DEPARTMENT OF HEALTH AND HUMAN SERVICES

Washington, D.C. 20201

February 2, 2022

Via e-mail: rationalbasis@protonmail.com

Dear Petitioner:

Thank you for your petition, attached as Exhibit A, submitted by email to the Good Guidance inbox on September 21, 2021, and directed to the U.S. Department of Health and Human Services (HHS or Department), the Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), and all other component agencies of HHS.

In your email submission, you requested that HHS and its agencies:

> "revise each guidance document, order, and regulation that relates to SARS-CoV-2/COVID-19 and:
> 1. Recommends or requires children under the age of 12 to wear masks in any setting;
> 2. Recommends or requires children to be administered more than one dose of vaccine."

You assert that "HHS/CDC/FDA guidance, orders, and regulations" should: (1) raise "any minimum age required or recommended for masking to an age greater than two" and (2) "consider when the potential risks of myocarditis…outweigh the benefits of multi-dose vaccination regimens" in children, especially young men. You further assert that your petition should be addressed under 45 CFR § 1.5[1] and 5 U.S.C. § 533(e).

After careful review, CDC and FDA have determined that your email submission does not satisfy the requirements for a petition under the Good Guidance Practices (GGP) regulations. 45 CFR Part 1. We also decline your request under 5 U.S.C. § 553(e) of the Administrative Procedure Act (APA) to engage in rulemaking, to the extent that provision is applicable. HHS, and CDC and FDA in particular, are already actively engaged in considering evolving science and regulating certain matters concerning COVID-19 specifically including the matters recommended in your request. Therefore, your petition is denied.[2]

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[1] HHS has proposed to repeal the Good Guidance Practices regulations. *See* 86 Fed. Reg. 58042 (Oct. 20, 2021).

[2] This letter focuses on the primary reasons for denying your petition and does not waive other bases for denial of your petition not raised herein.

Response under the GGP Regulations, 45 CFR §§ 1.1 - 1.9

1. "Guidance Document" Requirements

Your submission fails to meet the requirement to identify any "particular guidance document" under 45 CFR § 1.5. Your submission does not identify a single specific guidance document with which you take issue. Instead, your submission requests a generalized review of all guidance, orders, and regulations that involve masks and vaccines for children to reduce the spread of the SARS-CoV-2 virus and the resulting coronavirus disease 2019 (COVID-19). Accordingly, your submission does not identify a "guidance document" under 45 CFR § 1.2(a) or a "particular guidance document" under 45 CFR § 1.5(a) to be revised. Under 45 CFR § 1.2(a), a "guidance document" is "any Department statement of general applicability, intended to have future effect on the behavior of regulated parties and which sets forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation." Under 45 CFR § 1.5(a), an "interested party may petition the Department to … modify any **particular guidance document**" (emphasis added).

Your petition also cites to three CDC webpages.[3] The three webpages are not "guidance documents" that are subject to petition under the GGP regulations because they are not HHS or CDC statements that "set[] forth a policy on a statutory, regulatory, or technical or scientific issue, or an interpretation of a statute or regulation." 45 CFR § 1.2(a). Rather, the webpages offer public health recommendations to the general public, and contain neutral, technical or scientific information that is not intended to be covered by the GGP regulations. As the preamble to the GGP regulation states, "[a]gency releases of technical or scientific information by itself would not constitute guidance unless the release also contains a policy on, or related to, technical or scientific information that is intended to affect the future behavior of regulated parties." *See* 85 Fed. Reg. at 78772. In addition, the third webpage does not involve the main subjects of your submission (masks and vaccines).

Additionally, your petition does not identify any particular FDA guidance document that the petition seeks to have modified or withdrawn. Nor has FDA identified any such guidance document based on the description in your petition.

2. Regulations and Orders

Your petition seeks to revise unspecified regulations and orders about masks and vaccines for children. However, the GGP regulations provide for petitions regarding guidance documents and does not apply to regulations and orders.

Under 45 CFR § 1.5(a), "Any interested party may petition the Department to withdraw or modify any particular guidance document." Furthermore, the term "guidance document" explicitly "does not include rules promulgated pursuant to notice and comment" under § 553 of the APA. 45 CFR § 1.2(a).

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[3] The pages are: (1) https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html; (2) https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html, and (3) https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html.

