

Additional Questions for the Record

Dr. Rochelle P. Walensky, M.D., M.P.H., Director, Centers for Disease Control and Prevention

The Honorable Cathy McMorris Rodgers

1. From February 1, 2022 to February 1, 2023, please provide the number of days that you physically worked for the majority (more than 4 hours) of the day at CDC headquarters in Atlanta, Georgia?

CDC Response: Whether in an office building, domestic or international official travel, or teleworking, CDC leadership works around the clock to address critical public health issues. As always, our north star will continue to be delivering on our mission which means building on the innovations and technology that we have put to work over the last three years to ensure we are enhancing the health and well-being of all Americans.

2. From February 1, 2022 to February 1, 2023, please provide the number of days that each of your direct reports physically worked for the majority of the day (more than 4 hours) at CDC headquarters in Atlanta, Georgia?

CDC Response: Whether in an office building, domestic or international official travel, or teleworking, CDC leadership works around the clock to address critical public health issues. As always, our north star will continue to be delivering on our mission which means building on the innovations and technology that we have put to work over the last three years to ensure we are enhancing the health and well-being of all Americans.

3. As of Sept 30, 2022, please provide the total number of CDC employees.

CDC Response: CDC/ATSDR employs 12,745 full-time direct employees in fiscal year (FY) 2023.

4. How many of the total number of CDC employees worked the majority of their time (more than 16 hours a week or 32 hours biweekly) in person at CDC headquarters in Atlanta, Georgia, or their assigned office, if applicable, and how many worked the majority of their time remotely? Please break down your answer for each of the offices and centers under your direct report.

CDC Response: CDC employees are working full time. CDC is unique in that it has thousands of mission critical employees who never left their worksites, even at the height of the COVID-19 pandemic. Some individuals are on-site full-time while others are fully remote out of necessity. Regardless of an employee's physical location, they continue to work hard

every day to carry out the mission of CDC.

5. President Biden has announced that the Public Health Emergency will end on May 11, 2023. What steps is CDC taking to ensure that employees who previously worked in person, as well as new hires, will return to working at CDC headquarters in Atlanta, Georgia, or their assigned office, if applicable, for the majority of their time?

CDC Response: CDC believes that organizational health and organizational performance should be the foundation for future operational decisions as we continue to increase meaningful in-person work.

6. If applicable, given that there are cost of living adjustments (COLA) for various regions throughout the nation, what process has CDC implemented to ensure that the regional COLA applied to a CDC employee reflects the location where they are working remotely?

CDC Response: The geographic location and appropriate locality pay for all CDC hires is determined upon hire. CDC reviews and updates employee telework agreements and official duty codes to inform necessary personnel actions to update duty station codes and corresponding locality pay.

7. It has come to our attention that there are a number of remote workers within the federal government who no longer reside in the Washington, DC metro region, yet continue to receive the Washington, DC COLA pay. Please send us the exact number of CDC employees who currently live outside of the Washington, DC metro region and remain on the Washington, DC COLA pay scale.

CDC Response: CDC is not aware of any employees receiving inaccurate locality pay. All CDC employees' personnel actions reflect the duty station code and locality pay associated with their official worksite.

8. Can you guarantee that no CDC employees are benefitting from a Washington, DC regional payscale who no longer reside in the Washington, DC region? If not, please provide us the number of employees who are benefitting from this error, and the steps that you are taking to address it and to ensure an appropriate use of taxpayer funds.

CDC Response: CDC is not aware of any employees receiving inaccurate locality pay. All CDC employees' personnel actions reflect the duty station code and locality pay associated with their official worksite.

9. The American Rescue Plan provided \$47.8 billion to the Department of Health and

Human Services (HHS) for “activities to detect, diagnose, trace, and monitor SARS CoV-2 and COVID-19 infections and related strategies to mitigate the spread of COVID-19,” as well as \$1 billion specifically to the CDC for “vaccine confidence” activities.

A. Please explain, in specific detail, how this funding was utilized to build confidence in the vaccine and subsequent boosters.

CDC Response: High levels of confidence in COVID-19 vaccines within communities lead to more adults, adolescents, and children getting vaccinated, which leads to fewer COVID-19 illnesses, hospitalizations, and deaths. Vaccination rates remain strong nationally, but pockets of under-vaccination persist in some locations, putting communities at risk for outbreaks. Vaccine confidence can be bolstered by using effective information and materials that are tailored to a specific community or population, as well as using platforms and messengers who are already trusted as sources of information, such as health care providers. CDC supports states, cities, and counties to find these communities and take steps to protect them.

Trust in vaccines is not built through a top-down approach, but through millions of conversations between parents, doctors, nurses, pharmacists, and community members. The Vaccinate with Confidence strategy that CDC developed and implemented to reinforce confidence in COVID-19 vaccines includes building trust, empowering health care personnel, and engaging communities and individuals. CDC expands resources for health care professionals to support effective vaccine conversations. To help stop misinformation from eroding public trust in vaccines, CDC works with local partners and trusted messengers to improve confidence in vaccines among at-risk groups; establish partnerships to contain the spread of misinformation; and reach critical stakeholders to provide clear information about vaccination and the critical role it plays in protecting the public.

CDC, along with components of HHS, utilized vaccine confidence activity funds for numerous purposes, including: development of messaging for a public education campaign; state, tribal, local, and territorial (STLT) jurisdiction awards (including \$5.7 million for Washington state); trusted messenger campaigns; Rural Health Clinic Vaccine Confidence program (RHCVC); Partnering for Vaccine Equity (P4VE) (including 11 award recipients in Washington state); and pediatric, adolescent, maternal, and school-focused activities.

The most effective practices for improving vaccination rates in each community require tailored approaches; however, CDC provides several strategies and frameworks to assist local communities in planning and implementing a successful vaccination campaign. CDC is collaborating with national, state, and community level partners to increase uptake and access to vaccination across the lifespan, particularly among people and communities experiencing disparities.

As an example, CDC launched the [Partnering for Vaccine Equity \(P4VE\)](#) program in 2020, which is focused on increasing equity in adult immunization. The program aims to increase

vaccine equity, currently among adults belonging to racial and ethnic communities, by partnering with national, state, local, and community organizations who are working on the ground to increase vaccine confidence and access in their communities. Since its launch, the program has funded 500+ partners at the national, state, and local levels working in 225+ cities and all 50 states to equip influential messengers, increase vaccination opportunities, and enhance provider partnerships.

As of September 2022, the *Partnering for Vaccine Equity* program has accomplished the following:

- Partnered with vaccine administrators to vaccinate an estimated 2 million people.
- Reached 2.4 million people in communities of focus through promotional events.
- Achieved 395 million engagements through social media campaigns sharing vaccine information.
- Trained and empowered 220,000 trusted messengers.
- Trained over 500,000 clinicians through new strategies and resources.

Through the *Partnering for Vaccine Equity* program, CDC supported 13 national organizations and 400 affiliates, community-based organizations, state and local health departments, and community health centers. These partners work to implement vaccination activities and equip influential messengers to reduce disparities in adult immunization among racial and ethnic populations. As of September 2022, these partners have conducted 181 educational campaigns, reaching 47 states (including Washington, D.C.) through tailored campaigns in ~50 languages and dialects.

A strong vaccination recommendation from a health care provider is a leading factor in vaccine acceptance. Members of medical and health-focused professional associations act as influential messengers to their patients and community members by sharing culturally competent vaccine information to increase confidence and uptake of the vaccine. Through the *Partnering for Vaccine Equity* program, CDC builds alliances with and funds professional and medical associations that represent physicians of color and serve racial and ethnic minority groups. As of September 2022:

- 505,547 clinicians have been reached through new strategies and resources;
- 967 health care organizations have been reached through new strategies and resources; and
- 150 trainings have been provided for clinicians or individuals affiliated with health care organizations.

Additionally, CDC has worked with over 500 partners, including the following:

- **Houston County Board of Health's (Houston County, GA) H-CHAMP program** creates, develops, and empowers ambassadors (influential messengers) from within this rural community to spread the word about upcoming vaccine

events, to dispel the myths about vaccination, and to reduce barriers to vaccination. Some highlights of the program have been determining social drivers associated with low coverage rates and working with faith-based organizations to hold vaccine events and disseminate information on the safety, efficacy, and importance of vaccination.

- **National Hispanic Medical Association (NHMA)'s Gulf Coast Chapter (LA)** partnered with the Ochsner Health Hispanic employee resource group to better understand the reasons behind COVID-19 vaccine hesitancy in the Hispanic community in the Greater New Orleans area. They conducted focus groups and interviews to understand barriers and developed actionable interventions to increase vaccination rates in the local Hispanic community.
- **Association of American Indian Physicians (AAIP)**, which advocates for pursuing excellence in Native American health care, planned an educational session titled “Traditional Approaches to COVID-19” for the 2022 Cross Cultural Medicine Workshop open to health care professionals, practitioners, and students.

10. In the FY 2023 Consolidated Appropriations Act,⁴ there were provisions included to attempt to modernize and streamline current data use and contract agreements, both between federal agencies, as well as between federal agencies, their state and local partners, and private stakeholders. This includes issuing updated guidance and memorandums on best practices and reviewing the current structure of agreements. A report on the status of these updates was due to Congress within 90 days of enactment. President Biden signed the omnibus into law on December 29, 2022.

A. Please provide a status update on the report regarding data use and contract agreements, and when Congress should anticipate receipt.

CDC Response: CDC anticipates being able to transmit the report in the coming weeks.

11. In the FY 2023 Consolidated Appropriations Act,⁵ there were provisions included to improve information sharing between agencies and health care providers, labs, and state and locals. There was also a mandate to ensure these efforts would be limited to the minimum burden necessary.

A. Please outline how CDC will ensure any efforts to improve information sharing will decrease the reporting burdens on providers.

