DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Centers for Disease Control
and Prevention (CDC)
Atlanta GA 30333

November 29, 2021

William Marshall
Judicial Watch, Inc.
425 Third Street, SW
Suite 800
Washington, District of Columbia 20024
Via email: bmarshall@judicialwatch.org

Dear Mr. Marshall:

This letter is regarding your Centers for Disease Control and Prevention and Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Freedom of Information Act (FOIA) request of September 9, 2021, assigned #21-02203-FOIA (copy enclosed).

We located 314 pages of responsive records (all pages released in full or in part). You may view and download the records at https://centersfordiseasecontrol.sharefile.com/d-s9ea7a7b0ffd643f68adda1b15179d323.

After a careful review of these pages, some information was withheld from release pursuant to 5 U.S.C. §552 Exemption (b)(6).

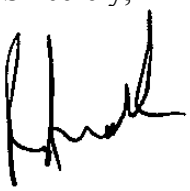
Exemption 6 protects information in personnel and medical files and similar files when disclosure would constitute a clearly unwarranted invasion of personal privacy. The information that has been withheld under Exemption 6 consists of personal information, such as identities and contact information of private citizens, and personal email addresses. We have determined that the individuals to whom this information pertains has a substantial privacy interest in withholding it.

No fees are assessed in this instance.

You may contact our FOIA Public Liaison at 770-488-6277 for any further assistance and to discuss any aspect of your request. Additionally, you may contact the Office of Government Information Services (OGIS) at the National Archives and Records Administration to inquire about the FOIA mediation services they offer. The contact information for OGIS is as follows: Office of Government Information Services, National Archives and Records Administration, 8601 Adelphi Road-OGIS, College Park, Maryland 20740-6001, e-mail at ogis@nara.gov; telephone at 202-741-5770; toll free at 1-877-684-6448; or facsimile at 202-741-5769.

If you are not satisfied with the response to this request, you may administratively appeal to the Deputy Agency Chief FOIA Officer, Office of the Assistant Secretary for Public Affairs, U.S. Department of Health and Human Services, via the online portal at https://requests.publiclink.hhs.gov/App/Index.aspx. Your appeal must be electronically transmitted by February 27, 2022.

Sincerely,



Roger Andoh
CDC/ATSDR FOIA Officer
Office of the Chief Operating Officer
(770) 488-6399
Fax: (404) 235-1852

Enclosures

21-02203-FOIA

Submit New Request

Requester Details

To modify request details please update your requester profile or contact the our office for assistance.

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Requester Default Category: Educational

General Information

Action Office	HQ
Action Office Instructions	CDC/ATSDR FOIA Office 1600 Clifton Road, N.E., MS D-54 Atlanta, Georgia 30152
Request Type	FOIA
Requester Category	All Others
Delivery Mode	E-mail

Shipping Address

Street1	425 Third Street, SW
Street2	Suite 800
City	Washington
State	District of Columbia
State (Other)	
Country	United States
Zip Code	20024

Request Information

Description	All emails sent to and from CDC Director Rochelle Walensky referencing the terms "Antibody Dependent Enhancement", "ADE" (when used to represent Antibody Dependent Enhancement), "pathological priming", "pre-priming", "paradoxical immune enhancement", and/or "disease enhancement".
Date Range for Record Search:From	01/01/2021
Date Range for Record Search:To	09/09/2021
Description Document Consent	

Fee Information

Willing Amount	$25
Fee Waiver Requested	Yes
Fee Waiver Request Reason	Judicial Watch is a non-profit, non-partisan 501(c)(3) educational foundation, promoting transparency, accountability and integrity in government and fidelity to the rule of the law.
Willing to Pay All Fees	No

Billing Address

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State (Other)	
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State	District of Columbia
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Country	United States
Zip Code	20024

Expedite Information

Expedite Reason

From: (b)(6)
Sent: Mon, 26 Jul 2021 18:19:08 -0700
To: Walensky, Rochelle (CDC/OD)
Subject: Fwd: pdfs being posted
Attachments: BNT162b2 6 month analysis 072621.pdf, BNT162b2 6 month analysis suppl 072621.pdf

This 6 month data will be posted tomorrow and subsequently be in NEJM which gave permission to post.

Sent from my iPhone

Begin forwarded message:

Six Month Safety and Efficacy of the BNT162b2 mRNA COVID-19 Vaccine

Stephen J. Thomas, M.D.[1] , Edson D. Moreira Jr., M.D.[2], Nicholas Kitchin, M.D.[3a], Judith Absalon, M.D.[3b], Alejandra Gurtman, M.D.[3b], Stephen Lockhart, D.M.[3a], John L. Perez, M.D.[3c], Gonzalo Pérez Marc, M.D.[4], Fernando P. Polack, M.D.[5], Cristiano Zerbini, M.D.[6], Ruth Bailey, B.Sc.[3a], Kena A. Swanson, Ph.D.[3b], Xia Xu, Ph.D.[3c], Satrajit Roychoudhury, Ph.D.[7], Kenneth Koury, Ph.D.[3b], Salim Bouguermouh, M.D., Ph.D.[3b], Warren V. Kalina, Ph.D.[3b], David Cooper, Ph.D.[3b], Robert W. Frenck, Jr., M.D.[8], Laura L. Hammitt, M.D.[9], Özlem Türeci, M.D.[10], Haylene Nell, M.D.[11], Axel Schaefer, M.D.[12], Serhat Ünal, M.D.[13], Qi Yang, Ph.D.[3b], Paul Liberator, Ph.D.[3b], Dina B. Tresnan, D.V.M., Ph.D.[14a], Susan Mather, M.D.[14b], Philip R. Dormitzer, M.D., Ph.D.[3b], Uğur Şahin, M.D.[10]; William C. Gruber, M.D.[3b], Kathrin U. Jansen, Ph.D.[3b] and the C4591001 Clinical Trial Group

[1]State University of New York, Upstate Medical University, Syracuse , NY; [2]Associação Obras Sociais Irmã Dulce and Oswaldo Cruz Foundation, Bahia, Brazil; [3]Vaccine Research and Development, Pfizer Inc, [a]Hurley, UK, [b]Pearl River, NY, [c]Collegeville, PA; [4] iTrials-Hospital Militar Central, Buenos Aires, Argentina; [5]Fundacion INFANT, Buenos Aires, Argentina; [6]Centro Paulista de Investigação Clinica, São Paulo, Brazil; [7]Global Product Development, Pfizer Inc, Peapack, NJ; [8]Cincinnati Children's Hospital, Cincinnati, OH; [9]Johns Hopkins Bloomberg School of Public Health, Baltimore, MD; [10]BioNTech, Mainz, Germany; [11]Tiervlei Trial Centre, Karl Bremer Hospital, Cape Town, South Africa; [12]Medizentrum Essen Borbeck, Essen, Germany; [13]Hacettepe University, Ankara, Turkey; [14]Worldwide Safety, Safety Surveillance and Risk Management, Pfizer, Inc, [a]Groton, CT, [b]Collegeville, PA.

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ABSTRACT

Background: BNT162b2 is a lipid nanoparticle-formulated, nucleoside-modified RNA vaccine encoding a prefusion-stabilized, membrane-anchored SARS-CoV-2 full-length spike protein. BNT162b2 is highly efficacious against COVID-19 and is currently authorized for emergency use or conditional approval worldwide. At the time of authorization, data beyond 2 months post-vaccination were unavailable.

Methods: In an ongoing, placebo-controlled, observer-blinded, multinational, pivotal efficacy study, 44,165 ≥16-year-old participants and 2,264 12-15-year-old participants were randomized to receive 2 doses, 21 days apart, of 30 µg BNT162b2 or placebo. Study endpoints reported here are vaccine efficacy (VE) against laboratory-confirmed COVID-19 and safety data, both up to 6 months post-vaccination.

Results: BNT162b2 continued to be safe and well tolerated. Few participants had adverse events leading to study withdrawal. VE against COVID-19 was 91% (95% CI 89.0–93.2) through up to 6 months of follow-up, among evaluable participants and irrespective of previous SARS-CoV-2 infection. VE of 86%–100% was seen across countries and in populations with diverse characteristics of age, sex, race/ethnicity, and COVID-19 risk factors in participants without evidence of previous SARS-CoV-2 infection. VE against severe disease was 97% % (95% CI 80.3–99.9). In South Africa, where the SARS-CoV-2 variant of concern, B.1.351 (beta), was predominant, 100% (95% CI 53.5, 100.0) VE was observed.

Conclusion: With up to 6 months of follow-up and despite a gradually declining trend in vaccine efficacy, BNT162b2 had a favorable safety profile and was highly efficacious in preventing COVID-19. (ClinicalTrials.gov number, NCT04368728)

INTRODUCTION

METHODS

Objectives, Participants, Oversight

This randomized, placebo-controlled, observer-blind phase 1/2/3 study assessed BNT162b2 safety, tolerability, efficacy, and immunogenicity in adolescents and adults (NCT04368728). The current report focuses on phase 2/3 safety assessments in ≥16-year-old and prespecified VE assessments in ≥12-year-old participants through up to 6 months post-immunization. Because enrolment of 12-15-year-olds began on October 15, 2020, 6-month post-immunization data are currently unavailable for this age cohort. Shorter duration safety, immunogenicity, and efficacy data for 12-15-year-olds are reported separately;[11] however, data for this cohort are included in overall VE analyses reported here.

