FDA, the subject of which was "Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age," (the "Memoli/Brenner Memo"); and (3) a memo from [redacted] of the FDA to Secretary Robert F. Kennedy, Jr., the subject of which was "COVID-19 vaccine safety in pregnant women" (the "Høeg Memo").

In light of these facts, Plaintiffs contend that the following categories of documents should have been produced in the AR on the May 2025 Directive:

1. Documents[1] demonstrating when and why Secretary Kennedy[2] first considered directing the CDC to remove the routine recommendations that pregnant women and children receive the Covid-19 vaccine.
2. Any articles or studies that post-date the onset of the Covid-19 pandemic that Secretary Kennedy and/or the Office of the Secretary considered to support removing the recommendation that children receive the Covid-19 vaccine.
3. Any articles or studies that post-date the onset of the Covid-19 pandemic that Secretary Kennedy and/or the Office of the Secretary considered to support removing the recommendation that pregnant women receive the Covid-19 vaccine.
4. Any analyses of these articles, studies, or data that were performed to justify the changes in the Covid-19 vaccine recommendations for pregnant women and children.
5. Documents indicating with whom the Office of the Secretary consulted about issuing the May 2025 Directive both inside and outside of the federal government.
6. The script for the May 27, 2025, video and drafts thereof.
7. Documents demonstrating whether Secretary Kennedy consulted anyone on the Advisory Committee on Immunization Practices ("ACIP") before issuing the May 2025 Directive.
8. Documents explaining why Commissioner Makary and Director Bhattacharya appeared in the May 27, 2025, video alongside Secretary Kennedy and why leaders from CDC were excluded.
9. Documents demonstrating that Secretary Kennedy or the Office of the Secretary consulted with anyone at CDC about the May 2025 Directive.
10. In the May 27, 2025, video, Secretary Kennedy stated that there was a "lack of any clinical data to support the repeat [Covid] booster strategy" for children. The month before, however, multiple presentations were made at the April 15, 2025, meeting of the ACIP in which clinical data was presented that demonstrated the opposite: children and pregnant women should continue to receive Covid boosters. Accordingly, Plaintiffs question whether Secretary Kennedy did *in fact* consider the presentations that Defendants produced in the May 2025 Directive AR numbered HHS_AAP 001006 - HHS_AAP 001018, HHS_AAP 001019 - HHS_AAP 001045, HHS_AAP 001046 - HHS_AAP 001074, HHS_AAP 001075 - HHS_AAP 001089, and HHS_AAP 001090 - HHS_AAP 001158. Accordingly, Defendants should produce documents demonstrating that Secretary Kennedy, Commissioner Makary, and Director Bhattacharya *actually* received, reviewed, and considered these presentations before making the May 27 video.

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[1] As used herein, "Documents" and "Communications" include emails, text messages, instant messages, voice mail messages, memoranda, PowerPoint presentations, and any other document, whether in electronic or hard copy form, related to the specified subject matter.

[2] As used herein, "Secretary Kennedy" means Robert F. Kennedy, Jr., the individual, in his official capacity as Secretary of the Department of Health and Human Services. As used herein, "Office of the Secretary" means Robert F. Kennedy, Jr., his Chief of Staff, anyone in the Immediate Office of the Secretary, particularly Stephanie Spear, anyone in the Office of the Secretary, and anyone holding an Agency Leadership position. *See* https://www.hhs.gov/about/leadership/index.html.

11. Communications between Commissioner Makary, Director Bhattacharya, the Office of the Secretary, and Secretary Kennedy related to the May 27, 2025, video announcing the May 2025 Directive.
12. Attached to the Decision Memo were the Memoli/Brenner Memo, the Høeg Memo, and the May 2025 Directive. Any other documents that Kennedy considered when drafting the Decision Memo should be produced.
13. Documents showing with whom Kennedy consulted about the Decision Memo or who provided input or revisions to the Decision Memo.
14. Documents identifying who drafted and offered input or revisions to drafts of the May 2025 Directive.
15. Communications between Commissioner Makary, Director Bhattacharya, the Office of the Secretary, and the Secretary related to the May 2025 Directive.
16. Communications and/or documents related to the CDC's interpretation of the May Directive and publication of the updated schedule.
17. Communications related to the May 2025 Directive that were sent to or received from Children's Health Defense.
18. Communications related to the May 2025 Directive that were sent to or received from the law firm [redacted] or from any individual affiliated with the law firm of [redacted].
19. Communications related to the May 2025 Directive that were sent to or received from the Informed Consent Action Network.
20. Communications demonstrating that the Secretary considered Commissioner Makary's and Vinay Prasad's May 20, 2025 New England Journal of Medicine article ("An Evidence-Based Approach to Covid-19 Vaccination")—which stated that "pregnancy and recent pregnancy" are factors which "increase a person's risk of severe COVID-19."
21. Documents that explain why [redacted] and [redacted] drafted the Memoli/Brenner Memo.
22. Documents that explain why [redacted] drafted the Høeg Memo.
23. Communications between [redacted] and [redacted] regarding the Memoli/Brenner Memo.
24. Communications between [redacted], [redacted], [redacted], and [redacted] about the Memoli/Brenner Memo and/or the May 2025 Directive.
25. Communications between [redacted], [redacted], and [redacted] about the Memoli/Brenner Memo, the Høeg Memo, or the May 2025 Directive.
26. Communications between [redacted], [redacted], the Office of the Secretary, and Secretary Kennedy about the [redacted] memo.
27. Communications between [redacted], the Office of the Secretary, and Secretary Kennedy about the Høeg Memo.
28. Communications between [redacted], [redacted], and anyone at the CDC about the Memoli/Brenner Memo.
29. Communications between [redacted] and anyone at the CDC about the Høeg Memo.