CDC Response: CDC is supporting health care providers and health systems with implementation and on-boarding for electronic case reporting (eCR). Implementation of eCR helps reduce dependence on manual, paper-based reporting processes, replacing them with automated, electronic transmission of case information to state and local public health authorities. These electronic reporting tools allow health care providers to

spend less time and resources sending individual reports to public health and more on delivering clinical care to patients while also improving the timeliness and quality of information being sent to the health department. Since early 2020, the number of facilities capable of sending electronic case reports has increased from less than 200 to more than 23,600 facilities in all 50 states,¹ representing more than 23 percent of Centers for Medicare & Medicaid Services (CMS) hospitals and 21 percent of critical access hospitals.

12. Currently, the CDC cannot compel states to share data, though it can incentivize states to report data and marshal cooperation across other federal agencies, including CMS, the VA and DoD.
 - A. How is the CDC leveraging its current authorities to improve the sharing of data across the federal agencies and from the states?
 - B. Is there a role for the Office of the National Coordinator for Health Information Technology in helping improve the collection of this data?

CDC Response: CDC is working with HHS leadership, such as the Office of the National Coordinator for Health Information Technology (ONC), as well as other HHS OpDivs, including CMS and the Administration for Strategic Preparedness and Response, to better understand and coordinate the way data is collected, shared, and analyzed. These efforts also support ongoing work to update the HHS data strategy and ensure that data is available, accessible, timely, equitable, meaningfully usable, and protected, as appropriate—and being actively used by HHS, HHS’s partners, and the public to realize HHS’s mission.

CDC currently lacks the necessary congressional authorization to fully support the reporting of public health data from state and local health departments and health care facilities. The result is a fragmented approach to public health reporting that is hindered by a patchwork of laws, regulations, and policies, which vary from jurisdiction to jurisdiction and may act to prohibit CDC from developing a clear national picture of disease burden across the country. The lack of a consistent, comprehensive reporting framework is burdensome on health care providers, who must attempt to meet many and varied requirements, and leaves large gaps in the federal government’s ability to prepare for and respond to disease burden and outbreaks. This discordance also reduces the quality of data that can be shared back with jurisdictions and with interagency partners, such as the Department of Veterans Affairs (VA) and the Department of Defense (DoD).

The need to provide CDC with modernized public health data authority is a key lesson learned during the COVID-19 pandemic. Without congressional support to address this issue as requested in the FY 2024 Budget, the national picture of public health data will remain fragmented and have implications for data quality and timeliness. Authority for

¹ <https://www.cdc.gov/ect/facilities-map.html>

CDC to require the submission of data would allow the United States to keep pace with its international partners, who already have full access to their own public health data. It will also allow CDC to collect the data needed to provide a picture of the national health landscape quickly, seamlessly, and consistently to improve responses to future health threats. This will in turn improve CDC's ability to share high quality data with its interagency partners, like the VA and DoD, on a wide array of public health issues, including the overdose epidemic. For example, the ability to require emergency department data would help CDC and states to more rapidly detect unusual spikes in visits related to overdoses, facilitating a more rapid response.

13. During the COVID-19 pandemic, the CDC faced criticism around its ability to provide clear, accurate, timely, reasonable, and easy-to-understand guidance. This included concerns around transparency of the review and publication process, including the scientific basis on which guidance is issued; timelines for informal and formal publishing; adherence to revising guidance based on updated data; contextual clarity on the rationale for issuing specific guidance; and general dissemination practices for widespread public utilization. The agency also struggled against allegations of political interference and restricted expert engagement when developing this critical public health guidance. While technically issued as guidance, these outputs often translate to recommendations or, in some cases, mandates, at the state and local level.

In contrast, comparable federal agencies require good guidance practices and frameworks for the development and issuance of public agency policy and interpretations, with the understanding these will be relied upon by private and governmental actors. This includes more inclusive external stakeholder engagement, formal notice and comment periods, and required timelines for publication. The Trump Administration had recognized this lack of uniform good guidance practices, and had taken steps to require an open, consistent process across federal agencies.⁶ The Biden Administration reversed and revoked these initiatives on President Biden's first day in office.⁷

- A. Please explain in specific detail the Biden Administration's rationale for revoking the efforts started under the Trump Administration.

CDC Response: On October 9, 2019, the Trump Administration issued Executive Order (EO) 13891, "Promoting the Rule of Law Through Improved Agency Guidance Documents." This EO served as the basis for a Final Rule promulgated by HHS in December 2020: "Department of Health and Human Services Good Guidance Practices," 85 FR 78770. President Biden, under a new Administration, issued Executive Order 13992, which revoked the EO that served as the basis for the rule and instructed agencies to rescind, "as appropriate and consistent with applicable law," any rules that were based on the revoked EO. Consistent with that instruction, HHS carefully reconsidered the Final Rule and concluded that it hinders HHS's ability to issue guidance and take other appropriate actions that advance HHS's mission. HHS continues to abide by its longstanding commitment to follow applicable principles of administrative law. In addition, the Final

Rule created a single set of procedures for guidance documents for the entire Department, which it believes is contrary to the efficient and effective administration of the wide array of programs carried out by the Department, given the diversity of those programs.

- B. What is CDC doing to improve the CDC guidance consideration, development, and final publishing process to ensure a more transparent, comprehensive, inclusive, and scientifically sound framework? This includes ensuring guidance is more easily digestible for constituents, as well as how best to communicate the legally binding nature of guidance.

CDC Response: A variety of stakeholders and partners rely on the CDC for the latest scientific information and data to inform their actions and decision-making. CDC remains committed to releasing clear and timely information and is always looking for ways to improve its processes. As part of the CDC Moving Forward initiative, CDC is reviewing, and if necessary, modifying its process for developing public health guidance both during and outside public health emergencies. This review includes listening sessions and outreach with a range of partners, including both public and private sector partners at the state, tribal, local, and territorial levels and other organizations involved in public health.

The Honorable Morgan Griffith

1. In response to questions about the influence of teachers' unions on the CDC's COVID-19 guidance, including school reopening guidance, you testified:

“There was a key piece missing in that penultimate version, and that is what do you do for teachers who are getting breast cancer treatment, teachers who have had a heart transplant. That piece had been missing. It was the reason that we requested that feedback, is so that we can say, "What is missing to implement?" And it was that piece that was changed after those discussions.”

In addition to language regarding accommodations for immunocompromised teachers, the CDC also appears to have changed its guidance on at least two other occasions because of political pressure from teachers' unions or their allies in the Biden Administration.

- The final version of the CDC's February 2021 school re-opening guidance included the statement, “[i]n the event of high community-transmission results from a new variant of SARS-CoV-2, a new update of these guidelines may be necessary.”¹

This language was sent to CDC leadership by senior American Federation of Teachers officials just days before the school reopening guidance was publicly released and in response to the AFT's review of a draft of the reopening guidance that was provided to them, but which presumably did not include such language.²

- On May 13, 2021, the CDC announced that vaccinated Americans would no longer need to wear masks indoors or outside.³ Freedom of Information Act litigation has subsequently revealed that the CDC Chief of Staff spoke with National Education Association (NEA) President Becky Pringle and AFT President Randi Weingarten on May 14, 2021.⁴ The subject of these calls, facilitated by the Biden White House, appear to be NEA and AFT displeasure at the CDC's May 13 recommendation that vaccinated Americans no longer had to wear masks indoors.⁵ NEA even provided the Biden Administration and CDC with a critical draft statement condemning the May 13, 2021 guidance.⁶

On May 15, 2021, the day after the calls with AFT and NEA, the CDC changed its guidance to say that everyone at schools, regardless of vaccination status, needed to continue to wear masks.⁷

In light of this information, please clarify your testimony:

- A. What information related to immunocompromised teachers was used by CDC in developing its February 2021 re-opening guidance or May 13, 2021, masking guidance?
- B. Please specify the studies, and how it influenced the guidance's, respectively.
- C. If there was information presented to the CDC related to immunocompromised teachers, who presented, when, and what was presented?

CDC Response: Evidence emerged from early data on COVID-19 that persons with certain medical conditions were more likely to get sick and at an increased risk for hospitalization, intensive care use, and death from COVID-19. A person's risk of severe illness from COVID-19 increases with the number of underlying medical conditions. In particular, people who are immunocompromised or have a weakened immune system because of a medical condition or a treatment for a condition are at a very high risk for severe illness and death from COVID-19. This includes people who have cancer and are on chemotherapy, or who have had a solid organ transplant and are taking medication to keep their transplant. CDC used information about the risks of exposure and illness from COVID-19 among immunocompromised and other high-risk persons to consider ways to ensure guidance for schools and other settings addressed the needs of varied populations. Throughout the COVID-19 pandemic, CDC received numerous requests from school officials (including school superintendents and school district representatives, principals, school boards, and others) as well as employers to help understand how they could ensure safe work environments for their employees.

As communities planned safe delivery of in-person instruction in K-12 schools, it was essential for schools to decide when and under what conditions to help protect students, teachers, and staff and slow the spread of SARS-CoV-2 virus. CDC's school guidance emphasized that staff and students at increased risk of severe illness or death if infected with SARS-CoV-2 should continue to have options for online or virtual education and employment. This approach, when implemented at times when vaccination was not available

or not yet widely available, would allow school officials to adjust their strategies based on the unique needs of the population of students and staff served by their schools. In this way, the information in CDC’s guidance noted what steps schools could take to address the needs of immunocompromised teachers, helping school officials to develop a COVID-19 prevention strategy that best met the profile and needs of their school community.