Participants who were healthy or had stable chronic medical conditions were eligible. An active immunocompromising condition or recent immunosuppressive therapy were exclusion criteria. Participants with a COVID-19 medical history were excluded, though evidence of current or prior SARS-CoV-2 infection on laboratory testing of study-obtained samples was not an exclusion. Study responsibilities and ethical conduct are summarized in the **Supplementary Appendix**.

Procedures

Participants were randomized 1:1 by an interactive web-based system to receive 2 intramuscular injections 21 days apart of 30 μg BNT162b2 (0.3-mL volume/dose) or saline placebo. Starting in December 2020, following availability of BNT162b2 under emergency/conditional use authorizations, ≥16-year-old participants who became eligible for COVID-19 vaccination by national/local recommendations were given the option of unblinding. Those who had been randomized to placebo were offered BNT162b2. After unblinding, participants were followed in an open-label study period.

Safety

Safety endpoints included solicited, prespecified local reactions, systemic events, and antipyretic/pain medication use ≤7 days after receipt of each vaccine or placebo dose (electronic diary reported) and unsolicited adverse events from dose 1 through 1 month after each dose and serious adverse events from dose 1 through 1 and 6 months post-dose 2. Safety data are presented for blinded follow-up and open-label periods.

Efficacy

BNT162b2 efficacy against laboratory-confirmed COVID-19 with onset ≥7 days post-dose 2 was assessed descriptively in participants without serological or virological evidence of SARS-CoV-2 infection ≤7 days post-dose 2, and in participants with and without evidence of prior infection. Efficacy against severe COVID-19 was also assessed. Lineages of SARS-CoV-2 detected in midturbinate specimens are reported here for COVID-19 cases occurring ≥7 days

post-dose 2 in South African participants without evidence of prior infection. Methods for determining SARS-CoV-2 lineages and case definitions for confirmed and severe COVID-19 are summarized. See **Supplementary Appendix**.

Statistics

Study populations are summarized in **Table S1**. Safety analyses are presented for ≥16-year-olds without known HIV infection who provided informed consent and received ≥1 BNT162b2 or placebo dose. Safety analyses, which are descriptive and not based on formal hypothesis testing, are presented as counts, percentages and associated Clopper-Pearson 95% CIs for adverse events (according to MedDRA terms) and reactogenicity events for each vaccine group. Safety data reported up to March 13, 2021 are summarized here. CIs in this report are not adjusted for multiplicity.

VE analyses during the blinded period are presented for all randomized ≥12-year-olds without known HIV infection who received ≥1 BNT162b2 or placebo dose. VE was estimated by 100×(1–IRR). IRR is the ratio of the rate of confirmed COVID-19 illness per 1000 person-years follow-up in the BNT162b2 group to that in the placebo group. Descriptive analyses of VE and associated 95% CIs used the Clopper and Pearson method, adjusted for surveillance time, which accounts for potential differential follow-up between the 2 groups. As described in the Statistical Analysis Plan, hypothesis testing analyses were performed using a Bayesian approach and the descriptive analyses presented in this manuscript were performed using a frequentist approach for clarity of communication. Because the percentage of participants who reported symptoms but were missing a valid polymerase-chain-reaction test result was small and slightly higher in the placebo arm, data for these participants were not imputed in the analysis.

The previously reported primary efficacy objective was achieved based on analysis of 170 accrued, evaluable COVID-19 cases (data cut-off: November 14, 2020).[9] The current report provides updated efficacy analyses conducted on cases accrued up to March 13, 2021.

RESULTS

Participants

Between July 27, 2020 and October 29, 2020, 45,441 ≥16-year-olds were screened, and 44,165 randomized at 152 sites (US [n=130], Argentina [n=1], Brazil [n=2], South Africa [n=4], Germany [n=6], Turkey [n=9]) in the phase 2/3 portion of the study. Of these participants, 44,060 were vaccinated with ≥1 dose (BNT162b2, n=22,030; placebo, n=22,030), and 98% received dose 2 (**Fig.1**). During the blinded period, 51% of participants in each group had 4 to <6 months of follow-up post dose 2; 8% of BNT162b2 recipients and 6% of placebo recipients had ≥6 months follow-up post-dose 2. During blinded and open-label periods combined, 55% of BNT162b2 recipients had ≥6 months follow-up post-dose 2. Participants were 49% female, 82% White, 10% Black/African American, and 26% Hispanic/Latinx; median age was 51 years. Thirty-four percent had BMI ≥30.0 kg/m^2, 21% had ≥1 underlying comorbidity, and 3% had baseline evidence of prior/current SARS-CoV-2 infection (**Tables 1, S2**).

Between October 15, 2020 and January 12, 2021, 2306 12-15-year-olds were screened, 2264 were randomized across 29 US sites, 2260 were vaccinated with ≥1 dose (BNT162b2, n=1131; placebo, n=1129), and 99% received dose 2.[11] Of vaccinated participants, 58% had ≥2 months

follow-up post-dose 2, 49% were female, 86% were White, 4.6% were Black/African American, and 12% were Hispanic/Latinx. Full demographic characteristics are reported elsewhere.[11]

Safety

Reactogenicity

The reactogenicity subset of participants reported here (those using electronic diary for reporting events) includes 9839 ≥16-year-olds. Of this subset, 8183 were included in the previous analysis, and 1656 were enrolled after the data cut-off for that analysis.[9] The reactogenicity profile for this expanded subset did not differ substantially from that described previously.[9] The reactogenicity subset included 364 participants with evidence of prior SARS-CoV-2 infection, 9426 without, and 49 who lacked data required to determine prior infection status.

More BNT162b2 than placebo recipients reported local reactions, most commonly mild-to-moderate injection site pain (**Fig. S1A**). Participants with or without evidence of prior SARS-CoV-2 infection reported local reactions with similar frequency and of similar severity. No Grade 4 local reactions were reported.

More BNT162b2 than placebo recipients reported systemic events, most commonly fatigue (**Fig. S1B**). Systemic events were mostly mild-to-moderate, but occasionally severe. Systemic reactogenicity was similar in those with and without evidence of prior SARS-CoV-2 infection, although BNT162b2 recipients with evidence of prior infection reported systemic events more often post-dose 1, and those without evidence reported systemic events more often post-dose 2. For example, 12% of recipients with evidence of prior SARS-CoV-2 infection and 3% of those without reported fever post-dose 1; 8% of those with evidence of prior infection and 15% of those without reported fever post-dose 2. The highest temperature reported was a transient fever >40.0°C on day 2 post-dose 2 in a BNT162b2 recipient without evidence of prior infection.

Adverse events

Adverse event analyses during the blinded period are provided for 43,847 ≥16-year-olds (**Table S3**). Reactogenicity events among participants not in the reactogenicity subset are reported as adverse events, resulting in imbalances in adverse events (30% vs 14%), related adverse events (24% vs 6%), and severe adverse events (1.2% vs 0.7%) between BNT162b2 and placebo groups. Decreased appetite, lethargy, asthenia, malaise, night sweats, and hyperhidrosis were new adverse events attributable to BNT162b2 not previously identified in earlier reports. Few participants had serious adverse events or adverse events leading to study withdrawal. No new serious adverse events assessed as related by investigators were reported after data cut-off for the previous report.[9]

Cumulative safety follow-up was available up to 6 months post-dose 2 from combined blinded and open-label periods for 12,006 participants originally randomized to BNT162b2. The longer follow-up for this report, including open-label observation of original BNT162b2 recipients and placebo recipients who received BNT162b2 after unblinding, revealed no new safety signals relative to the previous report.[9]

During the blinded, controlled period, 15 BNT162b2 and 14 placebo recipients died; during the open-label period, 3 BNT162b2 and 2 original placebo recipients who received BNT162b2 after

unblinding died. None of these deaths were considered related to BNT162b2 by investigators. Causes of death were balanced between BNT162b2 and placebo groups (**Table S4**).

Safety monitoring will continue per protocol for 2 years post-dose 2 for participants who originally received BNT162b2 and for 18 months after the second BNT162b2 dose for placebo recipients who received BNT162b2 after unblinding.

Efficacy

Among 42,094 evaluable ≥12-year-olds without evidence of prior SARS-CoV-2 infection, 77 COVID-19 cases with onset ≥7 days post-dose 2 were observed through the data cut-off (March 13, 2021) among vaccine recipients and 850 among placebo recipients, corresponding to 91.3% VE (95% CI [89.0-93.2]; **Table 2**). Among 44,486 evaluable participants, irrespective of prior SARS-CoV-2 infection, 81 COVID-19 cases were observed among vaccine and 873 among placebo recipients, corresponding to 91.1% VE (95% CI [88.8-93.0]).

In the all-available population with evidence of prior SARS-CoV-2 infection based on positive baseline N-binding antibody test, 2 COVID-19 cases were observed post-dose 1 among vaccine and 7 among placebo recipients. In participants with evidence of SARS-CoV-2 infection by positive nucleic acid amplification test at baseline, no difference in COVID-19 cases was observed between vaccine (n=10) and placebo (n=9) recipients (**Table S5**). COVID-19 was less frequent among placebo recipients with positive N-binding antibodies at study entry (7/542; ~1.3% attack rate) than among those without evidence of infection at study entry (1015/21,521; ~4.7% attack rate), indicating ~72.6% protection by previous infection.