30. Communications between [redacted] r, and anyone on the ACIP or in the Office of the Executive Secretary of the ACIP about the Memoli/Brenner Memo and/or the May 2025 Directive.
31. Communications between [redacted] and anyone on the ACIP or in the Office of the Executive Secretary of the ACIP about the Høeg Memo and/or the May 2025 Directive.
32. Documents demonstrating that Secretary Kennedy, the Office of the Secretary, Commissioner Makary, and/or Director Bhattacharya considered any of the following before the May 2025 Directive was issued:
    a. the legality of bypassing the ACIP in issuing the May 2025 Directive;
    b. the impact that the May 2025 Directive would have on insurance coverage of the Covid vaccine;
    c. the impact that the May 2025 Directive would have on the VFC program;
    d. the impact that May 2025 Directive would have on medical practices, other health care providers, health care facilities, and suppliers;
    e. the impact that the May 2025 Directive would have on pharmacies;
    f. the impact that the May 2025 Directive would have on rates of Covid-19 infection;
    g. the impact that the May 2025 Directive would have on rates of serious illness and/or death from Covid-19;
    h. the impact that the May 2025 Directive would have on Covid-19 vaccination rates;
    i. the impact that the May 2025 Directive would have on skepticism about the Covid-19 vaccine;
    j. the impact that the May 2025 Directive would have on the public's trust in the Covid-19 vaccine;
    k. the impact that the May 2025 Directive would have on the public's trust of vaccines in general.

If you contend that any of the foregoing categories of document are protected from disclosure under any privilege, please specify which privilege Defendants contend apply to each of the categories of documents delineated above. Further, please provide a privilege log. *See Roe v. Mayorkas*, Case No. 22-cv-10808-ADB, 2024 WL 5198705, at *10 (D. Mass. Oct. 2, 2024) (noting "a growing consensus that agencies must submit a privilege log if they withhold privileged materials from the administrative record."); *Salazar*, 701 F.Supp.2d at 237; *Sierra Club v. U.S. Army Corps of Eng'rs*, Case No. 2:20-cv-396-LEW, 2022 WL 2953075, at *3–4 (D. Me. July 26, 2022); *Alliance for Retired Ams. v. Bessent*, Case No. 25-0313, 2025 WL 2576530, at *2 (D.D.C. Mar. 4, 2025) (requiring privilege log for documents withheld under the attorney-client privilege); *see also Defs. of Wildlife v. U.S. Dep't of the Interior*, No. 18-2090 (4th Cir. Feb. 5, 2019) (granting motion to compel completion of the administrative record and directing the government to submit a privilege log identifying any documents withheld under the guise of deliberate process privilege or any other privilege).

We would appreciate a response to this letter by April 7, 2026.

Sincerely,

James J. Oh

CATEGORIES OF DOCUMENTS MISSING FROM AR #4
(CHILDHOOD IMMUNIZATION SCHEDULE)

As alleged in Plaintiffs' Fourth Amended Complaint, "[t]he events in the public record leading up to the January 5 Action demonstrate an orchestrated plan to unilaterally change the U.S. Childhood Schedule without examining the relevant data or providing a reasonable explanation." (ECF 245, ¶ 38; *see also* ¶¶ 39-70). Accordingly, Plaintiffs assert that the following should have been included in AR #4:

1. All documents related to Cynthia Nevison's presentation at the December 4, 2025, meeting of the Advisory Committee on Immunization Practices ("ACIP") on the "Burden of Disease," including documents showing who invited Dr. Nevison to present at the December 4, 2025, ACIP meeting and why, the materials reviewed or relied upon to prepare Dr. Nevison's December 4 presentation, and all communications regarding Dr. Nevison's presentation at the December 4, 2025, ACIP Meeting. (*See* ECF 245, ¶ 40).

2. All documents related to Mark Blaxill's presentation at the December 4, 2025, ACIP Meeting on "HBV Vaccine Safety," including documents showing who invited Mr. Blaxill to present at the December 4, 2025, ACIP meeting and why, the materials reviewed or relied upon to prepare Mr. Blaxill's December 4 presentation, and all communications regarding Mr. Blaxill's presentation at the December 4, 2025, ACIP Meeting. (*See* ECF 245, ¶ 40).

3. All documents related to Aaron Siri's presentation at the December 5, 2025, on "The Childhood/Adolescent Immunization Schedule," including documents showing who invited Mr. Siri to present at the December 5, 2025, ACIP meeting and why, the materials reviewed or relied upon to prepare Mr. Siri's December 5 presentation, and all communications regarding Mr. Siri's presentation at the December 5, 2025, ACIP Meeting. (*See* ECF 245, ¶ 41).

4. All documents related to [redacted] presentation at the December 5, 2025, ACIP Meeting on the "U.S. vs. Danish Vaccine Schedule," including documents showing who invited [redacted] to present at the December 5, 2025, ACIP meeting and why, the materials reviewed or relied upon to prepare [redacted] December 5 presentation, and all communications regarding [redacted] presentation at the December 5, 2025, ACIP Meeting. (*See* ECF 245, ¶ 43).

5. All documents related to the creation of the Presidential Memoranda dated December 5, 2025, titled "Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries" (the "Presidential Memo"), including all drafts of the Presidential Memo,[1] documents showing who and what prompted the Presidential Memo, who was involved in drafting the Presidential Memo, who reviewed and approved a final draft of the Presidential Memo before presented to the President for

[1] Presumably, the drafts are dated. If not, Plaintiffs request the metadata for these drafts to identify the dates on which the drafts were written and/or revised.

signature, and all communications regarding the Presidential Memo. (*See* ECF 245, ¶¶ 44-46).

