HHS Responses to Select Subcommittee Majority Draft Final Report (11.29.2024)		
Draft Report Page	**Assertion**	**HHS Response**
1	"On March 13, 2020, the CDC released guidance advising schools that closing for at least eight weeks may be the most effective way to contain the novel coronavirus." …."Accordingly, many public health authorities—including the CDC—supported closing the schools until more could be learned about the novel virus."	This statement is not factually accurate. The footnoted *New York Times* article mischaracterized CDC guidance. CDC did not in fact recommend that schools close due to concerns about student access to education, nutrition, and other services and supports. In technical assistance to state, local, and external partners, CDC advised that closing was not the best option. However, decisions about closures were made at the local level. The document mentioned in the *New York Times* article was a CDC resource document to help health officials and school administrators determine when and how to implement temporary school closures, in the event of an outbreak in a school.
3	"Fourth, the evidence supporting that Covid-19 came from an animal at the Huanan Seafood Market in Wuhan is tenuous. Dr. Chan points of that 'the existing genetic and early case data show that all known Covid-19 cases probably stem from a single introduction of SARS-CoV-2 into people, and the outbreak at the Wuhan market probably happened after the virus had already been circulating in humans.' Furthermore, no infected animal has been verified at the Wuhan market or its supply chain."	The Committee may wish to review the scientific publications found at the following sites: https://pubmed.ncbi.nlm.nih.gov/35881010/; https://pubmed.ncbi.nlm.nih.gov/39303692/.
3	"For example, the CDC published a study from Wood County, Wisconsin to support the proposition that multi-layered mitigation efforts—namely, masking and social distancing—were effective at reducing in-school transmission. However, these conclusions appear to be a gross exaggeration of the scope of the data, as the study explicitly stated that it did not include a comparative unmasked control group to make such a conclusion."	The study in question was conducted and published by CDC as a demonstration that schools could reopen safely for in-person instruction. The mitigation strategies employed by the Wisconsin school – masking and some level of distancing – were decided by school officials, and the characterization of this being an exaggeration of the scope of the data is not factually correct. The comparison group was the surrounding community and the data showed that COVID-19 incidence in schools was 37% lower than that in the surrounding community. The report also fails to mention that there were multiple updates to CDC guidance documents that strongly recommended that schools should reopen for in-person instruction, including a March 19, 2021, update that indicated schools did not need to use social distancing to minimize spread of illness. As noted above, CDC never recommended that schools close. To the contrary, CDC recommendations at the time advised schools to remain open, and recommended that schools should only consider closing in the event of an outbreak of disease in the school community.
9	"Dr. Greta Massetti, the current Principal Deputy Director of the National Center for Injury Prevention and Control and former Principal Deputy Incident Manager at the CDC . . ."	"Dr. Greta Massetti, the current Principal Deputy Director of the National Center for Injury Prevention and Control and former Principal Deputy Incident Manager **for CDC's COVID-19 Emergency Response** . . . "
12	"According to Dr. Greta Massetti, an Associate Director at the CDC..."	"According to Dr. Greta Massetti, **who at the time was part of the CDC's COVID-19 Emergency Response**"
183	"It was designed to be a stopgap for local emergency services and biohazard events."	"It was designed to be a stopgap for local **medical countermeasures** and biohazard events."
183	"Again, the SNS was not created to be the only source of emergency services in the time of a crisis. However, it is the nation's foremost supply of emergency services."	"Again, the SNS was not created to be the only source of emergency **medical countermeasures** in the time of a crisis. However, it is the nation's foremost supply of emergency **medical countermeasures**."
184	"Table 3: Strategic . . ." and chart that follows	Note that there is a $1 billion gap between PHEMCE estimates and annual appropriations received by the Strategic National Stockpile.
188	"Finding: The United States Must Reduce . . . Medical Supplies."	Note that $17 billion has been invested into domestic manufacturing via ASPR. The current FY 25 budget request is for $95 million.