From dose 1 to before dose 2, 46 COVID-19 cases were observed in BNT162b2 and 110 in placebo recipients (with or without evidence of prior infection), corresponding to 58.4% VE (95% CI [40.8-71.2]) (**Fig. 2**). During the interval from the approximate start of observed protection at 11 days post-dose 1 to before dose 2, VE increased to 91.7% (95% CI 79.6-97.4). From its peak post-dose 2, observed VE declined. From 7 days to <2 months post-dose 2, VE was 96.2% (95% CI [93.3-98.1]); from 2 months to <4 months, VE was 90.1% (95% CI [86.6-92.9]); and from 4 months to the data cut-off, VE was 83.7% (95% CI [74.7-89.9]).

Of 31 cases of severe, FDA-defined COVID-19,[12] with onset post-dose 1, 30 occurred in placebo recipients, corresponding to 96.7% VE (95% CI 80.3-99.9) against severe COVID-19 (**Fig. 2, Table S6**).

Although the study was not powered to definitively assess efficacy by subgroup, supplemental analyses indicated that VE post-dose 2 among subgroups defined by age, sex, race, ethnicity, presence of comorbid conditions, and country was generally consistent with that observed in the overall population (**Tables 3, S7**).

Given concern about SARS-CoV-2 lineage B.1.351 (beta), which appears less efficiently neutralized by BNT162b2 immune sera than many other lineages,[13] whole viral genome sequencing was performed on midturbinate samples from COVID-19 cases observed in South Africa, where this lineage is prevalent. Nine COVID-19 cases were observed in South African participants without evidence of prior SARS-CoV-2 infection, all in placebo recipients, corresponding to 100% VE (95% CI 53.5-100.0; **Table 3**). Midturbinate specimens from 8/9

cases contained sufficient viral RNA for whole genome sequencing. All viral genomes were of the B.1.351 lineage (GISAID accession codes in **Supplementary Appendix**).

DISCUSSION

In this update to the preliminary safety and efficacy report of a 2-dose regimen of 30 μg BNT162b2 given 21 days apart, 91.1% VE against COVID-19 was observed from 7 days to 6 months post-dose 2 in ≥12-year-old participants. VE against severe disease with onset post-dose 1 was ~97%. This finding, combined with the totality of available evidence, including real-world effectiveness data,[14-17] alleviates theoretical concerns over potential vaccine-mediated disease enhancement.[18]

The benefit of BNT162b2 immunization started ~11 days post-dose 1, with 91.7% VE from 11 days post-dose 1 until dose 2. The study cannot provide information on persistence of protection after a single dose, as 98.5% of participants received dose 2 as scheduled during the blinded study period. As recently reported, although non-neutralizing viral antigen-binding antibody levels rise between the first and second BNT162b2 dose, serum neutralizing titers are low or undetectable during this interval.[19] Early protection against COVID-19 without robust serum neutralization indicates that neutralizing titers alone do not appear to explain early BNT162b2-mediated protection from COVID-19. Other immune mechanisms (e.g., innate immune responses, $CD4^+$ or $CD8^+$ T-cell responses, B-cell memory responses, antibody-dependent cytotoxicity) may contribute to protection.[20-25]

Efficacy peaked at 96.2% during the interval from 7 days to <2 months post-dose 2 and declined gradually to 83.7% from 4 months post-dose 2 to the data cut-off, an average decline of ~6% every 2 months. Ongoing follow-up is needed to understand persistence of the vaccine effect over time, the need for booster dosing, and timing of such a dose. Most participants who initially received placebo have now been immunized with BNT162b2, ending the placebo-controlled part of the study. Nevertheless, ongoing observation of participants through up to 2 years in this study, together with real-world effectiveness data,[14-17] will determine whether a booster is likely to be beneficial after a longer interval. Booster trials to evaluate safety and immunogenicity of BNT162b2 are underway to prepare for this possibility.

From 7 days post-dose 2, 86%-100% efficacy was observed across diverse demographic profiles, including age, sex, race/ethnicity and factors increasing risk of COVID-19, such as high BMI, and other comorbidities. BNT162b2 was also highly efficacious in various geographic regions including North America, Europe, South Africa and Latin America. Although VE was slightly lower in Latin American countries, BNT162b2 had high efficacy of ~86% in Argentina and Brazil. Circulation of SARS-CoV-2 variants, some of which are associated with more rapid transmission, and potentially, greater pathogenicity,[26] has raised concerns that such variants could evade vaccine-mediated protection. Our studies of in vitro neutralization of a variety of SARS-CoV-2 variants have, to date, found that all tested BNT162b2-immune sera neutralize all tested variants.[13,27-31] The variant with the greatest reduction in neutralization, B.1.351, which has been the dominant South African strain, is still neutralized at serum titers higher than those observed at the onset of protection against COVID-19 after the first vaccine dose.[9,13,19] Consistent with this finding, BNT162b2 had 100% (95% CI 53.5, 100.0) observed efficacy

against COVID-19 in South Africa (placebo recipients, 9 cases; BNT162b2 recipients, 0 cases), and 8/9 cases for which sequence information could be obtained were B.1.351 lineage SARS-CoV-2.

Safety data are now available for ~44,000 ≥16-year-old participants; 12,006 individuals have ≥6 months of safety follow-up data after a second BNT162b2 dose. The safety profile observed at a median of 2 months post-immunization was confirmed up to 6 months post-immunization in this analysis. No cases of myocarditis were noted.

Before immunization, 3% of ≥16-year-olds had evidence of SARS-CoV-2 infection. Although this group experienced slightly higher systemic reactogenicity events post-dose 1 than those without evidence of prior infection, the group experienced slightly less reactogenicity post-dose 2 than those without prior infection. Thus, there was minimal observed difference in the overall reactogenicity profile based on baseline infection status. Nine COVID-19 cases were observed among individuals with previous serologically defined natural infection: 2 cases in vaccine and 7 in placebo recipients. These data support the current practice of immunizing without screening for evidence of prior infection.

This report has several limitations. Duration of protection and safety data that could be collected in a blinded, placebo-controlled manner were limited by the ethical and practical need to immunize eligible initial placebo recipients under EUA and according to public health authority recommendations. Data presented here do not address whether vaccination prevents asymptomatic infection, but evaluation of that question is ongoing in this study, and real-world data suggest that BNT162b2 prevents asymptomatic infection.[32,33] Preliminary analyses of breakthrough cases have not yet identified a correlate of protection, as vaccine protection rates remain high. This report does not address VE and safety in pregnant women and in children younger than 12 years. Studies evaluating BNT162b2 in these populations are ongoing.

The data in this report demonstrate that BNT162b2 prevents COVID-19 effectively for up to 6 months post-dose 2 across diverse populations, despite the emergence of SARS-CoV-2 variants, including the B.1.351 lineage, and the vaccine continues to show a favorable safety profile.

Disclosures

All authors have completed the ICMJE uniform disclosure form at www.icmje.org/coi_disclosure.pdf.

Acknowledgements

We would like to thank all the participants who volunteered for this study.

We would also like to acknowledge the contributions of the C4591001 Clinical Trial Group (See supplemental appendix for full list).

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BioNTech: Corinna Rosenbaum, Christian Miculka, Andreas Kuhn, Ferdia Bates, Paul Strecker, Ruben Rizzi, Martin Bexon, Eleni Lagkadinou, and Alexandra Kemmer-Brück.

Polymun: Dietmar Katinger and Andreas Wagner

Funding

Supported by BioNTech and Pfizer

Data sharing statement

Upon request, and subject to review, Pfizer will provide the data that support the findings of this study. Subject to certain criteria, conditions, and exceptions, Pfizer may also provide access to

the related individual anonymized participant data. See https://www.pfizer.com/science/clinical-trials/trial-data-and-results for more information.