6. All documents related to the event that was scheduled for Friday, December 19, 2025, but canceled the day before, that the United States Department of Health and Human Services ("HHS") billed as "an event involving children's health" that a senior HHS official said was to be about the Danish childhood schedule,[2] including documents related to why the event was scheduled in the first place, what was to be announced at the event, scripts and/or talking points prepared for that event, why the event was canceled, and all communications related to that event. (*See* ECF 245, ¶¶ 48-51).

7. Minutes, notes, memoranda, or any other documentation of communications with any peer country other than Denmark, Germany, or Japan, before the release of the January 5, 2026, Decision Memo "Adopting Revised Childhood and Adolescent Immunization Schedule" ("Decision Memo").

8. Documents explaining the methodology of how countries were identified as peer countries for purposes of revising the U.S.'s childhood immunization schedule.

9. Documents related to the off-the-record press conference held by the Secretary and former Acting Director [redacted] the morning of January 5, 2026, including all drafts of talking points and/or scripts for the press conference, and any notes, minutes, or memoranda documenting what was said by whom at that press conference. (*See* ECF 245, ¶ 52).

10. Documents related to the changes made to the CDC's Childhood and Adolescent Immunization Schedule by Age that the CDC announced and posted on its website on or about April 24, 2026,[3] that reverted the childhood schedule to July 2, 2025, and classified the COVID-19 vaccination as Shared Clinical Decision Making, consistent with the Secretarial Directive dated May 19, 2025, titled SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN.

[2] https://www.politico.com/news/2025/12/20/rfk-kennedy-danish-vaccine-schedule-denmark-00701999
[3] https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

James J. Oh

To:	Isaac C. Belfer; James Harlow
Cc:	Richard H. Hughes IV; Kathleen A. Barrett; Daniella R. Lee; Elizabeth McEvoy; Robert Wanerman
Subject:	Administrative Records ## 3, 4, and 1
Attachments:	RE: AAP AR #3 - Request to Meet and Confer; 2026-03-31 Letter to DOJ re May Directive Administrative Record.pdf; Categories of Documents Missing From AR _4 5.18.26.pdf

May 18, 2026

Isaac,

We appreciate that the government has met the deadlines for producing the six Administrative Records set forth in the Court's March 24, 2026, Order (ECF 296). Plaintiffs, however, do not believe that the ARs produced are complete and, as previously indicated, would like to meet and confer ASAP about the ARs produced. You indicated that you would be ready to talk mid-week this week. I am attending an out-of-town graduation this week, Monday-Wednesday, so can we please schedule a time on Thursday, May 21, to discuss? When we talk, Plaintiffs would like to prioritize discussion and completion of ARs #3, #4, and #1, in that order. For now, we can table discussion of the other ARs until we have reached the point of a resolution between the parties on these ARs or when we have exhausted efforts to meet and confer.

The issues for discussion on Thursday are as follows:

1. **Documents Marked as Confidential in the Administrative Record Index for AR # 3 (ACIP Reconstitution) and Protective Order**

In the Administrative Record Index for AR #3 served on Friday, April 17, footnote 1 states: "Index entries marked with an asterisk (*) indicate that some or all of the documents have been withheld as confidential." In an April 20, 2026, email to me, you indicated that "[w]hen the footnote in AR #3 index said certain documents were 'withheld as confidential,' that meant the documents contain information that would be designated as 'Confidential Information' under the proposed protective order. It did not refer to privileged information."

In an email a few days later, you indicated that the documents marked with an asterisk on AR #3 index were so marked because "The Privacy Act protects 'any item, collection, or grouping of information about an individual that is maintained by an agency, including, but not limited to, his education ... and ... employment history.' 5. U.S.C. § 552a(a)(4)." (See your email of 4/23/2026 at 7:01 PM). By the title of the documents listed in the AR Index for AR #3, it is unclear how some of the documents could contain information on an individual's employment history. Nor can we readily identify any other category of "Confidential Information" set forth in the proposed P.O. into which any of the documents marked with an asterisk in AR Index #3 might fall. Accordingly, Plaintiffs need to understand how any document marked with an asterisk in AR Index #3 contains information covered by the Privacy Act or falls into a "Confidential Information" category in the proposed P.O.

We also question whether a P.O. is necessary or appropriate in the first place in this case. The Secretary has been operating under the banner of "Radical Transparency" since his nomination and confirmation, and, therefore, we would think that Defendants would welcome all documents produced in the ARs in this case becoming part of the public record. We also are having difficulty understanding how documents such as the "Decision Memo re: Removal of Current and Prospective ACIP Members," or the "June 24, 2025 Decision Memo re: Appointment of New Members to the ACIP, CDC," or a "Financial Operating Plan" could contain either employment history or Confidential information. Furthermore, the Curricula Vitae of nominees to the ACIP have been withheld from production as Confidential, but they are at the very heart of this claim. We note that subsection (b)(11) of 5 U.S.C. § 552a "permits a court of competent jurisdiction to order disclosure of Privacy Act protected information that would otherwise be prohibited from disclosure without prior written consent of the individual to whom the record pertains." United States Department of Justice Overview of the Privacy Act of 1974, p. 119 (2020 edition). When we meet, let's discuss whether the parties can submit an Agreed Order to the Court to produce documents marked with an asterisk in the AR #3 index.

2. **Completeness of AR #3 (ACIP Reconstitution**

Attached hereto is my email of Saturday, April 18, identifying categories of documents that Plaintiffs believe should have been produced in AR #3.