The evidence is summarized in the following resources:

[People with Certain Medical Conditions | CDC](#)

[People Who Are Immunocompromised | CDC](#)

[Factors Associated with Severe Outcomes Among Immunocompromised Adults Hospitalized for COVID-19 — COVID-NET, 10 States, March 2020–February 2022 \(cdc.gov\)](#)

[Data and Policy to Guide Opening Schools Safely to Limit the Spread of SARS-CoV-2 Infection | Pediatrics | JAMA | JAMA Network](#)

2. You testified that the CDC “reached out to over 50 key stakeholder groups. That included parents, superintendents, that included teachers.” Please identify all stakeholder groups that the CDC “reached out to” regarding the February 2021 school reopening guidance.
 - A. For each group or individual consulted by the CDC in developing the February 2021 school reopening guidance, please provide a description of how CDC determined they were a “key stakeholder” with respect to the school reopening guidance. Include in this description any third parties that recommended, requested, or ordered CDC to consult with the group or individual.
 - B. For each group or individual consulted by the CDC in developing the February 2021 school reopening guidance, please provide information on the date, length, and attendees of any meetings with the CDC and any recommendations made by the group or individual.

CDC conducted extensive partner engagements to disseminate its COVID-19 school guidance and share additional tools and resources to support schools in providing safe, in-person instruction. CDC used existing partner engagements and long-standing relationships to compile a list of impacted groups relevant to school guidance. The Division of Adolescent and School Health in CDC’s [National Center for HIV, Viral Hepatitis, STD, and TB Prevention](#) and the Division of Population Health/School Health Branch in the [National Center on Birth Defects and Developmental Disabilities Home](#) were particularly engaged in identifying stakeholders. Additionally, CDC supported schools and school districts with direct technical assistance, through numerous calls and virtual engagements, including listening sessions and “virtual school walk-throughs” to provide recommendations and feedback. These collaborations and engagements were essential in shaping CDC’s understanding of challenges for schools and informing CDC’s guidance to ensure it is feasible and meets the needs of educators and families.

Beginning in late January of 2021, CDC partnered with the Department of Education to coordinate the National Safe School Reopening Summit. The purpose of this event was to

facilitate discussion about the importance of schools reopening across the United States. This event was also focused on dissemination of best practices in schools that had safely reopened across the United States and sharing the key recommendations from CDC's K-12 Operational Strategy. Held in March 2021, the event reached hundreds of participants and highlighted rural, urban, and suburban school districts and schools that had safely reopened using CDC-recommended strategies.

Please see below for the list of impacted groups that CDC engaged throughout the process of developing, updating, and revising guidance for preventing COVID-19 transmission in schools.

- US Department of Education
- American Academy of Pediatrics (AAP)
- School Superintendents Association (AASA)
- American College Health Association (ACHA)
- American Federation of Teachers (AFT)
- American School Counselor Association
- American School Health Association (ASHA)
- Association for Supervision and Curriculum Development (ASCD)
- Association for the Advancement of Sustainability in Higher Education
- Association of Community Tribal Schools
- Association of Latino Administrators and Superintendents
- Association of School and Programs of Public Health (ASPPH)
- Association of State and Territorial Health Officials (ASTHO)
- Association of Public Health Laboratories (APHL)
- Autism Speaks
- Big Cities Health Coalition
- Bureau of Indian Education (BIE)
- Communities in Schools
- Council of Chief State School Officers (CCSSO)
- Council of Great City Schools
- Council of State and Territorial Epidemiologists (CSTE)
- Georgia Department of Education
- National Association of County and City Health Officials (NACCHO)
- National Association of Secondary School Principals (NASSP)
- National Alliance for Public Charter Schools
- National Alliance of Black School Educators
- National School Board Association
- National Association of School Nurses (NASN)
- National Association of County and City Health Officials (NACCHO)
- National Association of Elementary School Principals (NAESP)
- National Association of Independent Schools
- National Association of Private Schools

- National Association of School Nurses (NASN)
 - National Association of Secondary School Principals (NASSP)
 - National Association of State Boards of Education (NASBE)
 - National Association of State Boards of Education
 - National Association of State Directors of Teacher Education and Certification (NASDTEC)
 - National Association of Student Personnel Administrators (NASPA)
 - National Council on School Facilities
 - National Education Association
 - National Indian Education Association
 - National Parent Teacher Association
 - National Recreation and Park Association (NRPA)National Rural Education Association
 - National School Boards Association
 - Ready Education
 - School Based Health Alliance.
 - School Social Work Association of America
 - School Superintendents Association (AASA)
 - School-Based Health Alliance
 - Society for Public Health Education (SOPHE)
 - YMCA-USA
 - National Governors Association
3. You testified that CDC is working to “standardize” its outreach with respect to guidance documents and other external communications. Please explain how CDC is going to standardize its outreach.
- A. Please provide relevant internal documents explaining CDC’s standardized outreach process, including any documentation on selecting stakeholders that receive draft guidance documents and are permitted to send CDC edits or comments.
 - B. As part of this standardization process will CDC plan to make draft guidance documents available for a period of public comment before being finalized?
 - C. Once CDC has standardized its guidance drafting process, does CDC plan to issue a Federal Register notice explaining the process? If not, why not?

CDC Response: A variety of stakeholders and partners rely on the CDC for the latest scientific information and data to inform their actions and decision-making. CDC remains committed to releasing clear and timely information and is always looking for ways to improve its processes. As part of the CDC Moving Forward initiative, CDC is reviewing and, if necessary, modifying its process for developing public health guidance both during and outside public health emergencies. This review includes listening sessions and outreach with a range of partners, including both public and private sector partners at the state, tribal, local, and territorial levels and other organizations involved in public health.

4. You testified that the randomized control trials (RCT) considered in the Cochrane Library’

Systematic Review of mask effectiveness were less relevant than other, non-RCT studies because, among other reasons, as the people in many of the studies were “not actually engaged in the intervention.”

In response to continued questions about the Cochrane Library study, you again stressed that CDC believed if individuals are not wearing a mask correctly it will not be an effective intervention against COVID-19, “but if they don't take -- uptake the intervention, then it is not going to prove[sic] working.”

The CDC's mask guidance has extensive recommendations regarding how to wear, take off, clean, store, and replace masks. Beyond making sure that masks are fitted and worn correctly, CDC recommendations include:

For reusable cloth masks

- If your cloth mask is wet or dirty, put it in a sealed plastic bag until you can wash it. This will keep it from getting moldy.
- If your cloth mask is dry and clean, you can store it in a breathable bag (like a paper or mesh fabric bag) to keep it clean between uses in the same day.
- Cloth masks should be washed at least once a day or as soon as they become wet or dirty. You can either wash and dry your masks by hand or use a washer and dryer.
 - Wash or sanitize your hands after removing any mask.
 - Disposable masks should be thrown away after they're worn once.
 - Avoid frequent touching of the mask and face
 - Limit sucking, drooling, or having excess saliva on the mask
 - Pick a mask with multiple layers to keep your respiratory droplets in and others' out

Please provide a list of studies showing that, among individuals who wear masks regularly, most follow the CDC's mask guidance and thus are properly engaged in the intervention. Please include in your answer any studies you are aware of, but are not yet published. Please explain how CDC would design a study to determine mask effectiveness.

CDC Response: CDC recommends the use of a mask or respirator to prevent causing illness in others any time an individual feels like they might have a respiratory infection that could be COVID-19. In addition, CDC recommends the use of a mask or respirator to reduce self-exposure to respiratory infections when COVID-19 Community Levels are high. CDC does not recommend masks or respirators for anyone who is unable to wear one safely and unable to remove it if they are having difficulty breathing; this includes individuals of any age with physical or other limitations that might interfere with removal.

CDC's masking recommendations reflect the clear science that demonstrates the efficacy of

blocking the release of secretions from the nose and mouth to reduce the spread of respiratory infections, as well as that showing that inhaling through a filtering material can reduce exposure to viruses that cause respiratory infections. Evidence is summarized in the CDC Science Brief on the topic (<https://www.cdc.gov/coronavirus/2019-ncov/science/science-briefs/masking-science-sars-cov2.html>) and is consistent with longstanding accepted practices in health care settings to protect health care personnel and others.

The Honorable Brett Guthrie

1. It is my understanding that, beginning in 2018, CDC's Overdose 2 Action (OD2A) grant included "special conditions" that required states to adopt RxCheck, a prescription drug monitoring program (PDMP) data hub that is nominally overseen by a nonprofit organization but is otherwise owned and operated by the Department of Justice's Bureau of Justice Assistance (BJA). I further understand that these special conditions were preceded by similar requirements in BJA grants.

A. Does CDC plan to include special conditions requiring RxCheck integration in the forthcoming round of OD2A grant making? If so, please provided a detailed justification, including the agency's rationale for including these special conditions both historically and going forward if CDC plans to continue them for the next round of OD2A grants as well as at the level within the Department of Health and Human Services at which that decision was made.

CDC Response: CDC released a new five-year cooperative agreement called Overdose Data to Action in States and has created strategies and a framework that best positions health departments to combat an ever-evolving epidemic now centered around illicit fentanyl and resurgent stimulants such as methamphetamine while still advancing scalable, equitable PDMP work. As such, CDC is focusing on prioritizing prevention strategies that can help in saving lives, linking people to care and treatment, and advancing innovative public health and public safety partnerships, in addition to continuing to advance health IT and bidirectional data exchange that can facilitate safer prescribing and appropriate care. This new notice of funding opportunity (NOFO) does not include an award condition requiring that states or jurisdictions connect to RxCheck. As stated in the NOFO, a recipient may spend up to 20 percent of its overall prevention budget on health IT/PDMP enhancement activities. If a recipient's PDMP system meets the requirements of a qualified PDMP with open standards and open architecture in alignment with 45 CFR part 170, Subpart B: Standards and Implementation Specifications for Health Information Technology, then a recipient may spend up to 30 percent of its overall prevention budget on health IT/PDMP enhancement activities. CDC has also indicated that if a state wants to dedicate a larger percentage of their funding towards health IT/PDMP enhancement activities, CDC will approach that on a case-by-case basis with the state.

B. For the most recent calendar year in which all data are available, how many prescriber

queries were made using RxCheck, and how many were made using other data hubs?