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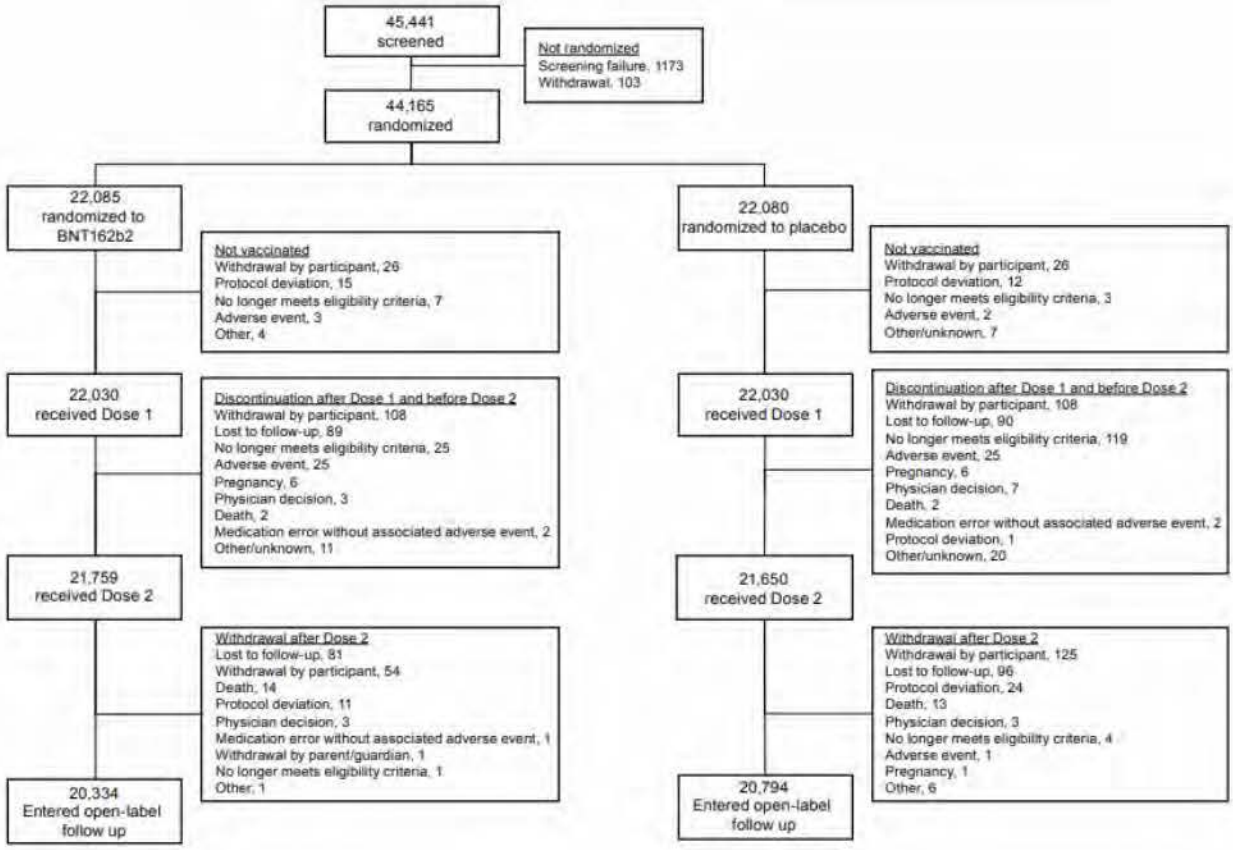
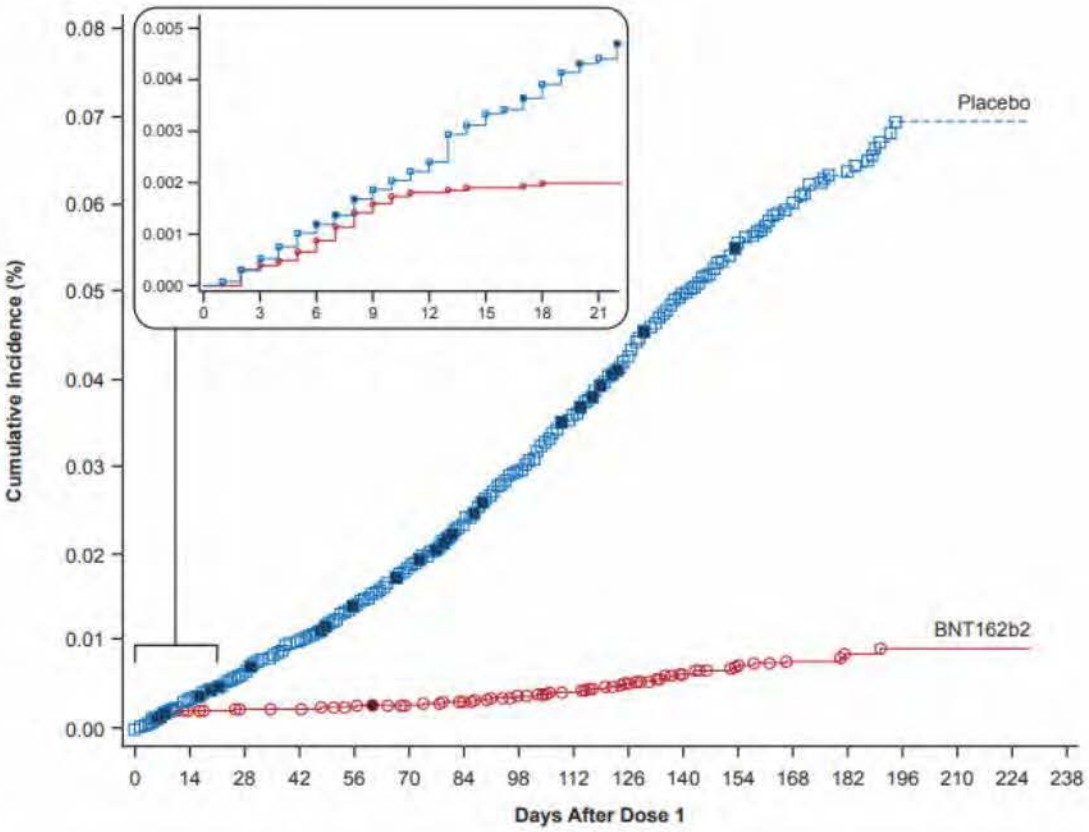


Figure 1 | Disposition of Participants. Disposition is presented for all enrolled participants ≥16 years old through the data cut-off (March 13, 2021). Includes 2 deaths in HIV-infected participants (not included in text). Disposition of participants 12-15 years of age has been reported previously.[11]



Efficacy Endpoint Subgroup	Vaccine Group				VE (95% CI)
	BNT162b2 (N=23,040)		Placebo (N=23,037)		
	No. of participants	Surveillance time (no. at risk)	No. of participants	Surveillance time (no. at risk)	
First COVID-19 occurrence after dose 1	131	8.412 (22,505)	1034	8.124 (22,434)	87.8 (85.3, 89.9)
After dose 1 to before dose 2	46	1.339 (22,505)	110	1.331 (22,434)	58.4 (40.8, 71.2)
After dose 1 to <11 days after dose 1	41	0.677 (22,505)	50	0.675 (22,434)	18.2 (−26.1, 47.3)
≥11 Days after dose 1 to before dose 2	5	0.662 (22,399)	60	0.656 (22,369)	91.7 (79.6, 97.4)
Dose 2 to 7 days after dose 2	3	0.424 (22,163)	35	0.422 (22,057)	91.5 (72.9, 98.3)
≥7 Days after dose 2	82	6.649 (22,132)	889	6.371 (22,001)	91.2 (88.9, 93.0)
≥7 Days after dose 2 to <2 months after dose 2	12	2.923 (22,132)	312	2.884 (22,001)	96.2 (93.3, 98.1)
≥2 Months after dose 2 to <4 months after dose 2	46	2.696 (20,814)	449	2.593 (20,344)	90.1 (86.6, 92.9)
≥4 Months after dose 2	24	1.030 (12,670)	128	0.895 (11,802)	83.7 (74.7, 89.9)

Figure 2 | Efficacy of BNT162b2 against COVID-19 Occurrence after Dose 1 During the Blinded Placebo-controlled Follow-up Period. Cumulative incidence curve of first COVID-19 occurrence after dose 1 (all-available efficacy population; ≥12 years of age). VE=vaccine efficacy. Each symbol represents COVID-19 cases starting on a given day, and filled symbols

represent severe COVID-19 cases. Due to overlapping dates, some symbols represent more than one case. The inset shows the same data on an enlarged y axis, through 21 days. Total surveillance time in 1000 person-years is for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from dose 1 to the end of the surveillance period for the overall row and from the start to the end of the range stated for each time interval. CI for VE was derived based on the Clopper and Pearson method adjusted for surveillance time.

TABLES

Table 1 | Demographics

	BNT162b2 (N[a]=22,026) n[b] (%)	Placebo (N[a]=22,021) n[b] (%)	Total (N[a]=44,047) n[b] (%)
Sex			
Male	11,322 (51.4)	11,098 (50.4)	22,420 (50.9)
Female	10,704 (48.6)	10,923 (49.6)	21,627 (49.1)
Race			
White	18,056 (82.0)	18,064 (82.0)	36,120 (82.0)
Black or African American	2098 (9.5)	2118 (9.6)	4216 (9.6)
American Indian or Alaska Native	221 (1.0)	217 (1.0)	438 (1.0)
Asian	952 (4.3)	942 (4.3)	1894 (4.3)
Native Hawaiian or other Pacific Islander	58 (0.3)	32 (0.1)	90 (0.2)
Multiracial	550 (2.5)	533 (2.4)	1083 (2.5)
Not reported	91 (0.4)	115 (0.5)	206 (0.5)
Racial designation			
Japanese	78 (0.4)	78 (0.4)	156 (0.4)
Ethnicity			
Hispanic/Latinx	5704 (25.9)	5695 (25.9)	11,399 (25.9)
Not reported	111 (0.5)	114 (0.5)	225 (0.5)
Country			
Argentina	2883 (13.1)	2881 (13.1)	5764 (13.1)
Brazil	1452 (6.6)	1448 (6.6)	2900 (6.6)
Germany	249 (1.1)	250 (1.1)	499 (1.1)
South Africa	401 (1.8)	399 (1.8)	800 (1.8)
Turkey	249 (1.1)	249 (1.1)	498 (1.1)
USA	16,792 (76.2)	16,794 (76.3)	33,586 (76.3)
Age group (at vaccination)			
16-55 years	13,069 (59.3)	13,095 (59.5)	26,164 (59.4)
>55 years	8957 (40.7)	8926 (40.5)	17,883 (40.6)
Age at vaccination (years)			
Median	51.0	51.0	51.0
Min, max	(16, 89)	(16, 91)	(16, 91)
Baseline SARS-CoV-2 status			
Positive[c]	689 (3.1)	716 (3.3)	1405 (3.2)
Negative[d]	21,185 (96.2)	21,180 (96.2)	42,365 (96.2)
Missing	152 (0.7)	125 (0.6)	277 (0.6)
Body mass index			
Obese (≥30.0 kg/m^2)	7543 (34.2)	7629 (34.6)	15,172 (34.4)
Missing	7 (0.0)	6 (0.0)	13 (0.0)