3. **Completeness of AR #4 (Childhood Schedule)**

Attached hereto is a list of categories of documents that Plaintiffs believe should have been produced in AR #4.

4. **Completeness of AR #1 (May 2025 Secretarial Directive)**

Attached hereto is my letter of March 31, 2026, identifying categories of documents that Plaintiffs believe should have been produced in AR #1. In an April 10, 2026, email, you stated that "having considered the issues raised in your letter, we are conducting additional searches to confirm that the administrative record for the May 2025 Secretarial Directive is complete. We will update you after we have finished reviewing the search results." When we meet and confer, please provide an update.

For your convenience, I have attached a .pdf of this email and all attachments.

Please advise on a time we can schedule a call for this Thursday, May 21.

Thank you.

Jimmy

James J. Oh
Epstein Becker Green
227 W. Monroe
Suite 4500
Chicago, IL 60606
(312) 499-1470

AR #3

James J. Oh

From: James J. Oh
Sent: Saturday, April 18, 2026 6:19 PM
To: Belfer, Isaac C.
Cc: Robert Wanerman; Elizabeth McEvoy; Daniella R. Lee; Kathleen Barrett; Harlow, James W.
Subject: RE: AAP AR #3 - Request to Meet and Confer

Isaac,

Following-up on the Certified Administrative Index on AR#3 re the Reconstitution of the ACIP that was produced last evening, the footnote on page 1 of the Certification of the Administrative Record states: "Index entries marked with an asterisk (*) indicate that some or all of the documents have been withheld as confidential." I request a Zoom meet and confer this Monday, April 20, for you to explain what the footnote means. Does this mean that the government will produce the documents marked with an asterisk once a protective order is in place? Or does this footnote mean that the government will not produce them because they are privileged and therefore confidential. I note that there are no corresponding Bates #s next to the documents on the index with an asterisk, and there are no gaps in the Bates numbering of the documents that were produced that are not marked with an asterisk, indicating that the government has no intention of producing the documents marked with an asterisk unless compelled by a court order. I could be wrong about this, which is why I think it best that we talk about this in a call.

AR#3 Documents Marked with an Asterisk

By the title of the documents on the certified index, I don't see how most, if not all, of the documents marked with an asterisk could be "Confidential," whatever that means in this context. Questions about the documents marked with an asterisk include the following:

1. Decision Memos:
    a. June 9, 2025 Decision Memo re: Removal of Current and Prospective ACIP Members
    b. June 24, 2025 Decision Memos re: Appointment of New Members to the ACIP, CDC
    c. June 24, 2025 Decision Memo re: Nominations to ACIP
    d. November 26, 2025 Decision Memo re: Nomination to the ACIP
    e. December 3, 3025 Decision Memo re: Chair and Vice Chair Nominations to the ACIP
    f. December 23, 2025 Decision Memo re: Nominations to the ACIP
    g. I don't understand how these Decision Memos could be Confidential where the government has produced other Decision Memos that have not been marked Confidential. See May 27, 2025 Decision Memo re: Recission of CDC Recommendations for COVID-19 Vaccines for Healthy Children and Pregnant Women," HHS_AAP 000092-93; and October 3, 2025 Decision Memo re ACIP Recommendation for COVID-19 Vaccination," HHS_AAP 1914-17.
2. June 9, 2025 Notification Letters of ACIP Termination.
    a. Assuming that these are the letters sent to the terminated ACIP Members on June 9 (which I understand actually were short emails), I don't understand how a letter sent to a fired ACIP Member and third party could be considered Confidential.

3. Attachment D – Financial Operating Plan attached to the September 10, 2025 Decision Memo and December 3, 2025 Decision Memo re: Chair and Vice Chair Nominations to the ACIP.
    a. Please explain why the Financial Operating Plan presumably for the ACIP, a federal advisory committee, is Confidential and not knowledge the public is entitled to know.
4. Attachment E – Curricula Vitae of Nominees attached to September 10, 2025 Decision Memo, November 26, 206 Decision Memo.
    a. I am having difficult understanding why anyone's curriculum vitae is Confidential, where the CVs were submitted to the federal government for a position on a public federal advisory committee.
5. HS-532 Requests for Approval of Nominees for Public Advisory Committees attached to:
    a. June 24, 2025 Decision Memo
    b. September 10, 2025 Decision Memo
    c. November 26, 2025 Decision Memo re Nomination to the ACIP
    d. December 3, 2025 Decision Memo re: Chair and Vice Chair Nominations to the ACIP
    e. December 23, 2025 Decision Memo re Nominations to the ACIP
    f. Please explain why these Requests for Approval are confidential.
6. Biographies of ACIP Candidates
    a. I don't understand how these possibly could be Confidential.
7. HHS Correspondence with **External** Stakeholders re: ACIP Reform and Committee Nominations (emphasis added)
    a. Correspondence with external stakeholders cannot be privileged, since it is correspondence with a third party.
    b. The description of this correspondence indicates that this correspondence goes to the heart of Plaintiffs' FACA claim re inappropriate influence by special interests and, therefore, should be produced.
8. Communications between HHS and Potential ACIP Nominees.
    a. I need to hear an explanation as to why these communications are considered Confidential and have not been produced.
9. ACIP Nominations Submitted to the CDC Website and Resource Mailbox
    a. I need to hear an explanation as to why these documents are considered Confidential and have not been produced.
10. HHS Meeting re: Potential ACIP Nominees
    a. I need to hear an explanation as to whether this is one document or many, why the document(s) is/are Confidential, and whether Defendants will identify at least how many meetings occurred and who attended. At a minimum, the information on the identities of who participated in these meetings cannot be protected from disclosure.
11. Public and Congressional Comments on ACIP Reconstitution.
    a. If these are public documents, how can they be Confidential?