CDC Response: While CDC works closely with the Bureau of Justice Assistance (BJA), the federal agency that maintains RxCheck, CDC defers to BJA on the number of transactions made using RxCheck. Additionally, CDC does not have access to the number of queries made by other proprietary data hubs.

C. Please provide a list of all of the features that RxCheck offers and what, if any fees, are further associated with such features?

CDC Response: CDC defers to BJA, the federal agency that maintains RxCheck, regarding RxCheck features and any related fees.

D. Do you commit to being fully transparent regarding all aspects of RxCheck?

CDC Response: CDC is fully committed to transparency and has engaged in a number of webinars, calls, and discussions with partners related to its efforts.

E. How many states were connected to at least one PDMP data hub prior to the imposition of the special conditions in the DOJ grants and the CDC's OD2A grants?

CDC Response: During development of OD2A award conditions, 47 states were connected to at least one PDMP data-sharing hub and had taken great strides in improving data sharing *across* states (e.g., interstate data integration). The aim is to make PDMP data more actionable both within (intrastate) and across state borders. While most states are now connected to a PDMP data-sharing hub enhancing interstate sharing, CDC aims to increase intrastate integration across health systems and improve integration into electronic health records.

F. Is it accurate that only three states were connected to RxCheck prior to the imposition of the special conditions in the DOJ grants and the OD2A grants?

CDC Response: Prior to the initial OD2A award, four states were connected to RxCheck.

G. How many states are currently connected to RxCheck, and how many states are currently connected to a different hub?

CDC Response: As of November 2022, [50 jurisdictions are currently connected to RxCheck](#). As of December 2020, [52 PDMPs are connected to PMPi Interconnect](#). [PMPi Interconnect is a PDMP platform offered through the National Association of Boards of Pharmacy to share data across state lines that requires a private vendor solution in order to incorporate any intrastate integration](#).

H. Have any states notified CDC that they intend, or intended, to forego OD2A grant funding due to the special conditions and/or raised any other concerns regarding the

special conditions? If so, please list the states and the date on which CDC was informed of this information, as well as the nature of the concerns and a description of any actions CDC took to address such concerns.

CDC Response: In 2019, Mississippi applied for and received OD2A funding but did not meet the award condition to connect to RxCheck. CDC met with officials in Mississippi in October 2019 to address questions related to the OD2A award conditions, but the Mississippi Board of Pharmacy, which administers the state PDMP, expressed that it did not wish to connect. This decision resulted in a 25% reduction of the state's prevention budget in year 3 and the supplemental expansion year 4 of the program. CDC offered flexibility around this award condition in that no budget impacts were executed until year 3 of the program. CDC continued to work with Mississippi during the first two years of the program to offer assistance so that the state could potentially comply with the award conditions.

North Dakota chose not to apply for OD2A funding. CDC was contacted by the North Dakota state health officer in April 2019 to learn more about PDMP award conditions. CDC conducted follow-up calls with the state health department as well as the state board of pharmacy to provide additional information on award conditions. Ultimately, the state did not apply for OD2A funding. CDC did not receive any formal written communication from North Dakota on the state's decision not to apply but was made aware that the state health department was prohibited from applying due to state budget language.

The Honorable Troy Balderson

1. Much of the public agrees that our agencies need to now return to their original, intended purposes and be proactive toward future pandemics, instead of retroactive to continue focusing on COVID-19 at the expense of the litany of other diseases and health challenges facing Americans. What changes will your agencies make in preparation for the PHE ending on May 11th? What resources and offices will continue to be dedicated to COVID-19?

CDC Response: The announcement that the public health emergency (PHE) will end on May 11 acknowledges that the United States is in a different phase of the pandemic because there is now a persistent decline in cases, hospitalizations, and deaths. While this is an important milestone, this transition must not have a detrimental impact on CDC's continued work to combat the virus and provide the latest scientific evidence to the American people.

CDC is actively working with other federal government agencies and offices to maintain equitable access to vaccines, testing, and therapeutics to the extent possible. Most CDC COVID-19 data activities are not directly affected by the PHE (e.g., case and death reporting, national genomic surveillance, sentinel surveillance, wastewater surveillance, traveler genomic surveillance). Hospital data reporting will continue through April 30, 2024, but reporting may be reduced from the current daily reporting to a lesser frequency. The end of a public health

emergency does not equate to the end of the current national vaccine distribution program or the availability of vaccines commercially. CDC continues to work with HHS on this process and is collecting questions to help ensure CDC addresses the needs of jurisdictions and partners.

CDC continues to implement lessons learned from the COVID-19 pandemic to prepare for future threats. In particular, reporting challenges are not unique to COVID-19 and will apply to any future emerging disease. Congress and the American people expect CDC to quickly and comprehensively share critical information to protect the health security of the nation. But CDC lacks the congressional authorization to compel the collection of public health data. This lack of authority results in a patchwork data collection effort that varies from jurisdiction to jurisdiction, which creates increased burden on health care providers and public health agencies. CDC currently receives some data from all 64 jurisdictions via individually negotiated data use agreements and sometimes must ask other agencies to leverage their authorities to help CDC get the vital data it needs for public health, but even that is not enough. If enacted, the Preparedness legislative proposal included in the FY 2024 Budget to provide the HHS Secretary with new data authority would enable CDC to be able to allow for more complete and timely data sharing to support decisions at the federal, state, and local levels, while reducing burden on providers.

It is important to note that throughout the COVID-19 pandemic, CDC's work on emerging and existing threats, from diabetes and heart disease to Ebola and mpox did not stop. CDC staff worked 24/7 throughout the pandemic to continue the agency's work across the public health spectrum and support understaffed and overworked state and local health departments.

Prior to and during the pandemic, state and local public health departments lost a significant amount of the public health workforce, leaving health departments severely understaffed and unable to adequately provide essential public health services to communities. CDC is supporting training and education for public health workers in health departments across the country, and recently awarded \$3 billion in American Rescue Plan Act funding to 107 jurisdictional health departments to strengthen their workforce. The public health workforce is the nation's most precious asset in confronting and combatting public health challenges, and CDC is working to ensure they are trained and ready to confront future threats.

Globally, during the pandemic, CDC's strength in fighting top global health security risks was evident as CDC pivoted to address the outbreak, with surveillance systems to quickly catch outbreaks before they spread; laboratory networks to accurately diagnose diseases and identify new pathogens; workforce development of frontline staff to identify, track, and contain outbreaks at their source; and emergency management systems to coordinate response efforts when crises occur.

2. Over the past few months, Columbus and central Ohio experienced a measles outbreak. 85 children got sick, and 36 had to be hospitalized. The Columbus Health Department

said the spread was mostly driven by a lack of vaccination in the community. I believe this is partly due to the vaccine mistrust surrounding the COVID-19 vaccination mandates promulgated by your department and Biden's administration. 35% of parents now oppose schools requiring certain vaccinations. That number has increased from 23% in 2019. How specifically do you plan to restore trust in our normal vaccination regimens?

- a. You received \$1 billion for vaccine confidence activities. How did you spend that money? Do you think it was effective? Is there a single thing you would do differently?

CDC Response: High levels of confidence in COVID-19 vaccines within communities lead to more adults, adolescents, and children getting vaccinated, which leads to fewer COVID-19 illnesses, hospitalizations, and deaths. Vaccination rates remain strong nationally, but pockets of under-vaccination persist in some locations, putting communities at risk for outbreaks. Vaccine confidence can be bolstered by using effective information and materials that are tailored to a specific community or population, as well as using platforms and messengers who are already trusted as sources of information, such as health care providers. CDC supports states, cities, and counties to find these communities and take steps to protect them.

Child vaccination coverage remains high nationally, and most parents are confident in the safety and effectiveness of vaccines. However, the spread of myths and misinformation has put some communities at risk. Unfortunately, low vaccine confidence, predating the COVID-19 pandemic, persists in a few close-knit communities, which remain at risk for measles importation and spread. Trust in vaccines is not built through a top-down approach, but through millions of conversations between parents, doctors, nurses, pharmacists, and community members. The Vaccinate with Confidence strategy that CDC developed and implemented to reinforce confidence in COVID-19 vaccines includes building trust, empowering health care personnel, and engaging communities and individuals. CDC expands resources for health care professionals to support effective vaccine conversations. To stop misinformation from eroding public trust in vaccines, CDC works with local partners and trusted messengers to improve confidence in vaccines among at-risk groups; establish partnerships to contain the spread of misinformation; and reach critical stakeholders to provide clear information about vaccination and the critical role it plays in protecting the public.

With declines in measles vaccination rates globally during the COVID-19 pandemic, measles outbreaks are occurring in all World Health Organization (WHO) Regions. Large and disruptive outbreaks (≥ 20 reported measles cases per million population over a period of 12 months) have been reported in the European, African, Eastern Mediterranean, and Southeast Asian Regions. The United States has seen an [increase in measles cases](#) from 49 in 2021 to 121 in 2022, all among children who were not fully vaccinated, including outbreaks in Minnesota and Ohio.

The measles outbreak in central Ohio was declared over in February 2023, and 80 of the 85 children infected were unvaccinated. CDC deployed an Epi-Aid to provide direct assistance to the Ohio Department of Health and the Columbus Public Health Department (November 27 to December 10, 2022). In addition, the Columbus Public Health Department is providing extended vaccination services, supported by 13 Somali staff working within the community, and working with pediatric providers to send vaccine reminder/recall messages to all under-vaccinated children age ≥ 12 months in their practices. CDC immunization program awards supported MMR vaccines for 1,000 adult and 200 pediatric doses in the community. CDC has provided resources to the Columbus Public Health Department to improve vaccine confidence and address parental concerns about the safety of the MMR vaccine.