Data are summarized for participants ≥16 years old in the safety population. a. N=number of participants in the specified group or the total sample. This value is the denominator for the percentage calculations. b. n=Number of participants with the specified characteristic. c. Positive N-binding antibody result at Visit 1, positive nucleic acid amplification test (NAAT) result at Visit 1, or medical history of COVID-19. d. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19. Demographics for participants 12-15 years of age were reported previously.[11]

Table 2 | Vaccine Efficacy against COVID-19 from 7 Days after Dose 2 During the Blinded Placebo-Controlled Follow-up Period (Evaluable Efficacy Population, ≥12 Years Old)

	BNT162b2		Placebo				
Efficacy Endpoint	**n1[a]**	**Surveillance Time[b] (n2[c])**	**n1[a]**	**Surveillance Time[b] (n2[c])**	**VE (%)**	**(95% CI[d])**	**Posterior Probability (VE >30% | data)[e]**
		(N[f]=20,998)		**(N[f]=21,096)**			
COVID-19 occurrence from 7 days after dose 2 in participants without prior evidence of infection	77	6.247 (20,712)	850	6.003 (20,713)	91.3	(89.0, 93.2)	>0.9999
		(N[f]=22,166)		**(N[f]=22,320)**			
COVID-19 occurrence from 7 days after dose 2 in participants with and those without prior evidence of infection	81	6.509 (21,642)	873	6.274 (21,689)	91.1	(88.8, 93.0)	>0.9999

VE=vaccine efficacy. Participants who had no serological or virological evidence (prior to 7 days after receipt of the last dose) of past SARS-CoV-2 infection (ie, N-binding antibody [serum] negative at Visit 1 and SARS-CoV-2 not detected by NAAT [nasal swab] at Visits 1 and 2), and had negative NAAT (nasal swab) at any unscheduled visit prior to 7 days post-dose 2 were included in the analysis. a. n1=number of participants meeting the endpoint definition. b. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after dose 2 to the end of the surveillance period. c. n2=number of participants at risk for the endpoint. d. CI for VE was derived based on the Clopper and Pearson method adjusted for surveillance time. e. Posterior probability was calculated using a beta-binomial model with prior beta (0.700102, 1) adjusted for surveillance time. f. N=number of participants in the specified group; total population without prior baseline infection N=42,094; total population with and without prior infection N=44,486.

Table 3 | Vaccine Efficacy Overall and by Subgroup in Participants Without Evidence of Infection Prior to 7 Days After Dose 2 During the Blinded Placebo Controlled Follow-up Period.

First COVID-19 Occurrence after Dose 1	BNT162b2 (N[a]=20,998) n1[b]	BNT162b2 (N[a]=20,998) Surveillance Time[c] (n2[d])	Placebo (N[a]=21,096) n1[b]	Placebo (N[a]=21,096) Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Overall (≥12 years of age)	77	6.247 (20,712)	850	6.003 (20,713)	91.3	(89.0, 93.2)
Efficacy endpoint by subgroup						
Age group (years)						
16 to 17	0	0.061 (342)	10	0.057 (331)	100.0	(58.2, 100.0)
16 to 55	52	3.593 (11,517)	568	3.439 (11,533)	91.2	(88.3, 93.5)
>55	25	2.499 (8194)	266	2.417 (8208)	90.9	(86.3, 94.2)
≥65	7	1.233 (4192)	124	1.202 (4226)	94.5	(88.3, 97.8)
≥75	1	0.239 (842)	26	0.237 (847)	96.2	(76.9, 99.9)
Sex						
Male	42	3.246 (10,637)	399	3.047 (10,433)	90.1	(86.4, 93.0)
Female	35	3.001 (10,075)	451	2.956 (10,280)	92.4	(89.2, 94.7)
Race						
White	67	5.208 (17,186)	747	5.026 (17,256)	91.3	(88.9, 93.4)
Black or African American	4	0.545 (1737)	48	0.527 (1737)	91.9	(78.0, 97.9)
American Indian or Alaska Native	0	0.041 (186)	3	0.037 (176)	100.0	(–119.0, 100.0)
Asian	3	0.260 (946)	23	0.248 (934)	87.6	(58.9, 97.6)
Native Hawaiian or other Pacific Islander	0	0.015 (54)	1	0.008 (30)	100.0	(–1961.2, 100.0)
Multiracial	3	0.151 (518)	22	0.128 (476)	88.5	(61.6, 97.8)
Not reported	0	0.026 (85)	6	0.030 (104)	100.0	(2.8, 100.0)
Ethnicity						
Hispanic/Latinx	29	1.786 (5161)	241	1.711 (5120)	88.5	(83.0, 92.4)
Non-Hispanic/non-Latinx	47	4.429 (15,449)	609	4.259 (15,484)	92.6	(90.0, 94.6)
Not reported	1	0.032 (102)	0	0.033 (109)	–∞	(NA, NA)
Country						
Argentina	15	1.012 (2600)	108	0.986 (2586)	86.5	(76.7, 92.7)
Brazil	12	0.406 (1311)	80	0.374 (1293)	86.2	(74.5, 93.1)
Germany	0	0.047 (236)	1	0.048 (242)	100.0	(–3874.2, 100.0)

South Africa	0	0.080 (291)	9	0.074 (276)	100.0	(53.5, 100.0)
Turkey	0	0.027 (228)	5	0.025 (222)	100.0	(–0.1, 100.0)
USA	50	4.674 (16,046)	647	4.497 (16,094)	92.6	(90.1, 94.5)

Efficacy is presented for all randomized participants ≥12 years of age. a. N=number of participants in the specified group. b. n1=number of participants meeting the endpoint definition. c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after dose 2 to the end of the surveillance period. d. n2=number of participants at risk for the endpoint. e. CI for VE was derived based on the Clopper and Pearson method adjusted for surveillance time.

SUPPLEMENTARY APPENDIX

List of Investigators

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Smith, William	New Orleans Center for Clinical Research	New Orleans, LA, USA
Stacey, Helen	Diablo Clinical Research	Walnut Creek, CA, USA
Stephens, Michael	Fleming Island Center for Clinical Research	Fleming Island, FL, USA
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Thomas, Stephen	State University of New York, Upstate Medical University	Syracuse, NY, USA
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Tran, Van	Ventavia Research Group	Houston, TX, USA
Ünal, Serhat	Hacettepe University	Ankara, Turkey
Usdan, Lisa	CNS Healthcare	Memphis, TN, USA
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Varano, Susann	Clinical Research Consulting	Milford, CT, USA
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Walsh, Edward	University of Rochester/Rochester General Hospital	Rochester, NY, USA
Walter, Emmanuel	Duke Human Vaccine Institute	Durham, NC, USA
Wappner, Diego	Fundacion INFANT	Buenos Aires, Argentina
Whiles, Rick	Holston Medical Group	Bristol, TN, USA
Williams, Hayes	Achieve Clinical Research	Birmingham, AL, USA
Wilson, Jonathan	Piedmont Medical Research of Winston-Salem	Winston-Salem, NC, USA
Winkle, Peter	Anaheim Clinical Trials	Anaheim, CA, USA
Winokur, Patricia	University of Iowa	Iowa City, IA, USA
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Zerbini, Cristiano	Centro Paulista de Investigação Clínica - CEPIC	São Paulo, Brazil

Ethical Conduct of the Study

The trial was conducted in accordance with the protocol, the ethical principles derived from international guidelines including the International Council for Harmonisation Good Clinical Practice Guidelines, the Declaration of Helsinki and Council for International Organizations of Medical Sciences International Ethical Guidelines, and applicable laws and regulations (including applicable privacy laws). An independent data monitoring committee reviewed efficacy and unblinded safety data.

Study Responsibilities

Pfizer was responsible for the design, study conduct, data collection, data analysis, data interpretation, and writing of this manuscript. Both Pfizer and BioNTech manufactured clinical trial material. BioNTech was the sponsor of the study and contributed to data interpretation and writing of the manuscript. All study data were available to all authors who vouch for its accuracy and adherence of the study to the protocol.

Testing for SARS-CoV-2 Virus and Antibodies

Testing for SARS-CoV-2 virus was conducted using the Cepheid Xpert Xpress SARS-CoV-2 RT-PCR test. Testing for SARS-CoV-2 antibodies was conducted using the Roche Elecsys® Anti-SARS-CoV-2 antibody test.

Determination of SARS-CoV-2 Lineage

For determination of SARS-CoV-2 lineage, nucleic acid extraction of midturbinate swab specimens was performed using the MagMAX™ Viral/Pathogen Ultra Nucleic Acid Isolation Kit processed on a KingFisher™ Presto.