190	"Currently, drug labels from U.S. companies are not required to list the country of origin or specify reliance on different manufactures for APIs for the produced drugs. Drug labels not having the locations of where each chemical in the final product was originated could cause a severe breakdown in the supply chain as well as create a threat to national security."	"Currently, drug labels from U.S. companies are not required **to identify the original manufacturer** or specify reliance on different manufactures for APIs for the produced drugs. **Additionally**, **d**rug labels **do** not **include the original manufacturer of limited high-risk excipients, along with the API and finished drug product. Providing this information could help mitigate supply impacts, enhance national security, and improve public health preparedness.**"

191	"Finding: No Quantitative Scientific Support for Six Feet of Social Distancing"	This is inaccurate, and the report makes no mention of 1) the previous scientific evidence on droplets and 2) that in the pandemic, public health needed to make the best recommendations with limited data on the virus. Six feet of distance was developed using the understanding of droplets based on previous science. Further, CDC continuously assessed and updated its understanding. For example, an update to school guidance from March 19, 2021, indicated that it was not necessary to use 6 feet of distance in schools. GAO's report (released May 2020) on social distancing during pandemics (https://www.gao.gov/products/gao-20-545spis) also addressed this issue. In these guidelines (https://www.cdc.gov/infection-control/media/pdfs/Guideline-Isolation-H.pdf), CDC notes: "Historically, the area of defined risk for droplet transmission has been a distance of ≤3 feet around the patient, which is based on epidemiologic and simulated studies of selected infections. Using this distance for donning masks has been effective in preventing transmission of infectious agents via the droplet route. However, experimental studies with smallpox and investigations during the global SARS outbreaks of 2003 suggest that droplets from patients with these emerging or highly virulent infections could reach persons located 6 feet or more from their source. It is likely that the distance droplets travel depends on the velocity and mechanism by which respiratory droplets are propelled from the source, the density of respiratory secretions, environmental factors such as temperature and humidity, and the ability of the pathogen to maintain infectivity over that distance. Thus, a distance of ≤3 feet around the patient is best viewed as an example of what is meant by "a short distance from a patient" and should not be used as the sole criterion for deciding when a mask should be donned to protect from droplet exposure. Based on these considerations, it may be prudent to don a mask when within 6 to 10 feet of the patient or upon entry into the patient's room, especially when exposure to emerging or highly virulent pathogens is likely."
198	"Ultimately, no conclusive research substantiated that masks protected the public was produced, yet mandating the use of masks maintained the norm throughout the pandemic."	This is not an accurate statement. CDC published science briefs (e.g., https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.htmL) and has pointed to a robust body of evidence about the effectiveness of masks to reduce transmission of virus as shown below. Citations: -- Evidence from high-quality observational studies supports the reduced risk of SARS-CoV-2 with consistent and correct use of masks, with respirators being more effective than surgical masks or cloth masks. Observational studies are critical for topics with sparse randomized controlled trial data – as is the case for masking and SARS-CoV-2. -- Article summarizing >100 published reviews and primary studies: Greenhalgh T, MacIntyre CR, Baker MG, et al. Masks and respirators for prevention of respiratory infections: a state of the science review. Clin Microbiol Rev. 2024 Jun 13;37(2):e0012423. doi: 10.1128/cmr.00124-23. Epub 2024 May 22. PMID: 38775460; PMCID: PMC11326136. -- Article summarizing 35 studies in communities as well as 40 studies in healthcare settings: Boulos L, Curran JA, Gallant A, et al. Effectiveness of face masks for reducing transmission of SARS-CoV-2: a rapid systematic review. Philos Trans A Math Phys Eng Sci. 2023 Oct 9;381(2257):20230133. doi: 10.1098/rsta.2023.0133. Epub 2023 Aug 23. PMID: 37611625; PMCID: PMC10446908. -- Article summarizing high quality observational studies and detailing limitations of available RCTs during pandemic: Cash-Goldwasser S, Reingold AL, Luby SP, et al. Masks During Pandemics Caused by Respiratory Pathogens-Evidence and Implications for Action. JAMA Netw Open. 2023 Oct 2;6(10):e2339443. doi: 10.1001/jamanetworkopen.2023.39443. PMID: 37906187. -- Article summarizing high quality observational studies and detailing limitations of available RCTs during pandemic: Cash-Goldwasser S, Reingold AL, Luby SP, et al. Masks During Pandemics Caused by Respiratory Pathogens-Evidence and Implications for Action. JAMA Netw Open. 2023 Oct 2;6(10):e2339443. doi: 10.1001/jamanetworkopen.2023.39443. PMID: 37906187. -- Article summarizing high quality observational studies and detailing limitations of available RCTs during pandemic: Cash-Goldwasser S, Reingold AL, Luby SP, et al. Masks During Pandemics Caused by Respiratory Pathogens-Evidence and Implications for Action. JAMA Netw Open. 2023 Oct 2;6(10):e2339443. doi: 10.1001/jamanetworkopen.2023.39443. PMID: 37906187.