In addition, the GGP regulations do not provide for petitions regarding orders. Your email submission refers generally to "each" order related to masks and vaccines for children, but it identifies only one CDC Order: *Requirement for Persons To Wear Masks While on Conveyances and at Transportation Hubs*, 86 Fed. Reg. 8025 (Feb. 3, 2021) (the Order). The Order does not qualify as a "guidance document" under the GGP regulations. The Order describes itself as "an emergency action taken under the existing authority" of 42 U.S.C. § 264(a) and 42 CFR § 70.2, 71.31(b), and 71.32(b). *See* 86 Fed. Reg. at 8030.

3. Grounds for Petition

Section 1.5(a) identifies three specific objections that can be raised with respect to guidance documents. *See* 85 Fed. Reg. at 78783 (permitting challenges to guidance documents that (1) "impose binding obligations," or (2) "create additional legal obligations" beyond what is required by applicable statutes and/or regulations, or (3) which have been "improperly exempted" from the GGP regulations). HHS considers a petition to be subject to the process in section 1.5 only if it raises one of these three objections. *See*, *e.g.*, 85 Fed. Reg. at 78783 ("interested parties can petition HHS and assert one of three bases for the petition"). Your petition, however, only challenges scientific and technical determinations, not specific objections identified under section 1.5(a). Therefore, it is not the type of petition subject to section 1.5. CDC does not view those webpages as "guidance documents" as defined in the GGP regulations. Specifically, you have not petitioned CDC to modify those webpages on the bases of section 1.5 but instead have challenged the merits of the information on the websites. However, "the Good Guidance Practices regulations [do] not require HHS to justify the quality of information," nor does section 1.5 permit petitions challenging the merits of guidance documents. 85 Fed. Reg. at 78772, 78783.

In summary, your petition does not properly invoke 45 CFR § 1.5 because (1) it is does not identify a "particular guidance document" under the GGP regulations to revise, (2) orders and regulations are outside the scope of the GGP regulations, and (3) the grounds for your petition do not fit within the parameters of section 1.5.

Response under the APA, 5 U.S.C. § 553(e)

We also deny your petition for rulemaking under 5 U.S.C. § 553(e) of the APA, to the extent that provision applies, because such rulemaking is not warranted in the current regulatory environment regarding COVID-19. *See* 5 U.S.C. § 555(e) (providing for prompt notice of the denial of a petition with a brief statement of the grounds). Under the APA, each agency must "give an interested person the right to petition for the issuance, amendment, or repeal of a rule." 5 U.S.C. § 553(e). Your email submission does not identify a specific existing rule to amend. Moreover, CDC is extensively considering appropriate measures to combat COVID-19, including recommendations and requirements for mask-wearing by children and administering vaccine to children.

Inclusion of FDA

Your petition also asserts that, in revising the above guidance documents, orders, and regulations, "CDC and FDA should review the relevant literature to ensure that guidance and regulations (use authorizations and marketing permissions) include appropriate information about the risk of myocarditis." FDA has not issued any guidance documents, orders, or regulations that recommend

or require children under the age of 12 to wear masks in any setting or children to be administered more than one dose of vaccine, so this request is not applicable to FDA.

Please note, however, that FDA is actively engaged in an extensive evaluation of data regarding myocarditis risk following administration of the available COVID-19 vaccines, and information about myocarditis is in the respective labeling for each of the available COVID-19 vaccines. FDA has approved two vaccines, Comirnaty (COVID-19 Vaccine, mRNA) and Spikevax (COVID-19 Vaccine, mRNA), for the use in individuals 16 and 18 years of age and older, respectively. Additionally, FDA has authorized the Pfizer-BioNTech COVID-19 Vaccine for emergency use in individuals 5 years of age and older, and the Moderna and Janssen COVID-19 Vaccines for use in individuals 18 years of age and older. All of the COVID-19 vaccines are authorized/approved for the prevention of coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2). The prescribing information for Comirnaty and Spikevax, and both the Fact Sheet for Healthcare Providers Administering Vaccine and the Fact Sheet for Recipients and Caregivers for the Pfizer-BioNTech and Moderna COVID-19 vaccines inform about the risk of myocarditis in several sections of these documents, including the Warnings and Precautions section. The Fact Sheet for Healthcare Providers Administering Vaccine for the Janssen COVID-19 Vaccine lists myocarditis as an adverse reaction that has been identified during post-authorization use of the Janssen COVID-19 Vaccine.

For all of these reasons, CDC and FDA have concluded that, because your petition did not meet the requirements of 45 CFR § 1.5, your petition under that regulation is denied. Your petition for rulemaking under section 553(e) is also denied.