SARS-CoV-2 viral genome sequencing was performed using the Ion Torrent and Illumina NextSeq platforms. For the Ion Torrent sequencing platform, the Ion AmpliSeq™ SARS-CoV-2 Research Panel was used, which consists of 2 primer pools targeting a total of 237 PCR amplicons specific to SARS-CoV-2 and 5 human expression controls in each pool. Oligonucleotide primers based on available SARS-CoV-2 nucleotide sequences direct the amplification of the viral genome with amplicon lengths of 125–275 bp. The panel provides >99% coverage of the SARS-CoV-2 genome (~30 kb). To determine the optimal number of target amplification cycles, SARS-CoV-2 viral RNA content in the nucleic acid purified from the midturbinate specimens was quantified using the TaqMan™ 2019-nCoV Assay Kit v1, the TaqMan™ 2019-nCoV Control Kit v1, and TaqPath™ 1-Step RT-qPCR Master Mix, CG. cDNA was synthesized with the SuperScript VILO cDNA synthesis kit. Libraries were prepared using the Ion AmpliSeq™ Library Kit plus the Ion AmpliSeq™ SARS-CoV-2 Research Panel according to the manufacturer's instructions (ThermoFisher. Ion AmpliSeq™ Library Kit Plus USER GUIDE. Publication MAN0017003 version C.0.). Libraries underwent template preparation with Ion Chef according to the manufacturer's instructions. Prepared templates were loaded onto an Ion 530 chip for semiconductor sequencing on the Ion GeneStudio™ S5 plus sequencer according to the manufacturer's instructions. Raw sequencing reads generated by the Ion Torrent sequencer were quality and adaptor trimmed by Ion

Torrent Suite and the resulting reads were then mapped to the complete genome of the SARS-CoV-2 Wuhan-Hu-1 isolate (GenBank accession number MN908947.3) using TMAP 5.14.0. Variant calling was carried out with the Torrent Variant Caller using the BAM file from the mapping of the cleaned sequence reads onto the reference sequence of SARS-CoV-2.

SARS-CoV-2 viral genome sequencing performed using the Illumina NextSeq platform used the AmpliSeq for Illumina SARS-CoV-2 panel of PCR primers to enrich for SARS-CoV-2 in the biological specimen. This was a 2-pool design, containing a total of 237 SARS-CoV-2 specific amplicon/primer pairs plus 5 human expression controls in each pool. Oligonucleotide primers based on available SARS-CoV-2 nucleotide sequences directed the amplification of overlapping amplicons with lengths of 125–275 bp that cover >99% of the viral genome. Nucleic acid extracted from the midturbinate specimens was digested initially with DNase (Invitrogen TURBO DNA-free™ Kit, AM1907), and RNA was purified using MagMAX™ beads before cDNA synthesis. Synthesis of cDNA using random sequence primers and downstream steps were as described by the manufacturer. SARS-CoV-2 amplicons were generated from the cDNA, followed by ligation of Universal Next Generation Sequencing Adaptors to the ends of the amplicons. Amplicon libraries were purified with magnetic beads and loaded onto a flow cell for sequence determination using the Illumina NextSeq instrument, according to the manufacturer's instructions. Sequences with ≥30-fold coverage across the entire spike gene were advanced for viral lineage assignment. Single nucleotide variants were called using the "Low Frequency Variant Detection" function with the cut-off for sequence heterogeneity set at >10%.

SARS-CoV-2 lineage assignment was based on Pangolin 2.0 software, which runs a multinomial logistic regression model trained against lineage assignments based on isolate data from the Global Initiative on Sharing All Influenza Data (GISAID), a global science initiative established in 2008 that provides open-access to genomics data of influenza virus and SARS-CoV-2.

Definitions of Confirmed and Severe COVID-19 Cases

The definition of SARS-CoV-2-related cases was the presence of ≥1 of the following symptoms and SARS-CoV-2-NAAT positivity during or within 4 days before or after the symptomatic period: fever, new or increased cough, new or increased shortness of breath, chills, new or increased muscle pain, new loss of taste or smell, sore throat, diarrhea, and/or vomiting. The onset date of the case was the date that symptoms were first experienced by the participant. If new symptoms were reported ≤4 days after resolution of all previous symptoms, they were considered part of a single illness.

Confirmed severe COVID-19 required confirmation of COVID-19 and the presence of ≥1 of the following: clinical signs at rest indicative of severe systemic illness (respiratory rate ≥30 breaths per minute, heart rate ≥125 beats per minute, SpO_2 ≤93% on room air at sea level, or PaO_2/FiO_2 <300 mmHg); respiratory failure (defined as needing high-flow oxygen, non-invasive ventilation, mechanical ventilation, or extracorporeal membrane oxygenation); evidence of shock (systolic blood pressure <90 mmHg, diastolic blood pressure <60 mmHg, or requiring vasopressors); significant acute renal, hepatic, or neurologic dysfunction; intensive care unit admission; and/or death (https://www.fda.gov/media/137926/download).

Figure/Table Number	Figure/Table Title	Population(s)/Sample Size	Explanation
Figure 1	Disposition of Participants	All enrolled safety population ≥16 years of age N=44,165	Per protocol
Figure 2	Efficacy of BNT162b2 against COVID-19 Occurrence after Dose 1 During the Placebo-controlled Follow-up Period	N=46,077 (all available)	All randomized participants ≥12 years of age
Table 1	Demographics	Participants ≥16 years of age N=44,047	Includes HIV-infected individuals
Table 2	Vaccine Efficacy against COVID-19 from 7 Days after Dose 2 During the Blinded Placebo Controlled Follow-up Period (Evaluable Efficacy Population, ≥12 Years Old)	a. Efficacy endpoint including individuals **without** evidence of prior infection (N=42,094) b. Efficacy endpoint including individuals **with and those without** evidence of prior infection (N=44,486)	Evaluable population: • received 2 vaccinations as randomized • no major protocol deviations Excludes HIV+ participants
Table 3	Vaccine Efficacy Overall and by Subgroup in Participants Without Evidence of Infection Prior to 7 Days After Dose 2 During the Blinded Placebo Controlled Follow-up Period	N=42,094 (same as efficacy endpoint in Table 2, participants ≥12 years of age)	
Table S2	Baseline Comorbidities in Participants ≥16 Years of Age	N=44,047	Includes HIV-infected individuals
Table S3	Participants Reporting at Least 1 Adverse Event From Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period	Participants ≥16 years of age N=43,847	Vaccinated minus 200 HIV-infected participants
Table S4	Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old)	Participants ≥16 years of age N=43,847	Vaccinated minus 200 HIV-infected participants
Table S5	Vaccine Efficacy Overall and by Subgroup after Dose 1 During the Blinded Placebo Controlled Follow-up Period (All-Available Population)	N=46,077 (all available)	
Table S6	Vaccine Efficacy against Severe COVID-19 Occurrence after Dose 1 (All-Available Population)	N=46,077 (all available, participants ≥12 years of age)	
Table S7	Vaccine Efficacy from 7 Days after Dose 2 by Underlying Comorbidities (Risk Status) among Participants without Evidence of Infection Prior to 7 Days after Dose 2 (Evaluable Efficacy Population)	N=42,094 (same as efficacy endpoint in Table 2, participants ≥12 years of age)	
Figure S1	Local Reactions and Systemic Events Reported within 7 Days after Receipt of BNT162b2 or Placebo by Baseline SARS-CoV-2 Status	Reactogenicity subset of participants ≥16 years of age (ie, participants who used an electronic diary for reporting local reactions and systemic events) N=9839	Per protocol

Table S1 | Explanation of the Changes in Denominator Numbers in Various Analyses.

Charlson Comorbidity Index Category	BNT162b2 (N[a]=22,026)	Placebo (N[a]=22,021)	Total (N[a]=44,047)
	n[b] (%)	n[b] (%)	n[b] (%)
Participants with any Charlson comorbidity	4628 (21.0)	4511 (20.5)	9139 (20.7)
AIDS/HIV	100 (0.5)	100 (0.5)	200 (0.5)
Any malignancy	812 (3.7)	757 (3.4)	1569 (3.6)
Cerebrovascular disease	227 (1.0)	198 (0.9)	425 (1.0)
Chronic pulmonary disease	1783 (8.1)	1775 (8.1)	3558 (8.1)
Congestive heart failure	109 (0.5)	102 (0.5)	211 (0.5)
Dementia	7 (0.0)	11 (0.0)	18 (0.0)
Diabetes with chronic complication	116 (0.5)	130 (0.6)	246 (0.6)
Diabetes without chronic complication	1700 (7.7)	1699 (7.7)	3399 (7.7)
Hemiplegia or paraplegia	15 (0.1)	25 (0.1)	40 (0.1)
Leukemia	14 (0.1)	11 (0.0)	25 (0.1)
Lymphoma	26 (0.1)	36 (0.2)	62 (0.1)
Metastatic solid tumor	4 (0.0)	3 (0.0)	7 (0.0)
Mild liver disease	152 (0.7)	115 (0.5)	267 (0.6)
Moderate or severe liver disease	2 (0.0)	3 (0.0)	5 (0.0)
Myocardial infarction	225 (1.0)	218 (1.0)	443 (1.0)
Peptic ulcer disease	63 (0.3)	84 (0.4)	147 (0.3)
Peripheral vascular disease	144 (0.7)	139 (0.6)	283 (0.6)
Renal disease	140 (0.6)	153 (0.7)	293 (0.7)
Rheumatic disease	75 (0.3)	71 (0.3)	146 (0.3)

Table S2 | Baseline Comorbidities in Participants ≥16 Years of Age. Baseline comorbid conditions are classified according to the Charlson Comorbidity Index (Charlson M, Szatrowski TP, Peterson J, Gold J. Validation of a combined comorbidity index. J Clin Epidemiol 1994;47:1245-51.). a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=number of participants with the specified characteristic. Participants with multiple occurrences within each category are counted only once. For 'Participants with any Charlson comorbidity', n=number of participants reporting ≥1 occurrence of any Charlson comorbidity.