CDC has launched the Vaccinate with Confidence strategic framework to strengthen vaccine confidence and prevent outbreaks of vaccine-preventable diseases in the United States. CDC has developed Vaccine Confidence and Demand (VCD) partnerships with health care and community-based organizations to build vaccine confidence and generate demand. These partnerships are built on three main objectives, as follows:

- **Build public trust** by sharing clear, complete, and accurate messages about COVID-19 vaccines.
- **Empower health care personnel** in their decision to get vaccinated and recommend vaccination to their patients.
- **Engage communities and individuals** in a sustainable, equitable, and inclusive way.

CDC, along with components of HHS, utilized vaccine confidence activity funds for numerous purposes, including: development of messaging for a public education campaign; state, tribal, local, and territorial (STLT) jurisdiction awards ; trusted messenger campaigns; Rural Health Clinic Vaccine Confidence program (RHCVC); Partnering for Vaccine Equity (P4VE); and pediatric, adolescent, maternal, and school-focused activities.

The most effective practices for improving vaccination rates in each community require tailored approaches; however, CDC provides several strategies and frameworks to assist local communities in planning and implementing a successful vaccination campaign. CDC is collaborating with national, state, and community level partners to increase uptake and access to vaccination across the lifespan, particularly among people and communities experiencing disparities.

As an example, CDC launched the [Partnering for Vaccine Equity \(P4VE\)](#) program in 2020 focused on increasing equity in adult immunization. The program aims to increase vaccine equity, currently among adults belonging to racial and ethnic communities, by partnering with national, state, local, and community organizations who are working on the ground to increase vaccine confidence and access in their communities. Since its launch, the program has funded 500+ partners at the national, state, and local levels working in 225+ cities and all 50 states to equip influential messengers, increase vaccination opportunities, and

enhance provider partnerships.

As of September 2022, the *Partnering for Vaccine Equity* program has accomplished the following:

- Partnered with vaccine administrators to vaccinate an estimated two million people.
- Reached 2.4 million people in communities of focus through promotional events.
- Achieved 395 million engagements through social media campaigns sharing vaccine information.
- Trained and empowered 220,000 trusted messengers.
- Trained over 500,000 clinicians through new strategies and resources.

Through the *Partnering for Vaccine Equity* program, CDC supported 13 national organizations and 400 affiliates, community-based organizations, state and local health departments, and community health centers. These partners work to implement vaccination activities and equip influential messengers to reduce disparities in adult immunization among racial and ethnic populations. As of September 2022, these partners have conducted 181 nationwide educational campaigns, reaching 47 states (including Washington, D.C.) through tailored campaigns in ~50 languages and dialects.

A strong vaccination recommendation from a health care provider is a leading factor in vaccine acceptance. Members of medical and health-focused professional associations act as influential messengers to their patients and community members by sharing culturally competent vaccine information to increase confidence and uptake of the vaccine. Through the *Partnering for Vaccine Equity* program, CDC builds alliances with and funds professional and medical associations that represent physicians of color and serve racial and ethnic minority groups. As of September 2022:

- 505,547 clinicians have been reached through new strategies and resources;
 - 967 health care organizations have been reached through new strategies and resources; and
 - 150 trainings have been provided for clinicians or individuals affiliated with healthcare organizations.
- Additionally, CDC has worked with over 500 partners, including:
 - **Houston County Board of Health's (Houston County, GA) H-CHAMP program** creates, develops, and empowers ambassadors (influential messengers) from within the community to spread the word about upcoming vaccine events, to dispel the myths about vaccination, and to reduce barriers to vaccination. Some highlights of the program have been determining social drivers associated with low coverage rates and working with faith-based organizations to hold vaccine events and disseminate information on the safety, efficacy, and importance of vaccination.

- **National Hispanic Medical Association (NHMA)’s Gulf Coast Chapter (LA)** partnered with the Ochsner Health Hispanic employee resource group to better understand the reasons behind COVID-19 vaccine hesitancy in the Hispanic community in the Greater New Orleans area. They conducted focus groups and interviews to understand barriers and developed actionable interventions to increase vaccination rates in the local Hispanic community.
 - **Association of American Indian Physicians (AAIP)**, which advocates for pursuing excellence in Native American health care, planned an educational session titled “Traditional Approaches to COVID-19” for the 2022 Cross Cultural Medicine Workshop open to health care professionals, practitioners, and students.
3. The NIH published an article on their agency’s response to COVID-19 and acknowledged that “serious consideration of how better to empower trusted sources of information at the local level is needed.” I agree with this and believe many of our communication failures stemmed from allowing a top-down approach, rather than letting constituents hear from public health officials or leaders at the state or local level. How do you plan to better integrate state and local officials, particularly from a communications lens?

CDC Response: CDC agrees with the importance of empowering trusted sources of information to deliver messages and public health activities at the local level. CDC is committed to supporting communities to deliver public health messages and interventions in ways that work best in their own communities.

Through the CDC Moving Forward initiative, CDC is prioritizing public health communications. CDC’s goal is to put tools in the hands of state and local health departments to enable them to effectively communicate vital health information. As always, CDC will provide resources for state and local health departments to communicate to their communities, such as [Communication Resources for Health Departments | CDC](#), and during outbreaks of significance, CDC will continue to hold regular meetings to provide public health authorities with real-time information and materials to help inform their communications on the ground. CDC also hosts a State, Tribal, Local, and Territorial (STLT) Collaboration Space where communicators for state and local health agencies can access the Communication Resource Center, which has free, customizable CDC tools and resources that can enhance local communication efforts. It will be important to plan in advance, support, and activate these trusted sources faster and more often to better serve the public.

CDC is also focused on its communication with the American public. Through project “clean slate,” CDC is rebuilding the ‘front door’ to CDC so that its public website structure, operability, and utility is markedly enhanced using contemporary and future-

oriented communications technology used by certain private sector entities.

Additionally, as part of Moving Forward, CDC has instituted two major changes to strengthen the nation's public health infrastructure and workforce, of which communications is a critical component. First, CDC established a new National Center for State, Tribal, Local, and Territorial (STLT) Public Health Infrastructure and Workforce, which will strengthen the effective and efficient delivery of public health infrastructure and workforce development services to jurisdictions. This new center will enhance the connection with STLT health departments to help navigate subject matter expertise, data, and resources, including communications resources, across the agency.

Second, CDC is supporting state and local health departments by providing flexible resources and technical assistance to help them address their most pressing needs. Through the new Strengthening U.S. Public Health Infrastructure, Workforce, and Data Systems grant, CDC awarded \$3.2 billion to state and local health departments to strengthen public health workforce and foundational capabilities. CDC is awarding 70 percent of the Public Health Infrastructure and Capacity line to jurisdictional health departments to address foundational capabilities, including communications. Historically, foundational capabilities, like communications, have often been neglected in jurisdictional health departments, as funding streams are often siloed and disease specific. This new grant makes possible strategic investments that work to have lasting effects on public health agencies for critical infrastructure needs related to foundational capabilities, including communications. With this grant, CDC is bolstering the work of state and local health departments and providing jurisdictions with flexibility to meet the evolving and complex needs of the diverse U.S. population.

This approach will not dictate the approach or function of health departments. CDC's job—and this is a core tenet of the Moving Forward Initiative—is to help state and local health departments improve their work so that it's more effective. This includes sharing science, data, and information with state and local health officials to stand up strong programs and systems that will protect the people in their communities.

4. Over the course of the pandemic Congress has appropriated at least \$1 billion for CDC data modernization and public health infrastructure. Would you detail how that money has been spent by CDC, including how much has been allocated and what improvements have been made? What sort of resources are available for us or members of the public to track how modernization efforts are going? Does CDC plan to have public meetings to discuss these efforts?

CDC Response: Of the \$1 billion that has been appropriated for CDC's Data Modernization Initiative (DMI) in fiscal years 2020-2022, as of February 8, 2023, \$760 million has been obligated and the remaining \$240 million is allocated for modernization activities in fiscal year 2023. Information on CDC's 2021-2022 DMI

Implementation Strategy and CDC's Public Health Data Strategy, including key partnerships and notable milestones are available on the CDC DMI Website.² CDC's 2022 Snapshot will be on the website soon, reflecting recent impacts and progress.

5. What is the Consortium for Data Modernization? How do people become members? Are the meetings public? I am concerned that the website and linked documents do not provide a list of members or topics included.

CDC Response: The DMI Consortium is a group of varying multisector public health partners (government entities, public health associations, and academia), which convenes to increase dialogue, voice goals, and discuss potential real-life solutions to achieve a desired modernized future state of the public health data ecosystem. The purpose of the Consortium is to only seek individual perspectives and experiences, not group consensus advice from partners. The DMI Consortium is co-chaired by the Office of the National Coordinator (ONC) and participation varies based on topics to be discussed.

6. What is the status of the Data Modernization Initiative (DMI)? Which of [these outcomes](#) have been accomplished? How is the funding Congress has provided for DMI being used?

CDC Response: Information on CDC's 2021-2022 DMI Implementation Strategy and CDC's Public Health Data Strategy, including key partnerships and notable milestones are available on the CDC DMI Website.³ CDC's 2022 Snapshot will be on the website soon, reflecting recent impacts and progress.

The Honorable Neal Dunn

1. Bivalent boosters have indicated stroke signals. Are you communicating such a risk to the public?

CDC Response: Vaccine safety and transparent communication are top priorities for the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). U.S. government agencies use [multiple monitoring systems](#) to detect potential vaccine safety concerns as early as possible and then investigate, if needed.

Potential safety concerns detected during public health surveillance do not necessarily represent true safety problems or health events caused by the vaccine. These findings can often be due to factors other than the vaccine and require further assessment, which includes checking with other monitoring systems to see if those systems have observed similar findings. This cross-referencing helps scientists better understand the nature of the potential safety concern, and if a true safety problem is present.