Sincerely,

// Signed //

Tiffany Brown, JD, MPH
Deputy Chief of Staff
Centers for Disease Control and Prevention

cc: Lauren Roth
Associate Commissioner for Policy
Food and Drug Administration

EXHIBIT A

From:	rationalbasis
To:	Good.Guidance (HHS/OGC); Seshasai, Karuna (HHS/IOS); Robinson, Wilma (HHS/IOS); Becerra, Xavier (OS/IOS); janet.woodcock@fda.gov; rochelle.walensky@cdc.gov
Subject:	Re: Petition to modify masking/vaccine guidance and orders pursuant to 45 CFR 1.5 and the Administrative Procedure Act
Date:	Tuesday, September 21, 2021 8:24:20 PM

Secretary Becerra, Director Walensky, and Acting Commissioner Woodcock: Could you please confirm receipt of the petition below, which was submitted to you on Sunday evening?

------- Original Message -------
On Sunday, September 19th, 2021 at 7:12 PM, rationalbasis <rationalbasis@protonmail.com> wrote:

Via email only

Secretary Becerra, Director Walensky, and Acting Commissioner Woodcock:

I am petitioning the Department of Health and Human Services (HHS), the Center for Disease Control (CDC), the Food and Drug Administration (FDA), and all other component agencies of HHS to revise each guidance document, order, and regulation that relates to SARS-CoV-2/COVID-19 and:

1. Recommends or requires children under the age of 12 to wear masks in any setting;

2. Recommends or requires children to be administered more than one dose of vaccine.

At present, your guidance documents and orders/regulations are inconsistent with recommendations by international peers and fail adequately justify your recommendations for masking and vaccination of children. For example, World Health Organization (WHO) guidance[i] states (emphasis in original):

“In general, children **aged 5 years and under** should not be required to wear masks. This advice is based on the safety and overall interest of the child and the capacity to appropriately use a mask with minimal assistance. There may be local requirements for children aged 5 years and under to wear masks, or specific needs in some settings, such as being physically close to someone who is ill. In these circumstances, if the child wears a mask, a parent or other guardian should be within direct line of sight to supervise the safe use of the mask.”

Revisions to HHS/CDC/FDA guidance, orders, and regulations should:

1. **Raise any minimum age required or recommended for masking** to an age greater than two based on a robust benefit/risk assessment. Such an assessment should consider, among other factors, that many children are too developmentally immature to effectively wear a mask.

It is also inequitable to require children or their vaccinated teachers to wear masks in situations that may cause delays in language development or hinder communication. Please include a comprehensive justification for any measures recommended to reduce disease spread in schools to minimize the impact on childhood education, language development, and socialization. You should place an emphasis on ensuring children remain in school unless they test positive for COVID-19. Moreover, because we know vaccines are more effective than masks, you should consider whether public health messaging on the effectiveness of masks is leading to a misperception that masks

provide similar levels of protection to COVID-19 vaccines.

2. **Explicitly consider when the potential risks of myocarditis,** especially in young men, outweigh the benefits of multi-dose vaccination regimens. Children and their caregivers should be provided with nuanced information and be permitted to make a choice for themselves on whether the benefits of vaccination outweigh the risk of adverse events.

This petition should be addressed according to both 45 CFR 1.5 and 5 USC 533(e).

This petition adheres to the requirements of *Procedure to petition for review of guidance* under 45 CFR 1.5 and the requirements of the *Administrative Procedure Act* (APA) under 5 USC 553(e), which specifies: “Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.” In the absence of published procedures to petition HHS and its component agencies under the APA, please accept and respond to this petition as a petition to modify any guidance documents/orders/rules as specified above. I am not a public figure and do not wish to disclose my identity in pursuing this petition, and I believe that doing so is unnecessary under the procedures established by 45 CFR 1.5 and 5 USC 553(e). If your understanding differs, please notify me at this email address immediately.

CDC's February 2021 order, which has been renewed every 90 days, likely exceeds its statutory authority.