Adverse Event	BNT162b2 (N[a]=21,926) n[b] (%)	Placebo (N[a]=21,921) n[b] (%)
Any event	6617 (30.2)	3048 (13.9)
Related[c]	5241 (23.9)	1311 (6.0)
Severe	262 (1.2)	150 (0.7)
Life-threatening	21 (0.1)	26 (0.1)
Any serious adverse event	127 (0.6)	116 (0.5)
Related[c,d]	3 (0.0)	0
Severe	71 (0.3)	66 (0.3)
Life-threatening	21 (0.1)	26 (0.1)
Any adverse event leading to withdrawal	32 (0.1)	36 (0.2)
Related[c]	13 (0.1)	11 (0.1)
Severe	10 (0.0)	10 (0.0)
Life-threatening	3 (0.0)	7 (0.0)
Death	3 (0.0)	5 (0.0)

Table S3 | Participants Reporting at Least 1 Adverse Event from Dose 1 to 1 Month After Dose 2 During the Blinded Follow-up Period. The population included all ≥16-year-old participants who received ≥1 dose of vaccine irrespective of follow-up time. a. N=number of participants in the specified group. This value is the denominator for the percentage calculations. b. n=Number of participants reporting ≥1 occurrence of the specified event category. For 'any event', n=number of participants reporting ≥1 occurrence of any event. c. Assessed by the investigator as related to investigational product. d. Shoulder injury related to vaccine administration, right axillary lymphadenopathy, and paroxysmal ventricular arrhythmia (as previously reported). Adverse events for 12–15-year-old participants were reported previously.[11]

Reported Cause of Death[a]	BNT162b2 (N=21,926) n	Placebo (N=21,921) n
Deaths	15	14
Acute respiratory failure	0	1
Aortic rupture	0	1
Arteriosclerosis	2	0
Biliary cancer metastatic	0	1
COVID-19	0	2
COVID-19 pneumonia	1	0
Cardiac arrest	4	1
Cardiac failure congestive	1	0
Cardiorespiratory arrest	1	1
Chronic obstructive pulmonary disease	1	0
Death	0	1
Dementia	0	1
Emphysematous cholecystitis	1	0
Hemorrhagic stroke	0	1
Hypertensive heart disease	1	0
Lung cancer metastatic	1	0
Metastases to liver	0	1
Missing	0	1
Multiple organ dysfunction syndrome	0	2
Myocardial infarction	0	2
Overdose	0	1
Pneumonia	0	2
Sepsis	1	0
Septic shock	1	0
Shigella sepsis	1	0
Unevaluable event	1	0

Table S4 | Causes of Death from Dose 1 to Unblinding (Safety Population, ≥16 Years Old). a. Multiple causes of death could be reported for each participant. There were no deaths among 12–15-year-old participants.

First COVID-19 Occurrence after Dose 1	BNT162b2 (N[a]=23,040) n1[b]	BNT162b2 (N[a]=23,040) Surveillance Time[c] (n2[d])	Placebo (N[a]=23,037) n1[b]	Placebo (N[a]=23,037) Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
Overall (≥12 years old)	131	8.412 (22,505)	1034	8.124 (22,434)	87.8	(85.3, 89.9)
Efficacy endpoint by subgroup						
Select age groups (years)						
16 to 17	3	0.094 (373)	19	0.090 (370)	84.8	(48.4, 97.1)
16 to 55	95	4.845 (12,645)	693	4.669 (12,626)	86.8	(83.6, 89.5)
>55	33	3.310 (8740)	306	3.204 (8689)	89.6	(85.0, 92.9)
≥65	12	1.645 (4455)	138	1.596 (4437)	91.6	(84.8, 95.7)
≥75	2	0.326 (905)	26	0.310 (877)	92.7	(70.7, 99.2)
Sex						
Male	70	4.355 (11,560)	500	4.115 (11,312)	86.8	(83.0, 89.9)
Female	61	4.057 (10,945)	534	4.009 (11,122)	88.7	(85.3, 91.5)
Race						
White	115	6.957 (18,538)	916	6.719 (18,479)	87.9	(85.3, 90.1)
Black or African American	6	0.783 (2042)	53	0.770 (2063)	88.9	(74.1, 96.1)
American Indian or Alaska Native	1	0.061 (216)	7	0.055 (209)	86.9	(–1.6, 99.7)
Asian	4	0.348 (995)	26	0.337 (990)	85.1	(57.0, 96.2)
Native Hawaiian or other Pacific Islander	0	0.021 (58)	1	0.011 (32)	100.0	(–2000.0, 100.0)
Multiracial	5	0.208 (565)	25	0.190 (546)	81.8	(51.6, 94.6)
Not reported	0	0.035 (91)	6	0.042 (115)	100.0	(–0.7, 100.0)
Ethnicity						
Hispanic/Latinx	52	2.351 (5701)	302	2.282 (5673)	83.3	(77.5, 87.8)
Non-Hispanic/non-Latinx	78	6.018 (16,692)	730	5.799 (16,647)	89.7	(87.0, 92.0)
Not reported	1	0.043 (112)	2	0.043 (114)	49.4	(–872.9, 99.1)
Country						
Argentina	32	1.282 (2846)	146	1.269 (2840)	78.3	(68.0, 85.7)
Brazil	14	0.554 (1430)	95	0.520 (1420)	86.1	(75.6, 92.7)
Germany	2	0.067 (246)	1	0.069 (250)	–104.5	(–11,965.9, 89.4)
South Africa	0	0.128 (367)	11	0.125 (365)	100.0	(61.1, 100.0)
Turkey	3	0.048 (246)	12	0.045 (244)	76.4	(12.4, 95.7)
USA	80	6.333 (17,370)	769	6.095 (17,315)	90.0	(87.4, 92.1)
Baseline SARS-CoV-2 status						
Positive[f]	13	0.250 (692)	17	0.265 (736)	19.2	(–76.6, 63.9)
Positive N-binding only	2	0.192 (521)	7	0.198 (542)	70.5	(–54.7, 97.0)

Positive NAAT only	10	0.020 (66)	9	0.020 (69)	–10.5	(–207.3, 59.7)
Positive NAAT and N-binding	1	0.038 (105)	1	0.046 (124)	–20.5	(–9359.2, 98.5)
Negative[g]	116	8.101 (21,615)	1015	7.804 (21,521)	89.0	(86.6, 91.0)
Unknown	2	0.061 (198)	2	0.055 (177)	9.7	(–1145.4, 93.5)

Table S5 | Vaccine Efficacy Overall and by Subgroup after Dose 1 During the Blinded Placebo Controlled Follow-up Period (All-Available Population). Efficacy data are presented for participants ≥12 years old. a. N=number of participants in the specified group. b. n1=Number of participants meeting the endpoint definition. c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from dose 1 to the end of the surveillance period. d. n2=number of participants at risk for the endpoint. e. CI for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time. f. Positive N-binding antibody result at Visit 1, positive NAAT result at Visit 1, or medical history of COVID-19. g. Negative N-binding antibody result at Visit 1, negative NAAT result at Visit 1, and no medical history of COVID-19.