² <https://www.cdc.gov/surveillance/data-modernization/index.html>

³ <https://www.cdc.gov/surveillance/data-modernization/index.html>

Following the availability and use of the bivalent (updated) mRNA COVID-19 vaccines, CDC's Vaccine Safety Datalink (VSD), a near real-time safety monitoring system, detected a potential safety concern for ischemic stroke among people ages 65 and older who received the updated Pfizer-BioNTech COVID-19 vaccine. CDC conducted an assessment that found that many patients who experienced ischemic stroke within the first three weeks after vaccination had also received a high-dose (or adjuvanted) flu shot at the same time as the updated Pfizer-BioNTech COVID-19 vaccination. As time has passed and more safety data have accumulated, the initial finding has decreased, and scientists believe factors other than vaccination might have contributed to the initial finding. Based on this additional data and analysis, the current evidence is not sufficient to conclude that a safety problem exists. Multiple monitoring systems in the United States and globally have not detected a safety problem after the initial VSD analysis.

The potential safety concern for ischemic stroke was only identified in one monitoring system, the VSD, and only among people ages 65 and older who received the updated Pfizer-BioNTech COVID-19 vaccine. No concern was observed for the updated Moderna COVID-19 vaccine in VSD. Additionally, no other safety systems have detected a similar potential safety concern for ischemic stroke:

- Monitoring of updated (bivalent) vaccines (from Pfizer-BioNTech and Moderna) using the Centers for Medicare & Medicaid Services database revealed no increased risk of ischemic stroke.
- Monitoring via the Veterans Affairs (VA) database did not indicate an increased risk of ischemic stroke following an updated (bivalent) vaccine.
- The Vaccine Adverse Event Reporting System (VAERS) managed by CDC and FDA has not seen an increase in reporting of ischemic strokes following the updated (bivalent) vaccine.
- Pfizer-BioNTech's global safety database has not indicated a signal for ischemic stroke with the updated (bivalent) vaccine.
- Other countries have not observed an increased risk for ischemic stroke with updated (bivalent) vaccines.

These data and additional analyses were discussed at the [January 26 meeting](#) of the FDA's Vaccines and Related Biological Products Advisory Committee and at the [February 22-24 meeting](#) of the CDC's Advisory Committee on Immunization Practices (ACIP). In addition to outreach to health care providers, the public, media, and policymakers, CDC updated its [Selected Adverse Events Reported after COVID-19 Vaccination](#) website to provide additional information on this potential safety signal, and released [a new dedicated information page](#) for this potential safety signal, which was updated in March to provide updated information. CDC and FDA will continue to evaluate additional data on the safety of bivalent COVID-19 vaccines and provide information as it becomes available.

The evidence available to date is not sufficient to conclude that a safety problem exists. At this

time, no change in vaccination practice is recommended based on the potential safety signal. CDC continues to recommend that everyone eligible for an updated COVID-19 vaccine or a flu shot get vaccinated as recommended. Staying up to date with these vaccines is the most effective way to reduce risk of death, hospitalization, and illness from COVID-19 or flu. Receiving an updated COVID-19 vaccine reduces the risk of hospitalization from COVID-19 almost 3-fold, compared to not receiving an updated vaccine

(https://www.cdc.gov/mmwr/volumes/71/wr/mm715152e1.htm?s_cid=mm715152e1_w).

Also, compared to unvaccinated people, those receiving an updated COVID-19 vaccine have a reduced risk of death from COVID-19 of nearly 19-fold (<https://covid.cdc.gov/covid-data-tracker/#rates-by-vaccine-status>). While flu activity is low nationally at this time, flu viruses continue to circulate, and influenza vaccination is recommended as long as flu viruses continue to spread in the community.

2. How are you further monitoring, assessing, and communicating any COVID-19 vaccine risk?

CDC Response: CDC, and other U.S. government agencies (FDA, Centers for Medicare & Medicaid Services (CMS), VA), use a layered approach of [multiple, complementary safety monitoring systems](#) to help detect possible vaccine safety concerns (or “signals”), assess these possible safety signals, and communicate this information to the public. Each system is designed for a different purpose, with different strengths and limitations. Any discussion of [vaccine safety monitoring and surveillance](#) should take into account the contributions of each system in this comprehensive approach.

The [Vaccine Adverse Event Reporting System \(VAERS\)](#) is the national frontline vaccine monitoring system, co-managed by CDC and FDA, that serves as the nation’s early warning system for vaccine safety. Anyone (health care professionals, manufacturers, general public) can send a report of adverse events into VAERS after vaccination. There are also requirements for health care professionals and manufacturers to report serious adverse events to VAERS. To better understand the circumstances around a potential adverse event, VAERS staff from CDC and FDA request additional information, like medical records, for reports that are classified as “serious.” “Serious” reports include those that describe adverse events resulting in death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, or congenital anomaly/birth defect.

The [Vaccine Safety Datalink \(VSD\)](#) is a collaborative project between CDC’s Immunization Safety Office, thirteen integrated health care organizations (as of September 2022), and networks across the United States. Eleven of the participating sites link patient vaccination and electronic health record data. CDC uses electronic health data from participating sites to perform robust, near real-time monitoring of vaccine recipients to identify and characterize potential vaccine safety concerns and to conduct vaccine safety research. VSD data are analyzed weekly as the data come in. If observed adverse event rates for selected conditions exceed expected rates by a pre-specified threshold, then the

monitoring process generates a statistical signal.

The [Clinical Immunization Safety Assessment \(CISA\) Project](#) is a collaboration between CDC, seven medical research centers, and other vaccine safety experts. CISA provides consultations to U.S. health care providers with complex vaccine safety questions about their patients to assist with immunization decision-making. CISA sites and CDC staff also conduct clinical research to better understand vaccine safety and identify preventive strategies for adverse events following vaccinations.

[V-safe](#) is a new smartphone-based tool developed specifically for the COVID-19 vaccination program, with an additional module added later for mpox vaccines. V-safe uses text messaging and web surveys to provide personal health check-ins after vaccination and provides CDC with crucial information in near-real time to monitor adverse reactions and other potential safety concerns after vaccination and communicate this information to the public. V-safe enrollment is voluntary, and any participants who are pregnant when vaccinated or after vaccination could also be invited to participate in the CDC Pregnancy Registry for long-term safety monitoring after vaccination during pregnancy. Those reporting in v-safe that they received medical care after vaccination get a follow-up call encouraging a report to VAERS, which collects more detailed information about adverse events that could be related to vaccination.

CDC has been publicly presenting and openly discussing COVID-19 vaccine safety data at meetings of the Advisory Committee on Immunization Practices (ACIP), starting a week after the first COVID-19 vaccines were given in December 2020. CDC has also regularly published analysis of vaccine safety data in peer reviewed journals and CDC's Morbidity and Mortality Weekly Report (MMWR) to further inform health care providers on the latest vaccine safety data and any potential adverse events or safety signals. All of these are coupled with outreach to media, health care providers, policymakers, and the public. Deidentified databases for [VAERS reports](#) and [v-safe data](#) are also publicly available. For more information, please see CDC's [COVID-19 Vaccine Safety website](#), [website compiling vaccine safety publications](#) for COVID-19 and routine vaccinations, [frequently asked questions about COVID-19 vaccination](#), and [myths and facts about COVID-19 vaccines](#).

The Honorable Gus Bilirakis

1. According to the CDC's website the organization is the nation's leading science-based, data-driven, service organization that protects the public's health. For more than 70 years, we've put science into action to help children stay healthy so they can grow and learn; to help families, businesses, and communities fight disease and stay strong; and to protect the public's health. Yet your testimony did not address the fentanyl crisis or the pediatric mental health crisis, both of which were significantly exacerbated due to the COVID-19 pandemic.

A. What is the CDC doing to look at and address these public health concerns our nation is facing?

CDC Response: As the nation’s public health agency, CDC first identified the increase in opioid overdose deaths, and has since been applying scientific expertise to track the epidemic and develop and support the implementation of evidence-based prevention strategies. These efforts are especially needed in reaching youth populations, during a time in which illicit fentanyl is increasingly found across the drug supply, in particular in counterfeit pills that look like commonly misused prescription medications.

In the most recent MMWR on [Drug Overdose Deaths Among Persons Aged 10-19 years](#), CDC found the increase in adolescent overdose deaths occurred during a time of *decreasing* illicit drug use among middle and high school students from 2019 to 2020. This suggests that more potent drugs, such as illicitly manufactured fentanyls (IMFs), rather than an increase in adolescent drug use, are responsible for the increase in overdose deaths. That same data found counterfeit pills were present in nearly 25 percent of deaths. This is why the increase in counterfeit pill use among adolescents is particularly concerning, especially coupled with predatory marketing by people trafficking drugs aimed at this demographic and the [ease of buying pills via social media](#). It is important that prevention materials for adolescents highlight the potential presence of illicit fentanyl in counterfeit pills and other drugs and emphasize that prescription drugs should only be used when and how they are prescribed for an individual. CDC has worked to craft and amplify these messages through funded programs, including collaborating with the National Council for Mental Wellbeing on the [“Getting Candid: Framing the Conversation around Youth Substance Use Prevention.”](#) providing evidence-based key messaging to multi-sector partners through the [“What Works in Schools”](#) program, and managing the [Drug-Free Communities](#) program in partnership with the Office of National Drug Control Policy (ONDCP).

The same study on adolescent drug overdose deaths also found that about 40 percent of adolescents who died of a drug overdose had a history of mental health conditions or mental health treatment. This highlights the intersection of substance use and mental health among young people and underscores the need to address upstream factors that may impact adolescents’ choices related to substance use, including prescription medications not specifically prescribed to them by a medical professional. Adolescence is a time for young people to have a healthy start in life. The number of adolescents [reporting poor mental health is increasing](#), especially with the disruption, trauma, and loss from the COVID-19 pandemic. Building strong bonds and connecting to youth can protect their mental health and prevent initiation of substance use at a time when the drug supply is increasingly dangerous.