Missing from AR#3

When we meet and confer, we also need to discuss what is missing from AR#3, including, but not limited to, the following:

1. In his June 9, 2025, WSJ Commentary announcing the firing of the ACIP, RFK justified the terminations because "[t]he committee has been plagued with persistent conflicts of interest." Presumably, the Secretary has documentation of the then 17 members' conflicts of interest that

justified their terminations. Please produce such documents. Alternatively, please confirm that the Secretary did not review and/or does not possess any such documents.

2. The CDC's website currently states: "Upon appointment, each voting member is required to file an Office of Government Ethics 450 form (OGE450), a Confidential Financial Disclosure Report, which is reviewed by the ACIP Secretariat, the Federal Advisory Committee Management Branch and the Office of General Counsel at CDC." https://www.cdc.gov/acip/apply-for-membership/index.html (visited on 4/18/26).
    a. Please produce the OGE450s for every new ACIP member appointed by the Secretary or confirm that they do not exist.
    b. For example, [redacted]he Chair of the new ACIP that met for the first time on June 25, 2026, was an expert witness in legal cases against Merck. Presumably, he made disclosures about his role as an expert witness against Merck or any other pharmaceutical companies. https://www.statnews.com/2025/07/09/kennedy-conflict-of-interest-radical-transparency-acip-vaccine-experts/. Please produce such disclosures or confirm that he did not make them before, during, or after his appointment to the ACIP.
3. AR#3 includes no documents that ACIP candidates are supposed to submit for selection to the ACIP, including at least two letters of recommendation and a cover letter that includes a statement of interest. See https://www.cdc.gov/acip/apply-for-membership/index.html. Please produce such documents or confirm that they do not exist.
4. In a June 12, 2025, post on X, Robert Malone stated: "i have already completed three months of ethics vetting and COI training by appropriate HHS officials.'" No documents were produced in AR#3 on the ethics vetting and training Dr. Malone claims he completed or that any other ACIP member appointed by the Secretary completed. Please produce those documents.
5. In her Declaration filed on the record on February 17, 2026 (ECF 242), Diana Zuckerman attested that she was vetted for a position on the ACIP by a partner at Aaron Siri's law firm. Nothing was produced in AR#3 regarding Siri's law firm's involvement in the nomination and/or vetting process for Dr. Zuckerman or any other candidate. Please produce those documents.
6. As you know, a new ACIP Charter was published on April 9, 2026. Plaintiffs find the new Charter to be suspect and problematic. The facts indicate that Defendants, prompted by A[redacted] and the Informed Consent Action Network, adopted the new Charter specifically to do an end-run around Judge Murphy's March 16, 2026, preliminary injunction order. See https://www.facebook.com/del.bigtree/posts/huge-news-after-a-court-ruling-wiped-out-recent-vaccine-program-changes-made-by-/10162096421190964/ . The new Charter is thus related and relevant to Plaintiffs' ACIP Reconstitution claim. Accordingly, it is Plaintiffs' position that any and all documents related to the new ACIP Charter should be produced as part of AR#3.

If you decline to meet and confer on Monday, or if Defendants take the position that none of the documents marked with an asterisk will be produced, please let me know whether you agree that this email satisfies Plaintiffs' obligation under the local rules to meet and confer before filing a motion.

Thank you.

Jimmy

James J. Oh

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From: Belfer, Isaac C. <Isaac.C.Belfer@usdoj.gov>
Sent: Friday, April 17, 2026 8:27 PM
To: James J. Oh <JOh@ebglaw.com>
Cc: Richard H. Hughes IV <RHHughes@ebglaw.com>; Robert Wanerman <RWanerman@ebglaw.com>; Elizabeth McEvoy <EMcEvoy@ebglaw.com>; Gianna Costello <GCostello@ebglaw.com>; Daniella R. Lee <DLee@ebglaw.com>; Kathleen Barrett <KBarrett@ebglaw.com>; Harlow, James W. <James.W.Harlow@usdoj.gov>
Subject: AAP AR #3

***** EXTERNAL EMAIL *****

Jimmy,

Attached is the certified index for the administrative record due today. I will send you a link to download the nonconfidential documents in the record.

Thanks,
Isaac

Isaac C. Belfer
U.S. Department of Justice
Civil Division | Federal Programs Branch
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AR #4

CATEGORIES OF DOCUMENTS MISSING FROM AR #4
(CHILDHOOD IMMUNIZATION SCHEDULE)

As alleged in Plaintiffs' Fourth Amended Complaint, "[t]he events in the public record leading up to the January 5 Action demonstrate an orchestrated plan to unilaterally change the U.S. Childhood Schedule without examining the relevant data or providing a reasonable explanation." (ECF 245, ¶ 38; *see also* ¶¶ 39-70). Accordingly, Plaintiffs assert that the following should have been included in AR #4:

1. All documents related to [redacted] presentation at the December 4, 2025, meeting of the Advisory Committee on Immunization Practices ("ACIP") on the "Burden of Disease," including documents showing who invited [redacted] to present at the December 4, 2025, ACIP meeting and why, the materials reviewed or relied upon to prepare [redacted] December 4 presentation, and all communications regarding [redacted] presentation at the December 4, 2025, ACIP Meeting. (*See* ECF 245, ¶ 40).

2. All documents related to [redacted] presentation at the December 4, 2025, ACIP Meeting on "HBV Vaccine Safety," including documents showing who invited [redacted] to present at the December 4, 2025, ACIP meeting and why, the materials reviewed or relied upon to prepare [redacted] December 4 presentation, and all communications regarding Mr. Blaxill's presentation at the December 4, 2025, ACIP Meeting. (*See* ECF 245, ¶ 40).