200-201	"On April 18, a federal judge of the District Court for the Middle District of Florida . . . to modest measures of 'sanitation' like masks."	The section fails to mention the contrary opinion in *Wall v. CDC* , 6:21-cv-975, 2022 WL 1619516 (M.D. Fla. Apr. 29, 2022), in which the court granted the government's motion for summary judgment finding that the mask mandate was lawful. After both decisions were appealed to the 11th Circuit Court of Appeals, the HHS Secretary's declaration of a public health emergency expired on May 11, 2023, ending the mask order by its terms. Thereafter, the 11th Circuit determined that the cases were moot and ordered the judgements in *Health Freedom* and *Wall* vacated and dismissed.
202	"Out of 139 people, 67 customers chose to test for COVID-19 after receiving their service, and 19 of them tested negative."	"Out of 139 people, 67 customers chose to test for COVID-19 after receiving their service, **all of whom** tested negative."
203	"However, the authors noted the difference was not statistically significant, and thus the data could not be used to infer causal relationships."	This is not correct. Required masking for teachers and staff yielded a significant difference. See table one, RR .63 (.47 to .85) does not cross one and is significant.
206	"Yet even with the early knowledge children were not as suspectable to the virus, many students were subjected to wearing masks for much longer than necessary."	It is not clear what "early knowledge" the report is referring to. Early in the pandemic, it was not evident that children were not as susceptible to the virus. The report also does not acknowledge that children were at risk of death and severe illness with approximately 2,000 children dying and almost 200,000 being hospitalized.
290	"Specifically, the FDA tweeted on August 21, 2021, from its official Twitter (now X) account 'You are not a horse. You are not a cow. Seriously, y'all. Stop it.'"	"Specifically, **after receiving multiple reports of patients who required medical attention after self-medicating with ivermectin intended for livestock,** the FDA tweeted on August 21, 2021, from its official Twitter (now X) account 'You are not a horse. You are not a cow. Seriously, y'all. Stop it.'" It is important to note for context that this Tweet responded to reports of health incidents associated with people using ivermectin approved for veterinary use (see, e.g., https://www.avma.org/javma-news/2021-10-01/people-ingesting-veterinary-use-ivermectin-attempts-prevent-cure-covid-19). Currently available clinical trial data do not demonstrate that ivermectin is effective against COVID-19, and invermectin has not been authorized or approved for use in preventing or treating COVID-19 (see https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19).
298	"The decisions made by ACIP are not legally binding, yet, prior to September 2021, it appears that the CDC Director had only ever rejected a recommendation made by ACIP once."	The CDC Director did not "reject" ACIP recommendations. The CDC Director expanded upon them to support access for a larger group of people.
301	"Yet, Acting Commissioner Woodcock herself endorsed President Biden's plan to begin boosting all adults by September 20" and associated footnote.	The September 21, 2021 VRBPAC meeting summary reflects the accurate votes on the topic of boosters (see https://www.fda.gov/media/152597/download).
303-304	"Unfortunately, it appears that Director Walensky may not have meant what she said given that she flagrantly ignored ACIP's expertise and counsel on this key decision."	The characterization that Dr. Walensky ignored ACIP's recommendation is incorrect. It was carefully considered, as Dr. Walensky herself said. As the report states, ACIP is an advisory committee. Ultimately the CDC Director is responsible for the final decision. After carefully considering the available scientific data as well as the VRBPAC and ACIP discussions, the Director made the decision to expand access to the life saving vaccine for more Americans.