Currently, HHS and CDC require, with limited exceptions, children age two and older “to wear masks over the mouth and nose when traveling on any conveyance (e.g., airplanes, trains, subways, buses, taxis, ride-shares, ferries, ships, trolleys, and cable cars) into or within the United States [….] on any conveyance departing from the United States [and] while at any transportation hub within the United States” under the CDC’s February 2021 Notice of Agency Order (86 FR 8025). Additionally, HHS, CDC, and its component agencies provide guidance that recommends that unvaccinated children aged 2 or older wear masks in indoor public places.[ii]

Although these polices may be well-intended—HHS and the CDC have an interest in protecting individuals from disease and preventing community spread of disease, particularly from COVID-19—you likely exceeded your authority[iii] in requiring masks in your February 2021 order, and you have certainly failed to provide a rational basis for requiring or recommending masks for young children who do not have specific risk factors for COVID-19 infection.

Guidance documents should provide nuance and clarity to increase public trust in public health authorities.

The CDC’s general emphasis on masking detracts from vaccination efforts targeted at adults; vaccines are a far more effective means of slowing the spread of COVID-19, ensuring protection against infection of the most vulnerable individuals and populations. For example, you recommend “universal indoor masking for all teachers, staff, students, and visitors to K-12 schools, regardless of vaccination status.”[iv]

You have promulgated requirements and recommendations that suggest a dire need for children to wear masks despite the extremely low risk of severe disease in young children and despite the dearth of evidence that masking is an effective means of reducing infection or transmission in young children, especially in schools. A recent study suggests that strict adherence to masking among adults wearing surgical masks coupled with social distancing may modestly reduce disease prevalence.[v] However, this study did not include children among those surveyed, and it indicates that cloth masks of the type commonly worn in the US may provide no measurable benefit in preventing community spread. Further, we have a much more effective intervention for reducing

disease in adults: vaccines.

Vinay Prasad, MD MPH, recently highlighted many areas where the CDC's order and guidance diverge from those of other similar health authorities in an article excerpted here[vi]:

The World Health Organization, which recommends that children 12 and older wear masks under the same circumstances that adults do, specifically advises against masking kids age 5 and younger. Many European nations have been taking the agency's advice. The United Kingdom has emphasized rapid testing instead of masking and has not required elementary-school students or their teachers to wear a face covering.

In the United States, though, current CDC and American Academy of Pediatrics guidelines call for kids age 2 and up to wear a mask in indoor school or day-care settings; the CDC specifically makes exceptions for napping and eating. (Masking very young children during sleep is inadvisable because of the risk of suffocation.) In other words, the prevailing wisdom in the U.S. calls for 2-to-4-year-olds to wear masks in day care for six or more hours while they are awake, but go unmasked while sleeping side by side in the same room. Shielding children from all coronavirus exposure is difficult for another practical reason: Little kids fidget with their masks.

A health recommendation that takes little account of how human beings act and what they need is unlikely to be successful. […] [M]ask mandates can be challenging for little children to follow and deprive them of stimuli they need.

In addition to recommending masks for young kids, CDC guidelines also urge masks for most vaccinated caregivers who work in infant day-care centers. This advice also deviates from standard practice in other nations, including the U.K. Many studies support the importance of babies seeing caregivers' faces, and prior to the arrival of COVID-19, many American professional organizations, including the AAP, strongly agreed.

In the same article, Dr. Prasad describes schools that are taking drastic measures such as masking outdoors. One does not have to search far for other measures being taken by local authorities that go well beyond what is reasonable: in one instance, Montgomery County, MD purported to be following CDC guidance in quarantining a whole class following a single COVID-19-like symptom.[vii] Are these excesses truly what the CDC intends? If not, HHS, the CDC, and other component agencies should clarify guidance to provide a clear assessment of the benefits and risks involved in masking children.

It is imperative that CDC clarify its guidance on the risk profile of children for the general public.

By merely examining guidance documents, one could be excused from assuming that children have a similar COVID-19 risk profile to that of adults. We know, thankfully, and have known for at least a year, that this is not the case: COVID-19 risk increases enormously with age and other comorbidities such as obesity. We have long known that the risk to unvaccinated children by virtually any metric—symptomatic disease, hospitalization, death, etc.—is orders of magnitude below that of adults[viii],[ix], and your own data confirm that the risk to young children is well below that of even vaccinated adults. Yet, children two and older are subject to all of the most burdensome prevention measures, including constant masking indoors and on public conveyances, because they are unable to be vaccinated. These recommendations and requirements remain in your guidance documents and order despite the clear potential for developmental harm.

Policies that rely on HHS/CDC guidance are not equitable by definition because they are not fair to children, and children cannot voice their needs to government

officials without parental assistance.