CDC’s work to prevent overdoses and substance-use related harms is guided by [Six Principles and Five Strategic Priorities to Address the Overdose Crisis](#). More specifically, [CDC’s role in the Opioid Overdose Epidemic](#) is to collect, analyze, and disseminate timely and comprehensive data, improve patient safety through health care provider education and

health systems strategies, raise awareness about the risk of opioid misuse and empowering the public to make safe choices, support states and localities to implement effective evidence-based strategies, and collaborate with public safety and first responders. Within its role, CDC has seen a great number of [successes](#) across these areas, and CDC is continuing to make vital strides in accelerating data collection, analysis, and dissemination of nonfatal and fatal overdoses and increasing the use of innovative data science and modeling efforts to fight the current crisis and predict where it will go next.

In FY 2024, CDC is requesting an increase of \$207.8 million for Opioid Overdose Prevention and Surveillance; these resources would support integration of state and local prevention and response efforts, provide support for providers and health systems prevention (including use of prescription drug monitoring programs as a clinical decision support tool), enhance partnerships with public safety and first responders, establish and improve linkages to medications for opioid use disorder and other supportive services through harm reduction activities, and empower individuals to make informed choices. These activities support multiple initiatives included in ONDCP Policy Priorities and the National Drug Control Strategy.

It is important to note that overdose, suicide, and adverse childhood experiences (ACEs), which are potentially traumatic events that occur in childhood, are related and urgent public health crises. Experiencing any ACE in childhood, including losing a loved one to overdose or suicide, increases an individual's risk of substance use overdose, mental health challenges, and suicide later in [life](#). [Recent studies from CDC](#) show that ACEs occurring throughout the pandemic were strongly linked to poor mental health and suicidal behaviors among high school students. As of October 2022, 3 in 4 high school students experienced at least one ACE throughout the pandemic and the prevalence of poor mental health and suicide attempts among adolescents reporting four or more ACEs were four and 25 times as high as those reporting no ACEs, respectively. The same report asserted that exposure to certain ACEs (e.g., mental abuse) were associated with higher rates of poor mental health and suicidal behaviors.

CDC is strategically responding to these alarming trends in adolescent mental health. One such activity is the Overdose Data to Action (OD2A) program and specifically the prevention funding component of this program that allows recipients to implement optional strategies, which include prevention of ACEs. Seven recipients chose to identify children and families at greater risk for ACEs to target for necessary prevention resources. For example, New Hampshire is providing mini-grants to local organizations supporting grandparents or other relatives who are the full-time caregivers of children effected by the loss of their parents due to opioid-involved overdose death, incarceration, loss of parental rights, or those in long-term treatment. These efforts include addressing mental health challenges experienced by children in these circumstances. Wisconsin's OD2A recipients are building multi-sector, cross-agency partnerships to address the intersection of trauma and toxic stress related to substance harm through the application of effective principles and promising

practices outlined in the Injury Center's [Preventing ACEs Technical Package](#). CDC also supports seven Essentials for Childhood funded states in support of the expansion of their substance misuse-related ACEs prevention efforts. This funding is also supporting four community-level initiatives aimed at addressing the intersection of ACEs and opioid misuse and overdose. The intention is that this work will provide critical new insights into how to effectively engage communities to collaborate on ACEs prevention at the local level.

Similarly, CDC's [Preventing Adverse Childhood Experiences: Data to Action \(PACE:D2A\)](#) program recipients are conducting ACEs monitoring and prevention activities. PACE:D2A's goal is to build the state-level surveillance infrastructure necessary to collect, analyze, and act on timely ACEs data by implementing primary prevention strategies where they are most needed. Currently, CDC supports six recipients who are in the final year of activity with the intention to support nearly double the recipients with the new [forecasted cooperative agreement, Essentials for Childhood \(EfC\): Preventing Adverse Childhood Experiences through Data to Action](#), which combines PACE:D2A with the existing EfC [Framework](#) to increase efficiency and the number of recipients. The goals of EfC include reducing risk factors and increasing protective factors for ACEs and subsequent mental health challenges such as the promotion of positive parenting. Early successes include North Carolina's (NC) partnership with Prevent Child Abuse NC to implement *Connections Matter*, an evidence-informed education campaign to improve community connections and child wellbeing through engaging with faith-based organizations to train over 700 faith leaders in pilot communities. Recognizing the science demonstrating the strong connection between ACEs and subsequent mental health problems and risk behaviors such as substance use and overdose, these programmatic investments represent significant contributions CDC is making in response to the alarming youth mental health crisis the United States is facing.

In FY23, CDC's Injury Center is also standing up the Behavioral Health Coordination Unit (BHCU) to coordinate and leverage existing CDC activities related to mental health, with a particular focus on adolescent mental health activities and culturally responsive prevention and early intervention. The BHCU will identify opportunities for a streamlined, coordinated, and collaborative approach to CDC's mental health activities to amplify the impact across the agency in response to FY23 appropriations language.

In addition, in FY 2024, CDC is requesting an increase of \$30.6 million above the FY 2023 enacted level to expand the Healthy Schools program (currently in 16 states) to all states. CDC's Healthy Schools program plays a unique role in bringing together the education and public health sectors to support physical education, physical activity and healthy nutrition, management of chronic conditions, mental health, resilience, emotional wellbeing, and healthy and supportive school environments.

2. In February 2022, the cruise industry was still under a 4 Travel advisory which recommended that Americans avoid cruise travel regardless of vaccination status. This was issued when the cruise industry was one of the few sectors that required guests'

vaccinations and there were both vaccines and boosters widely available.

A. Why then would the CDC advise travelers not to cruise?

CDC Response: CDC uses [Travel Health Notices](#) (THNs) to alert travelers and other audiences about current health issues that impact travelers' health, like disease outbreaks, special events or gatherings, and natural disasters, in destinations around the world.

CDC issued a separate COVID-19 THN for cruise ships because the risk of COVID-19 transmission on cruise ships is different from that of shoreside travel and entertainment settings (such as U.S. resorts, restaurants, bars, and theme parks). Specifically, cruise ships are congregate residential settings with high risk of COVID-19 transmission among travelers (passengers and crew). They have thousands of travelers living for multiple days (or months for crew) on the same ship—eating, sleeping, and participating in activities together in one location. Data from the pandemic suggest COVID-19 spreads quickly in group settings, including on cruise ships, where opportunities for repeated exposure exist.

CDC developed COVID-19 THN criteria specific to cruise ships to inform the public regarding COVID-19 conditions on cruise ships. CDC used COVID-19 data reported by cruise ships and relevant public health authorities to make determinations about the cruise ship THN level. Additional information such as new variants of concern, vaccination rates, severity of disease (such as hospitalizations, medical evacuations, and deaths for crew or passengers) were considered when determining the cruise ship THN level. Furthermore, CDC worked with the cruise industry and public health authorities to gather additional data as appropriate.

In December 2021, when CDC raised the cruise THN level to Level 4 (the highest level at the time), the United States and the world were experiencing the largest surge in COVID-19 cases to date, caused by the newly identified Omicron variant. Numbers of cases reported on cruise ships at the time reflected this surge, increasing 5,000 percent compared to the previous five months combined.

CDC removed the COVID-19 cruise ship THN on March 30, 2022. While cruising continues to pose some risk of COVID-19 transmission, travelers can make their own risk assessment when choosing to cruise, much like they do in other travel settings, based on factors such as their health and vaccination status and personal risk tolerance.

B. Were advisories issued for any other sectors or businesses?

CDC Response: CDC has regulatory authority over cruise ships as opposed to other commercial settings (i.e., restaurants, bars, theme parks, resorts) where state or local authorities are the primary regulators.

C. What was the approval process for these advisories?

CDC Response: Decisions about posting the cruise ship THN, and at what level, were made by maritime public health subject matter experts within CDC's COVID-19 Response. All decisions were reviewed by Response and CDC leadership.

D. What lessons can be learned from the shutdowns and what could CDC do better in future pandemics particularly with regards to the travel and tourism sector?

CDC Response: Over the past three years, CDC has worked closely with the cruise industry, state, territorial, and local health authorities, and federal and seaport partners to provide a safer and healthier environment for cruise passengers and crew. CDC will continue to build upon collaborations with these partners to mitigate public health risks and promote healthy cruising for crew members, passengers, port personnel, and communities.

E. How will you change the CDC's approach to the way it handles regulating this important industry?

CDC Response: The Secretary of Health and Human Services has statutory responsibility under section 361 of the Public Health Service Act (42 U.S.C. § 264) for promulgating regulations to prevent the introduction, transmission, and spread of communicable diseases in the United States. Implementing regulations are found at 42 CFR part 71. Pursuant to its delegated authority, CDC implements and oversees these regulations, which includes provisions relating to preventing the introduction, transmission, and spread of communicable diseases both onboard cruise ships sailing on international voyages and into U.S. communities. Through the COVID-19 response, CDC and the cruise industry established more routine and frequent communications that helped to inform and guide the implementation of CDC's regulations. CDC will continue to build upon this stronger collaboration in the future.

3. I have been concerned by reports of CDC coordinating with Big Tech companies to flag posts as "misinformation" during the pandemic, particularly when the CDC's guidance itself was constantly changing.

A. Can you please provide all correspondence to your agencies' coordination with social media and other technology companies to flag or suppress public posts?

CDC Response: CDC is committed to quickly sharing data and science so individuals and families can make informed decisions about their health, and policy makers can better target resources.

The Honorable Dan Crenshaw

1. It was widely reported that the CDC will be reorganizing some of its offices to report to you directly, while adding an additional office, termed the “Office of Health Equity.” It’s one thing to say that you want more data-driven policy and a shift towards readiness, but it’s hard to not see this as just another effort to inject identity politics into decisions that should be based on science. The CDC should be preparing to protect us from emerging health threats; not following the woke crusade of this administration and promoting “diversity and equity” initiatives.
 - A. Does the addition of the “Office of Health Equity” require hiring more employees, or does it reassign your current workforce?