305-306	"However, the nuances of the vaccines' regulatory status were unclear to most regular people..."	Statements throughout this page are misleading: "Safe and effective" is a term of art under the law, which has specific requirements before an EUA is authorized. Additionally, FDA published the regulatory review packages with detailed information about the Agency's determination to authorize these two COVID-19 vaccines under an EUA as well as shared information to healthcare providers and the public about these authorizations. Lastly, FDA convened VRBPAC meetings to discuss these COVID-19 vaccines prior to authorization.
321	Section beginning "During the Select Subcommittee's February 15, 2024 hearing . . . "	This section's discussion of Dr. Marks's testimony removes all context from the same line of questioning from Chair Comer. Dr. Marks testified: "There were an increasing number of deaths from COVID-19 [during this period of time], and there was clear knowledge that having an approved vaccine would help Americans feel more comfortable getting vaccinated" (see https://oversight.house.gov/hearing/assessing-americas-vaccine-safety-systemspart-1/; see also https://plus.cq.com/doc/congressionaltranscripts-7944195?3).
322	"Agency Counsel."	"**HHS** Counsel."

340	"However, it was already evident then and is now commonly known that the vaccines do not prevent you from getting infected or transmitting the virus..."	Multiple independent studies using different methodologies have indicated that up to date vaccination against COVID-19 reduces transmission by roughly 50% (see, e.g., https://pubmed.ncbi.nlm.nih.gov/34355689/; https://www.nejm.org/doi/full/10.1056/nejm; https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2792598oa2116597). Even a moderate reduction in transmission reduces symptomatic COVID-19 infection and protects the public health at-large. Research also shows that COVID-19 vaccination prior to SARS-CoV-2 infection reduces the risk of developing Long COVID among both children and adults.
343	"Two weeks later, and in the wake of reports from Israel's Ministry of Health, CDC reversed their stance by saying the rates were 'higher than expected.'"	"**One week** later, **based on the best available data**, CDC reversed their stance by saying the rates were 'higher than expected.'" CDC issued a VaST report on May 24, 2021, that myocarditis and pericarditis rates in young adult males exceeded the expected rate (see https://archive.cdc.gov/www_cdc_gov/vaccines/acip/work-groups-vast/report-2021-05-24.html).
344	"The chart below presents data from VAERS as of February 2024" and the associated table.	The sentence suggests the table that follows will include data as of February 2024, but the heading in the table indicates that the data provided in the table is as of December 19, 2023.
345	Tables entitled "Worldwide Adverse Events" and "Worldwide Deaths"	There is no citation for these tables. It is unclear where these data come from or who created these tables.
345	"However, the vast discrepancy when comparing COVID-19 vaccines over three years, with all other vaccines over more than 30 years raises serious concerns."	It is important to note that under the EUAs for COVID-19 vaccines, the manufacturers (Pfizer and Moderna) as well as vaccination providers were required to report serious adverse events to VAERS irrespective of attribution of vaccination (see https://www.federalregister.gov/documents/2021/01/19/2021-01022/authorizations-of-emergency-use-of-two-biological-products-during-the-covid-19-pandemic-availability). In addition, the public was encouraged to report adverse events to VAERS. This was part of FDA's commitment to vaccine safety surveillance as the COVID-19 vaccines were rolled out across the US under EUA, and is a contributing factor to the number of VAERS reports for COVID-19 vaccines, especially compared to other vaccines. Without this context, this section is misleading.
345	"The Journal highlighted that other countries have acknowledged deaths that were 'likely' or 'probably' caused by COVID-19 vaccines, but CDC has not yet acknowledged a single one—which may be sign that the system is severely overwhelmed."	"The Journal highlighted that other countries have acknowledged deaths that were 'likely' or 'probably' caused by COVID-19 vaccines**.**" CDC has acknowledged nine deaths causally associated with J&J/Janssen COVID-19 vaccination (see https://archive.cdc.gov/www_cdc_gov/coronavirus/2019-ncov/vaccines/safety/adverse-events.html).
345	"The BMJ found that VAERS representatives were inconsistent at following up on reports made to the system."	The report suggests that CDC was not following up on serious VAERS reports, and that people were never contacted or contacted months later. As has been described previously, CDC may not contact every patient. The review starts with and is primary from the medical record and then further contact may be made if necessary.