3. All documents related to [redacted] presentation at the December 5, 2025, on "The Childhood/Adolescent Immunization Schedule," including documents showing who invited [redacted] to present at the December 5, 2025, ACIP meeting and why, the materials reviewed or relied upon to prepare [redacted] December 5 presentation, and all communications regarding Mr. Siri's presentation at the December 5, 2025, ACIP Meeting. (*See* ECF 245, ¶ 41).

4. All documents related to [redacted] presentation at the December 5, 2025, ACIP Meeting on the "U.S. vs. Danish Vaccine Schedule," including documents showing who invited [redacted] to present at the December 5, 2025, ACIP meeting and why, the materials reviewed or relied upon to prepare [redacted] December 5 presentation, and all communications regarding [redacted] presentation at the December 5, 2025, ACIP Meeting. (*See* ECF 245, ¶ 43).

5. All documents related to the creation of the Presidential Memoranda dated December 5, 2025, titled "Aligning United States Core Childhood Vaccine Recommendations with Best Practices from Peer, Developed Countries" (the "Presidential Memo"), including all drafts of the Presidential Memo,[1] documents showing who and what prompted the Presidential Memo, who was involved in drafting the Presidential Memo, who reviewed and approved a final draft of the Presidential Memo before presented to the President for

[1] Presumably, the drafts are dated. If not, Plaintiffs request the metadata for these drafts to identify the dates on which the drafts were written and/or revised.

signature, and all communications regarding the Presidential Memo. (*See* ECF 245, ¶¶ 44-46).

6. All documents related to the event that was scheduled for Friday, December 19, 2025, but canceled the day before, that the United States Department of Health and Human Services ("HHS") billed as "an event involving children's health" that a senior HHS official said was to be about the Danish childhood schedule,[2] including documents related to why the event was scheduled in the first place, what was to be announced at the event, scripts and/or talking points prepared for that event, why the event was canceled, and all communications related to that event. (*See* ECF 245, ¶¶ 48-51).

7. Minutes, notes, memoranda, or any other documentation of communications with any peer country other than Denmark, Germany, or Japan, before the release of the January 5, 2026, Decision Memo "Adopting Revised Childhood and Adolescent Immunization Schedule" ("Decision Memo").

8. Documents explaining the methodology of how countries were identified as peer countries for purposes of revising the U.S.'s childhood immunization schedule.

9. Documents related to the off-the-record press conference held by the Secretary and former Acting [redacted] the morning of January 5, 2026, including all drafts of talking points and/or scripts for the press conference, and any notes, minutes, or memoranda documenting what was said by whom at that press conference. (*See* ECF 245, ¶ 52).

10. Documents related to the changes made to the CDC's Childhood and Adolescent Immunization Schedule by Age that the CDC announced and posted on its website on or about April 24, 2026,[3] that reverted the childhood schedule to July 2, 2025, and classified the COVID-19 vaccination as Shared Clinical Decision Making, consistent with the Secretarial Directive dated May 19, 2025, titled SECRETARIAL DIRECTIVE ON PEDIATRIC COVID-19 VACCINES FOR CHILDREN LESS THAN 18 YEARS OF AGE AND PREGNANT WOMEN.

[2] https://www.politico.com/news/2025/12/20/rfk-kennedy-danish-vaccine-schedule-denmark-00701999
[3] https://www.cdc.gov/vaccines/hcp/imz-schedules/child-adolescent-age.html

AR #1

EPSTEIN
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March 31, 2026

VIA EMAIL

Isaac C. Belfer
United States Department of Justice
Isaac.C.Belfer@usdoj.gov

Re: ***American Academy of Pediatrics, et al. v. Kennedy, et al.:***
Administrative Record On The May 27 Directive

Dear Isaac:

On March 12, 2026, Defendants produced what they claim in a "Certification of Administrative Record" of that same date to be "a true, correct, and *complete* copy of the non-privileged information that was directly or indirectly considered in connection with the May 27 Secretarial Directive on Pediatric COVID-19 Vaccines for Children Less Than 18 Years of Age and Pregnant Women and the implementation of that directive." ("May 2025 Directive") (emphasis added). Plaintiffs believe that the Administrative Record ("AR") that Defendants produced on the May 2025 Directive is far from complete. Plaintiffs expected, but did not see, multiple categories of documents that should exist and should have been produced in the AR on the May 2025 Directive but were not. In this letter, Plaintiffs itemize those categories of documents that they contend are missing from the AR on the May 2025 Directive.

As you know, "[t]he administrative record is that which was before the agency at the time the decision being reviewed was made, and it consists of *all* documents and materials directly or indirectly considered by agency decision-makers and includes evidence contrary to the agency's position." *Towns of Norfolk & Walpole v. U.S. Army Corps of Engineers*, 137 F.R.D. 183, 185 (D. Mass. 1991), *aff'd*, 968 F.2d 1438 (1st Cir. 1992) (emphasis added). In addition, when an agency's decision-making process is the central issue in a case brought pursuant to the Administrative Procedure Act, as in this case, then the government cannot shield documents from disclosure under the deliberative process privilege. *See New York v. Salazar*, 701 F.Supp.2d 224, 237 (N.D.N.Y. 2010) (emphasis added) (holding documents could not be withheld on basis of deliberative process privilege because the "central theme of many of plaintiffs' claims" was that the "deliberative process itself was fatally flawed"); *see also Texaco Puerto Rico, Inc. v. Dep't of Consumer Affairs*, 60 F.3d 867, 885 (1st Cir. 1995) (acknowledging that the deliberate process privilege is a qualified privilege—not an absolute one—and that courts consider various factors when determining whether to permit the privilege, including "the interests of the litigants, society's interest in the