CDC Response: Congress codified the establishment of several Offices of Minority Health and Offices of Women’s Health across the Department of Health and Human Services (HHS) and its Operating Divisions, including within CDC through the Patient Protection and Affordable Care Act of 2010. The Office of Health Equity at CDC brings together these required programs along with other existing agency functions . During the COVID-19 and other responses, the agency stood up a Chief Health Equity Officer role in CDC’s Emergency Response structure to help ensure that populations across the entire country were protected from emerging public health threats, including populations that data show have historically experienced disproportionate health impacts (e.g., those in rural communities, members of racial and ethnic minority populations, and people living with disabilities; the functioning of this role was heavily supported by existing staff. The majority of staff within this office are already part of the existing units and/or are being reassigned from the current workforce. Some additional employees with specialized population experience (e.g., to serve people with disabilities) may be hired to ensure that the agency is meeting the needs of populations across the United States that experience higher rates of health disparities.

- B. Whether you are growing the federal bureaucracy or recategorizing it, does this undermine the CDC’s core mission, which I’d argue should be directed towards preventing pandemics and ensuring a robust response from the outset? How are you going to regain the trust of the American people?
- C. How do you respond to calls to make the CDC a leaner operation? Whether it’s former FDA director Gottlieb calling for a smaller agency, or President Obama’s CDC Director.

CDC Response: CDC works 24/7 to protect America from health threats. Whether diseases start at home or abroad, are chronic or acute, are curable or preventable, or human error or deliberate attack, CDC fights disease and supports communities and citizens to do the same. The idea that other agencies may be better equipped to address non-communicable disease health threats is misplaced; infectious and non-communicable diseases are inextricably linked. CDC’s work with state and local partners is critical to

tackling the nation’s leading causes of death and disability including heart disease, stroke, cancer, drug overdose and unintentional injuries, and the largely preventable and costly health disparities also associated with these conditions. At the same time, CDC must continue to strengthen its prevention and response efforts related to other health threats. People with chronic diseases are often the most at risk for more severe health outcomes during public health emergencies, including pandemics and natural disasters, making it critical that infectious and non-infectious emergency public health efforts be tightly aligned. Chronic disease (including cancer, heart disease and stroke) and overdose remain in the top 10 causes of death while responses to the increasing number of natural disasters will continue to have a critical role in maintaining the health and wellbeing of the American people. This work requires not only the experts at CDC, but also one of CDC’s greatest assets, the unique and trusted relationships that have been built between the agency and STLTs, which enables CDC to carry out its disease prevention mission. CDC is stronger when it leverages all aspects of the expertise that resides at the agency. As an example of the interdependent nature of infectious and non-communicable disease prevention, during the Zika outbreak in 2015, CDC employed a cross-agency response that utilized both infectious disease specialists and experts from the National Center on Birth Defects and Developmental Disabilities to reduce the risk and impact of Zika virus in pregnant women, infants, and children.

2. Tom Friedan, calling for “a culture focused less on publishing academic papers and more on nimble action.”^{[1] [2]}
 - A. The report issued by the CDC last year, entitled “Health Equity Guiding Principles for Inclusive Communication” includes directives for public health communicators.^[3] It includes noteworthy terminology to correct current medical speech, such as reclassifying:
 - i. “Drug users” as... “people who inject drugs.”
 - ii. “Persons who relapsed” as... “persons who returned to use.”
 - iii. “Smokers” as... “people who smoke.”

Why is the CDC in the business of creating speech codes? What could this possibly have to do with increasing “the health security of our nation?” – the stated mission of the agency?

CDC Response: The [Health Equity Guiding Principles for Inclusive Communication](#) is primarily intended for (but not limited to) public health communicators both at CDC and in the health communication field. They are anchored by the [10 essential public health services](#). These services provide a framework for public health to protect and promote the health of all people in all communities. CDC’s Health Equity Guiding Principles for Inclusive Communication contains suggestions for best practices. These best practice suggestions are designed for the user to consider the context and intended audience for communications and choose inclusive language accordingly.

CDC strives to apply best public health practices to all the work it does. This includes using inclusive, accurate, and accessible language in health communication messaging intended to show respect for all audiences and communities served. This approach is based on the understanding that people have different frames of reference for the same event or experience. CDC suggests considering inclusive terms for population groups while recognizing that there is not always agreement on which terms are best. Communicating with communities in the way they prefer is essential to public health interventions and the health of our nation. Beyond language choices, these guiding principles are intended to provide public health professionals with suggested ways to address communities in a manner that may advance efforts for all Americans to benefit from a fair and just opportunity to achieve optimal health and well-being.

Additional Answers to Questions Directed to FDA

The Honorable Neal Dunn

7. Does the administration commit to being transparent with the American people by communicating any adverse event risks associated with the mRNA COVID-19 vaccines?

CDC Response: Vaccine safety and transparent communication are top priorities for the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). U.S. government agencies use [multiple monitoring systems](#) to detect potential vaccine safety concerns as early as possible and then investigate, if needed.

Potential safety concerns detected during public health surveillance do not necessarily represent true safety problems or health events caused by the vaccine. These findings can often be due to factors other than the vaccine and require further assessment, which includes checking with other monitoring systems to see if those systems have observed similar findings. This cross-referencing helps scientists better understand the nature of the potential safety concern, and if a true safety problem is present.

a. Does the CDC believe it is important to communicate all risks associated with a medical countermeasure?

CDC Response: Yes, CDC believes it is important to communicate both the risks and benefits associated with a medical countermeasure.

b. The State of Florida recently saw a 1,700% increase in VAERS reports tied to the mRNA COVID-19 vaccines and various studies have found possible connections between the mRNA COVID-19 vaccine and several serious adverse events. Why has the CDC not communicated these risks will health care professionals and the public?

CDC Response: Potential safety concerns detected during public health surveillance do not

necessarily represent true safety problems or health events caused by the vaccine. These findings can often be due to factors other than the vaccine and require further assessment, which includes checking with other monitoring systems to see if those systems have observed similar findings. This cross-referencing helps scientists better understand the nature of the potential safety concern, and if a true safety problem is present.

CDC, and other U.S. government agencies (FDA, Centers for Medicare & Medicaid Services (CMS), VA), use a layered approach of [multiple, complementary safety monitoring systems](#) to help detect possible vaccine safety concerns (or “signals”), assess these possible safety signals, and communicate this information to the public. Each system is designed for a different purpose, with different strengths and limitations. Any discussion of [vaccine safety monitoring and surveillance](#) should take into account the contributions of each system in this comprehensive approach.

The [Vaccine Adverse Event Reporting System \(VAERS\)](#) is the national frontline vaccine monitoring system, co-managed by CDC and FDA, that serves as the nation’s early warning system for vaccine safety. Anyone (health care professionals, manufacturers, general public) can send a report of adverse events into VAERS after vaccination. There are also requirements for health care professionals and manufacturers to report serious adverse events to VAERS. To better understand the circumstances around a potential adverse event, VAERS staff from CDC and FDA request additional information, like medical records, for reports that are classified as “serious.” “Serious” reports include those that describe adverse events resulting in death, life-threatening illness, hospitalization or prolongation of hospitalization, permanent disability, or congenital anomaly/birth defect.

The [Vaccine Safety Datalink \(VSD\)](#) is a collaborative project between CDC’s Immunization Safety Office, thirteen integrated health care organizations (as of September 2022), and networks across the United States. Eleven of the participating sites link patient vaccination and electronic health record data. CDC uses electronic health data from participating sites to perform robust, near real-time monitoring of vaccine recipients to identify and characterize potential vaccine safety concerns and to conduct vaccine safety research. VSD data are analyzed weekly as the data come in. If observed adverse event rates for selected conditions exceed expected rates by a pre-specified threshold, then the monitoring process generates a statistical signal.

The [Clinical Immunization Safety Assessment \(CISA\) Project](#) is a collaboration between CDC, seven medical research centers, and other vaccine safety experts. CISA provides consultations to U.S. health care providers with complex vaccine safety questions about their patients to assist with immunization decision-making. CISA sites and CDC staff also conduct clinical research to better understand vaccine safety and identify preventive strategies for adverse events following vaccinations.

[V-safe](#) is a new smartphone-based tool developed specifically for the COVID-19 vaccination program, with an additional module added later for mpox vaccines. V-safe uses text messaging and web surveys to provide personal health check-ins after vaccination and provides CDC with crucial information in near-real time to monitor adverse reactions and other potential safety concerns after vaccination and communicate this information to the public. V-safe enrollment is voluntary, and any participants who are pregnant when vaccinated or after vaccination could also be invited to participate in the CDC Pregnancy Registry for long-term safety monitoring after vaccination during pregnancy. Those reporting in v-safe that they received medical care

after vaccination get a follow-up call encouraging a report to VAERS, which collects more detailed information about adverse events that could be related to vaccination.

CDC has been publicly presenting and openly discussing COVID-19 vaccine safety data at meetings of the Advisory Committee on Immunization Practices (ACIP), starting a week after the first COVID-19 vaccines were given in December 2020. CDC has also regularly published analysis of vaccine safety data in peer reviewed journals and CDC's Morbidity and Mortality Weekly Report (MMWR) to further inform health care providers on the latest vaccine safety data and any potential adverse events or safety signals. All of these are coupled with outreach to media, health care providers, policymakers, and the public. Deidentified databases for [VAERS reports](#) and [v-safe data](#) are also publicly available. For more information, please see CDC's [COVID-19 Vaccine Safety website](#), [website compiling vaccine safety publications](#) for COVID-19 and routine vaccinations, [frequently asked questions about COVID-19 vaccination](#), and [myths and facts about COVID-19 vaccines](#).

[1] <https://www.washingtonpost.com/opinions/2023/01/19/cdc-shortcomings-pandemic-solutions/>

[2] <https://www.theatlantic.com/ideas/archive/2022/08/cdc-reform-covid/671296/>

[3] https://www.cdc.gov/healthcommunication/Health_Equity.html