The young children and toddlers subject to masking should not be bearing the burden of taking measures to protect adults that are not proven, especially when vaccines—a far more effective countermeasure—are available to all adults in America, and when there are clear signs that masking interferes with childhood development. An intervention that provides no measurable health benefit to children and is in fact burdensome to childhood learning and development cannot be considered an effective let alone equitable intervention.

Children diagnosed with hearing loss or developmental disorders may be more severely impacted by the lack of exposure to full facial expressions among peers and teachers in schooling environments. A study of COVID-19 in England's schools states unequivocally: "Interventions should focus on reducing transmission in and among staff."[x] Why then, does CDC guidance focus on universal masking in schools rather than vaccination of staff?

I would assert that CDC guidance is not based on robust assessment of benefits and risks of mandating masks and other interventions for young children; further CDC has not adequately addressed equity concerns in regards to the risks of mandating masks and other interventions for children. For example:

· A study of 191,509 youth ages 5-17 found that youth gained more weight during the pandemic than before the pandemic with stark increases in body mass index.[xi] These outcomes are reasonable attributable to pandemic policies based on CDC guidance that led to school closures.

· When schools use CDC recommendations as justifications for unwarranted quarantines, the impact on poorer families can be stark in terms of economic equity. People who are able to work from home were healthier and wealthier than the majority of Americans[xii] who do not have the luxury of working from home or taking time off to look after a healthy child sent home by overreaching school policies.

Teens and young adults—along with their caregivers and medical providers—should be provided with appropriate information to determine the number of vaccine doses that they should receive. The CDC's own data and recent studies on vaccine adverse events indicate a significant number of myocarditis cases, especially in young males.[xiii] CDC and FDA should review the relevant literature to ensure that guidance and regulations (use authorizations and marketing permissions) include appropriate information about the risk of myocarditis. No teen or young adult should be forced by their school or employer to take more than one vaccine does if they believe that the risks do not outweigh benefits.

HHS/CDC/FDA should work to restore trust in our public health institutions by treating Americans to the nuance and updated guidance and regulations that they deserve. When public health officials are unwilling to grapple with school closures and vaccine hesitancy in a nuanced way, Americans notice. Unfortunately, the damage of a year of school closures has already been done, and we do not yet fully understand the damage caused by vaccine hesitancy nor masking of young developing children. Please work immediately to revise these guidance documents, orders, and regulations.

In the interest of disclosure, I have bcc'd people across the political and scientific spectrum who may be interested in this petition including members of the media and authors of some of the works cited herein.

Please forward this petition to the relevant individuals in HHS and its component agencies, and please thank your staff for their hard work. I look forward to your response

to this petition within the timeframes established by 45 CFR 1.5 (90 days) and 5 USC 553(e).

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[i] https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/q-a-children-and-masks-related-to-covid-19

[ii] https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/about-face-coverings.html

[iii] You were recently found to have exceeded your authority in *Alabama Association of Realtors v. Department of Health and Human Services*, which involved an order implementing an eviction moratorium. The order in this case relied on the same authorities used in your February 2021 order. The district court opinion stated the following:
"The quarantine provisions in § 264(b)–(d) are structurally separate from those in § 264(a). […] And regardless, like the enumerated measures in § 264(a), the quarantine provisions are cabined and directed toward individuals who are either entering the United States or "reasonably believed to be infected," 42 U.S.C. § 264(c)–(d), and "not to amorphous disease spread" more generally[.] The quarantine provisions in § 264(b)–(d) therefore do not provide support for the eviction moratorium." It is difficult to imagine that the same reasoning could not be applied to your February 2021 order requiring masks.

[iv] https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/k-12-guidance.html

[v] https://www.poverty-action.org/sites/default/files/publications/Mask_RCT____Symptomatic_Seropositivity_083121.pdf

[vi] https://www.theatlantic.com/ideas/archive/2021/09/school-mask-mandates-downside/619952/

[vii] https://twitter.com/DrScottBalsitis/status/1433868745512927232

[viii] https://www.bmj.com/content/370/bmj.m3259

[ix] https://www.cdc.gov/coronavirus/2019-ncov/covid-data/investigations-discovery/hospitalization-death-by-age.html

[x] https://www.thelancet.com/journals/laninf/article/PIIS1473-3099(20)30882-3/fulltext

[xi] https://jamanetwork.com/journals/jama/fullarticle/2783690

[xii] https://www.census.gov/library/stories/2021/03/working-from-home-during-the-pandemic.html

[xiii] https://www.medrxiv.org/content/10.1101/2021.08.30.21262866v1