accuracy and integrity of factfinding, and the public's interest in honest, effective government"). Finally, as Plaintiffs previously noted in our letter dated November 7, 2025, we expect that there are emails and text messages that influenced the decision makers on the May 2025 Directive. Currently, the AR on the May 2025 Directive is largely devoid of emails or other electronic communications. Plaintiffs are entitled to know with whom the Secretary consulted about the May 2025 Directive and the evidence relied upon—whether directly or indirectly—to issue the May 2025 Directive. *See Bimini Superfast Operations LLC v. Winkowski*, 994 F.Supp.2d 103, 106 (D.D.C. 2014) (holding emails were properly included in administrative record as documents that were directly or indirectly considered in decision making); *see also Towns of Norfolk & Walpole*, 137 F.R.D. at 185.

Before I list the categories of documents that Plaintiffs contend should have been produced in the May 2025 Directive AR but were not, a brief summary of the facts regarding the May 2025 Directive is in order to provide context for Plaintiffs' contentions.

On May 27, 2025, the Department of Health and Human Services ("HHS") posted a video on X in which Secretary Kennedy, with Food and Drug Administration ("FDA") Commissioner Marty Makary, and National Institutes of Health ("NIH") Director Jay Bhattacharya, at his side, announced that he had directed the Centers for Disease Control and Prevention ("CDC") to remove the recommendations that pregnant women and "healthy children" receive a Covid-19 booster. To be sure, the words spoken in the video were scripted. On that same day, HHS released the May 2025 Directive that instructed the CDC to remove the recommendations that pregnant women and healthy children receive the Covid-19 vaccine. However, two days later, the CDC did not remove from the childhood schedule the routine recommendation that children receive the Covid-19 vaccine but instead reclassified the Covid-19 vaccine for children to Shared Clinical Decision-Making ("SCDM"). To date, neither HHS nor the CDC nor the Secretary have provided any explanation why the instruction to remove the childhood recommendation was instead changed to SCDM.

On February 27, 2026, when Defendants filed their second opposition to Plaintiffs' preliminary injunction motion, Defendants for the first time produced three memos regarding the May 2025 Directive: (1) a "Decision Memo" dated May 27, 2025, from [redacted], Acting General Counsel that apparently was delivered to Secretary Kennedy "THROUGH: [redacted], Executive Secretary," the subject of which was: "DECISION – Recission of CDC Recommendations for COVID-19 Vaccines for Healthy Children and Pregnant Women" (the "Covid Decision Memo"); (2) a "Memorandum To The Secretary," "THROUGH: [redacted] Chief of Staff and [redacted], Executive Secretary," from [redacted] Principal Deputy Director, NIH, and [redacted] Principal Deputy Commissioner, FDA, the subject of which was "Medical and Scientific Assessment of Secretary Becerra's Determination Recommending COVID-19 Vaccination of Children Less Than 18 Years of Age," (the "Memoli/Brenner Memo"); and (3) a memo from [redacted] of the FDA to Secretary Robert F. Kennedy, Jr., the subject of which was "COVID-19 vaccine safety in pregnant women" (the "Høeg Memo").

In light of these facts, Plaintiffs contend that the following categories of documents should have been produced in the AR on the May 2025 Directive:

1. Documents[1] demonstrating when and why Secretary Kennedy[2] first considered directing the CDC to remove the routine recommendations that pregnant women and children receive the Covid-19 vaccine.
2. Any articles or studies that post-date the onset of the Covid-19 pandemic that Secretary Kennedy and/or the Office of the Secretary considered to support removing the recommendation that children receive the Covid-19 vaccine.
3. Any articles or studies that post-date the onset of the Covid-19 pandemic that Secretary Kennedy and/or the Office of the Secretary considered to support removing the recommendation that pregnant women receive the Covid-19 vaccine.
4. Any analyses of these articles, studies, or data that were performed to justify the changes in the Covid-19 vaccine recommendations for pregnant women and children.
5. Documents indicating with whom the Office of the Secretary consulted about issuing the May 2025 Directive both inside and outside of the federal government.
6. The script for the May 27, 2025, video and drafts thereof.
7. Documents demonstrating whether Secretary Kennedy consulted anyone on the Advisory Committee on Immunization Practices ("ACIP") before issuing the May 2025 Directive.
8. Documents explaining why Commissioner Makary and Director Bhattacharya appeared in the May 27, 2025, video alongside Secretary Kennedy and why leaders from CDC were excluded.
9. Documents demonstrating that Secretary Kennedy or the Office of the Secretary consulted with anyone at CDC about the May 2025 Directive.
10. In the May 27, 2025, video, Secretary Kennedy stated that there was a "lack of any clinical data to support the repeat [Covid] booster strategy" for children. The month before, however, multiple presentations were made at the April 15, 2025, meeting of the ACIP in which clinical data was presented that demonstrated the opposite: children and pregnant women should continue to receive Covid boosters. Accordingly, Plaintiffs question whether Secretary Kennedy did *in fact* consider the presentations that Defendants produced in the May 2025 Directive AR numbered HHS_AAP 001006 - HHS_AAP 001018, HHS_AAP 001019 - HHS_AAP 001045, HHS_AAP 001046 - HHS_AAP 001074, HHS_AAP 001075 - HHS_AAP 001089, and HHS_AAP 001090 - HHS_AAP 001158. Accordingly, Defendants should produce documents demonstrating that Secretary Kennedy, Commissioner Makary, and Director Bhattacharya *actually* received, reviewed, and considered these presentations before making the May 27 video.