347-349	"During her transcribed interview with the Select Subcommittee, staff asked Dr. Woodcock to expand upon her statements to the New York Times. Dr. Woodcock testified..."	This discussion is misleading and lacks context. During Dr. Woodcock's transcribed interview she states that she requested FDA vaccine surveillance teams to specifically look for neurological signals and that the FDA team did review for such signals, but were not able to find any. Omitting this part of the transcribed interview results in a misleading statement. We would request the report include this important context.
350	"Specifically, ICAN reports that the data show 782,913 individuals, or more than 7.7 percent of users, reported a health event requiring medical attention, emergency room intervention, and/or hospitalization. "	"Specifically, ICAN reports that the data show 782,913 individuals, or more than 7.7 percent of users, reported **experiencing** a health event **- whether or not believed to be due to vacccination -** requiring medical attention, emergency room intervention, and/or hospitalization." This survey asked whether respondents experienced **any** health event, not specifically those that respondents believed to be assocaited with a COVID-19 vaccination. Many of the reports were for common issues that were unlikely to be vaccine related.
350	"CDC is resistant to providing the free-text entries and have cited concerns that their release would be too burdensome, but a January 2024 court decision required the CDC release them over the course of the next 12 months."	"**CDC in defending the litigation argued that it would be overly burdensome to conduct a line-by-line review of millions of free-text fields and make necessary redactions in the requested data fields, as required under applicable law and regulations to protect personal privacy. CDC is releasing requested data that has been reviewed and redacted following the January 2024 decision on a rolling basis.**" The basis for the burdensomeness argument was the need to review each free-text field and redact personally identifiable information to protect the privacy of the individuals submitting information through V-Safe.

366	"Specifically, the FDA tweeted on August 21, 2021, from its official Twitter (now X) account 'You are not a horse. You are not a cow. Seriously, y'all. Stop it.'"	"Specifically, **after receiving multiple reports of patients who required medical attention after self-medicating with ivermectin intended for livestock,** the FDA tweeted on August 21, 2021, from its official Twitter (now X) account 'You are not a horse. You are not a cow. Seriously, y'all. Stop it.'" It is important to note for context that this Tweet responded to reports of health incidents associated with people using ivermectin approved for veterinary use (see, e.g., https://www.avma.org/javma-news/2021-10-01/people-ingesting-veterinary-use-ivermectin-attempts-prevent-cure-covid-19). Currently available clinical trial data do not demonstrate that ivermectin is effective against COVID-19, and invermectin has not been authorized or approved for use in preventing or treating COVID-19 (see https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19).
367	"Ultimately, the FDA agreed to delete and never publish this tweet (and several related statements) as part of the lawsuit's settlement."	"Ultimately, FDA agreed to delete and **not repost** this tweet (and several related **social media posts) and retire the consumer update article originally posted on March 5, 2021,** as part of the lawsuit's settlement. **FDA posted a revised consumer update article on April 5, 2024.**" Currently available clinical trial data do not demonstrate that ivermectin is effective against COVID-19, and invermectin has not been authorized or approved for use in preventing or treating COVID-19 (see https://www.fda.gov/consumers/consumer-updates/ivermectin-and-covid-19).
367-369	"During the Select Subcommittee's September 14, 2023 hearing, Dr. Jerry Williams testified that prescribed medications off-label many times before and during the COVID-19 pandemic, including Ivermectin and Hydroxychloroquine. He also testified that he believed the government's pressure campaign had made them more difficult to obtain:..."	The EUA for hydroxychloroquine was revoked by FDA in June 2020. Studies from the European Union reinforce that hydroxychloroquine is not an effective COVID-19 treatment and may be associated with increased mortality (see, e.g., https://www.politico.eu/article/hydroxychloroquine-could-have-caused-17000-deaths-during-covid-study-finds/).
410	"In contrast, a FOIA search of only Dr. Morens' official email account for only documents between himself and Dr. Daszak using the term "gain-of-function" yielded more than 30,000 pages of documents."	This assertion is factually inaccurate. The cited email, which appears on the following page, indicates that the search in question was for "documents from the e-mailboxes of Dr. David Morens **to or from Dr. Peter Daszac or containing the terms Daszac or** 'gain of function.'" Thus, the search captured **every** email in Dr. Morens's mailbox sent to or from Dr. Daszak, along with any other emails that included **either** the word "Daszak" **or** the phrase "gain of function." Finally, there is no indication that all or even a significant portion of those pages are responsive to the requests prioritized by the subcommittee.
412	"However, one FOIA search of one custodian for one search term resulted in 30,000 documents."	"However, one FOIA search of one custodian for one search term resulted in 30,000 **pages of** documents." As noted above, the relevant FOIA search included multiple search terms, along with every communication to or from Peter Daszak. Again, there is no indication that all or even a significant portion of those pages are responsive to the requests prioritized by the subcommittee.
412	"The facts support that HHS obstructed the Select Subcommittee."	Setting aside the factual errors noted above, the Department's regular, voluntary responses to the subcommittee reflected a good faith accommodation of the subcommittee's extremely broad requests, as guided by the subcommittee's own articulated priorities.
412	"All but 37 pages . . . irrelevant and public documents."	The subcommittee has never suggested that these materials were not responsive to its broadly framed requests, and simply because a document is public does not mean it is not responsive. In any event, at the subcommittee's request, the Department agreed to deprioritize the production of news clips that did not include substantive commentary.
412	"HHS' productions are . . . overly redacted."	The Department is not aware of a single document produced to the subcommittee that includes redacted information regarding HHS that the Department has declined to show the subcommittee upon specific request.
412	"For example . . . HHS redacted more information produced to Congress than it did to the FOIA requester.	The Department made this document available to the subcommittee without any redactions. Specifically, on August 3, 2023, the Department produced a version of this document with no redactions *in camera* .
415	"This instruction prohibited Dr. Lauer from speaking about the renegotiation and reinstatement of EcoHealth's grant--a primary line of inquiry of the Select Subcommittee."	Dr. Lauer was not "prohibited" from speaking to those or any other topics in his voluntary transcribed interview. To the contrary, in the voluntary interview, Dr. Lauer answered questions regarding the decision to reinstate the EcoHealth award, as well as EcoHealth's compliance with the terms and conditions of the reinstated award, including the specific award conditions added as a result of the reinstatement. HHS counsel did not object to these questions.
417	"On the eve of Dr. Morens' first interview, HHS instructed Dr. Morens to not provide 'information about your work for NIAID.'"	Following the initial interview, the Department promptly facilitated a second interview, during which Dr. Morens answered questions regarding his work on behalf of NIAID.

418	"Instructing a federal government employee to not comply with Congress is unacceptable and unlawful."	At no point did the Department instruct Dr. Morens, who was represented by personal counsel, to refuse to comply with the subcommittee's inquiry. Indeed, in the transcript cited on p. 419, HHS counsel explicitly disclaimed any authority to "interfere with an employee's ability to talk to Congress" and clearly communicated that Dr. Morens was "free to respond [to the subcommittee's inquiry] as he sees fit." In any event, as previously noted, following the initial interview, the Department promptly facilitated a second interview, during which Dr. Morens answered questions regarding his work on behalf of NIAID. Dr. Morens likewise appeared before the subcommittee in a public hearing, during which he answered each question posed to him by members of the subcommittee.
421	"Dr. Morens interpreted these instructions as binding and informed the Select Subcommittee he would not answer questions if instructed."	At no point did Dr. Morens indicate that he understood the Department's instructions to be binding, and the subcommittee's draft report cites no record evidence to support this assertion (FN1632 is blank). Rather, after consultation with his personal counsel, Dr. Morens indicated that he was not willing to answer the Subcommittee's questions during his initial interview. In any event, as previously noted, following the initial interview, the Department promptly facilitated a second interview, during which Dr. Morens answered questions regarding his work on behalf of NIAID. Dr. Morens likewise appeared before the subcommittee in a public hearing, during which he answered each question posed to him by members of the subcommittee.
421	"In sum, during two years of interaction with the subcommittee HHS . . . in responding to oversight requests."	The Department categorically rejects this baseless assertion, which the record clearly refutes.