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[1] As used herein, "Documents" and "Communications" include emails, text messages, instant messages, voice mail messages, memoranda, PowerPoint presentations, and any other document, whether in electronic or hard copy form, related to the specified subject matter.

[2] As used herein, "Secretary Kennedy" means Robert F. Kennedy, Jr., the individual, in his official capacity as Secretary of the Department of Health and Human Services. As used herein, "Office of the Secretary" means Robert F. Kennedy, Jr., his Chief of Staff, anyone in the Immediate Office of the Secretary, particularly Stephanie Spear, anyone in the Office of the Secretary, and anyone holding an Agency Leadership position. *See* https://www.hhs.gov/about/leadership/index.html.

11. Communications between Commissioner Makary, Director Bhattacharya, the Office of the Secretary, and Secretary Kennedy related to the May 27, 2025, video announcing the May 2025 Directive.
12. Attached to the Decision Memo were the Memoli/Brenner Memo, the Høeg Memo, and the May 2025 Directive. Any other documents that Kennedy considered when drafting the Decision Memo should be produced.
13. Documents showing with whom Kennedy consulted about the Decision Memo or who provided input or revisions to the Decision Memo.
14. Documents identifying who drafted and offered input or revisions to drafts of the May 2025 Directive.
15. Communications between Commissioner Makary, Director Bhattacharya, the Office of the Secretary, and the Secretary related to the May 2025 Directive.
16. Communications and/or documents related to the CDC's interpretation of the May Directive and publication of the updated schedule.
17. Communications related to the May 2025 Directive that were sent to or received from Children's Health Defense.
18. Communications related to the May 2025 Directive that were sent to or received from the law firm [redacted] or from any individual affiliated with the law firm of [redacted]
19. Communications related to the May 2025 Directive that were sent to or received from the Informed Consent Action Network.
20. Communications demonstrating that the Secretary considered Commissioner Makary's and Vinay Prasad's May 20, 2025 New England Journal of Medicine article ("An Evidence-Based Approach to Covid-19 Vaccination")—which stated that "pregnancy and recent pregnancy" are factors which "increase a person's risk of severe COVID-19."
21. Documents that explain why [redacted] drafted the Memoli/Brenner Memo.
22. Documents that explain why [redacted] drafted the Høeg Memo.
23. Communications between [redacted] regarding the Memoli/Brenner Memo.
24. Communications between [redacted] about the Memoli/Brenner Memo and/or the May 2025 Directive.
25. Communications between [redacted] about the Memoli/Brenner Memo, the Høeg Memo, or the May 2025 Directive.
26. Communications between [redacted] the Office of the Secretary, and Secretary Kennedy about the Memoli/Brenner memo.
27. Communications between [redacted] the Office of the Secretary, and Secretary Kennedy about the Høeg Memo.
28. Communications between [redacted] and anyone at the CDC about the Memoli/Brenner Memo.
29. Communications between [redacted] and anyone at the CDC about the Høeg Memo.

30. Communications between [redacted] and anyone on the ACIP or in the Office of the Executive Secretary of the ACIP about the Memoli/Brenner Memo and/or the May 2025 Directive.
31. Communications between [redacted] and anyone on the ACIP or in the Office of the Executive Secretary of the ACIP about the Høeg Memo and/or the May 2025 Directive.
32. Documents demonstrating that Secretary Kennedy, the Office of the Secretary, Commissioner Makary, and/or Director Bhattacharya considered any of the following before the May 2025 Directive was issued:
    a. the legality of bypassing the ACIP in issuing the May 2025 Directive;
    b. the impact that the May 2025 Directive would have on insurance coverage of the Covid vaccine;
    c. the impact that the May 2025 Directive would have on the VFC program;
    d. the impact that May 2025 Directive would have on medical practices, other health care providers, health care facilities, and suppliers;
    e. the impact that the May 2025 Directive would have on pharmacies;
    f. the impact that the May 2025 Directive would have on rates of Covid-19 infection;
    g. the impact that the May 2025 Directive would have on rates of serious illness and/or death from Covid-19;
    h. the impact that the May 2025 Directive would have on Covid-19 vaccination rates;
    i. the impact that the May 2025 Directive would have on skepticism about the Covid-19 vaccine;
    j. the impact that the May 2025 Directive would have on the public's trust in the Covid-19 vaccine;
    k. the impact that the May 2025 Directive would have on the public's trust of vaccines in general.

If you contend that any of the foregoing categories of document are protected from disclosure under any privilege, please specify which privilege Defendants contend apply to each of the categories of documents delineated above. Further, please provide a privilege log. *See Roe v. Mayorkas*, Case No. 22-cv-10808-ADB, 2024 WL 5198705, at *10 (D. Mass. Oct. 2, 2024) (noting "a growing consensus that agencies must submit a privilege log if they withhold privileged materials from the administrative record."); *Salazar*, 701 F.Supp.2d at 237; *Sierra Club v. U.S. Army Corps of Eng'rs*, Case No. 2:20-cv-396-LEW, 2022 WL 2953075, at *3–4 (D. Me. July 26, 2022); *Alliance for Retired Ams. v. Bessent*, Case No. 25-0313, 2025 WL 2576530, at *2 (D.D.C. Mar. 4, 2025) (requiring privilege log for documents withheld under the attorney-client privilege); *see also Defs. of Wildlife v. U.S. Dep't of the Interior*, No. 18-2090 (4th Cir. Feb. 5, 2019) (granting motion to compel completion of the administrative record and directing the government to submit a privilege log identifying any documents withheld under the guise of deliberate process privilege or any other privilege).

We would appreciate a response to this letter by April 7, 2026.

Sincerely,

James J. Oh