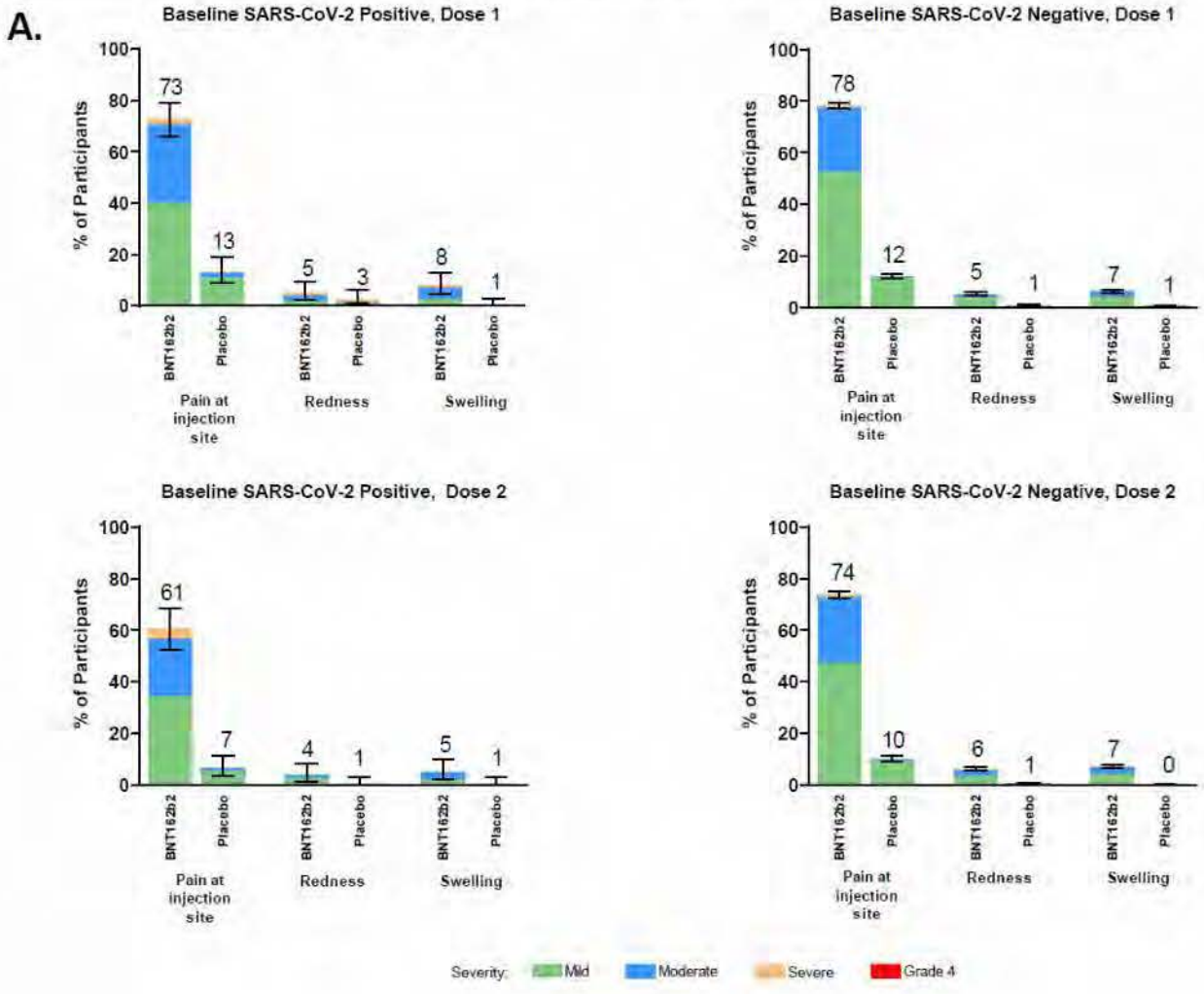
Efficacy Endpoint Subgroup	BNT162b2 (N[a]=23,040) n1[b]	BNT162b2 (N[a]=23,040) Surveillance Time[c] (n2[d])	Placebo (N[a]=23,037) n1[b]	Placebo (N[a]=23,037) Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First severe COVID-19 occurrence after dose 1	1	8.439 (22,505)	30	8.288 (22,435)	96.7	(80.3, 99.9)
After dose 1 to before dose 2	0	1.351 (22,505)	6	1.360 (22,435)	100.0	(14.5, 100.0)
Dose 2 to 7 days after dose 2	0	0.425 (22,170)	1	0.423 (22,070)	100.0	(–3783.5, 100.0)
≥7 Days after dose 2	1	6.663 (22,142)	23	6.505 (22,048)	95.7	(73.9, 99.9)

Table S6 | Vaccine Efficacy against Severe COVID-19 Occurrence after Dose 1 (All-Available Population). Efficacy data are presented for participants ≥12 years old. a. N=number of participants in the specified group. b. n1=number of participants meeting the endpoint definition. c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for severe COVID-19 case accrual is from dose 1 to the end of the surveillance period for the overall row, and from the start to the end of the range stated for each time interval. d. n2=number of participants at risk for the endpoint. [e]. CI for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time. Severe COVID-19 as defined by the US FDA [https://www.fda.gov/media/137926/download]).

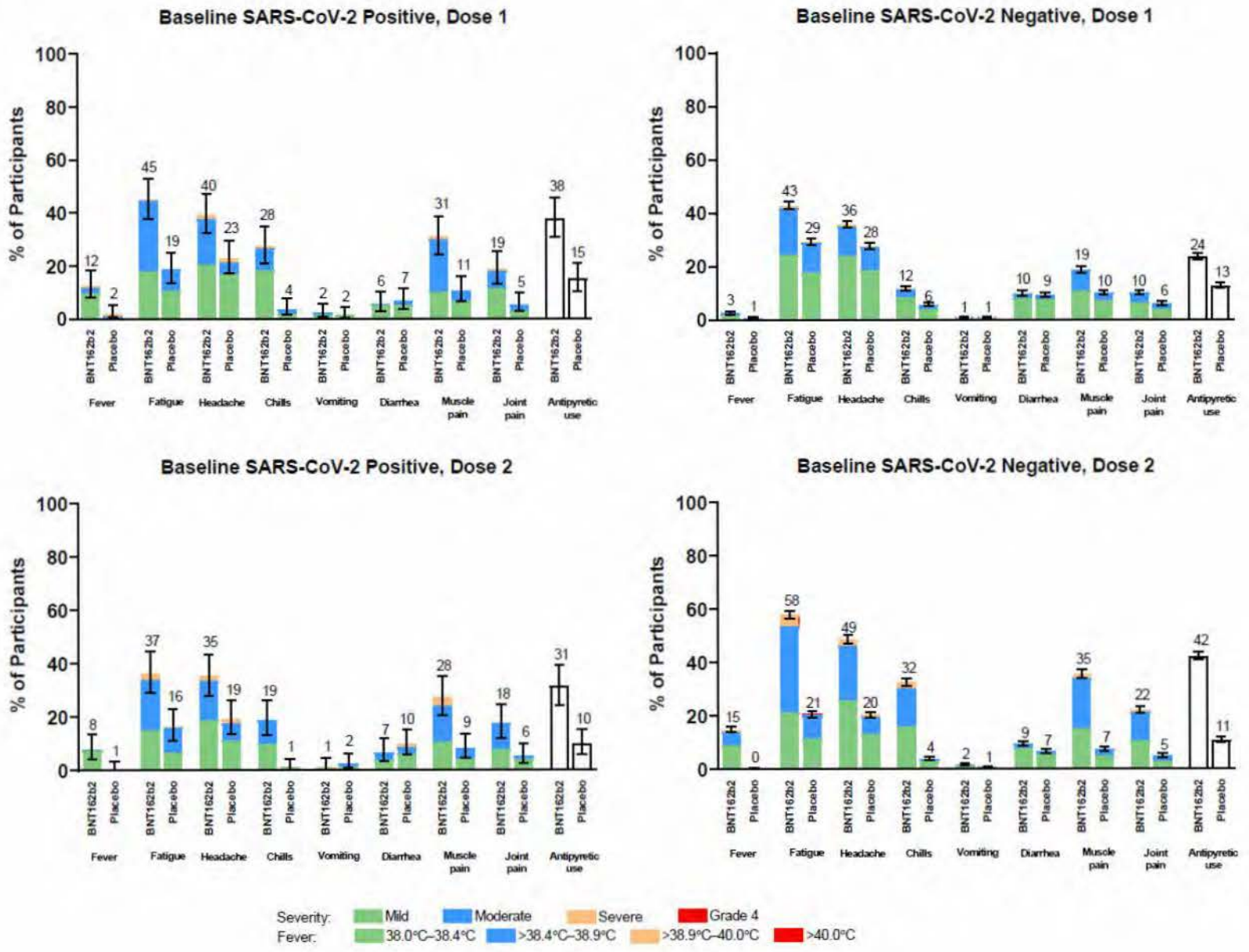
Efficacy Endpoint Subgroup	BNT162b2 (N[a]=20,998) n1[b]	BNT162b2 (N[a]=20,998) Surveillance Time[c] (n2[d])	Placebo (N[a]=21,096) n1[b]	Placebo (N[a]=21,096) Surveillance Time[c] (n2[d])	VE (%)	(95% CI[e])
First COVID-19 occurrence from 7 days after dose 2						
Overall (≥12 years old)	77	6.247 (20,712)	850	6.003 (20,713)	91.3	(89.0, 93.2)
At risk[f]						
Yes	35	2.797 (9167)	401	2.681 (9136)	91.6	(88.2, 94.3)
No	42	3.450 (11,545)	449	3.322 (11,577)	91.0	(87.6, 93.6)
Age group (years) and at risk						
16–64 and at risk	29	2.083 (6632)	325	1.993 (6629)	91.5	(87.5, 94.4)
≥65 and at risk	6	0.680 (2322)	71	0.656 (2304)	91.8	(81.4, 97.1)
Obese[g]						
Yes	27	2.103 (6796)	314	2.050 (6875)	91.6	(87.6, 94.6)
No	50	4.143 (13,911)	536	3.952 (13,833)	91.1	(88.1, 93.5)
Age group (years) and obese						
16–64 and obese	24	1.680 (5303)	266	1.624 (5344)	91.3	(86.7, 94.5)
≥65 and obese	3	0.404 (1370)	45	0.410 (1426)	93.2	(78.9, 98.7)

Table S7 | Vaccine Efficacy from 7 Days after Dose 2 by Underlying Comorbidities (Risk Status) among Participants Without Evidence of Infection Prior to 7 Days after Dose 2 (Evaluable Efficacy Population). Efficacy data are presented for participants ≥12 years old. a. N=number of participants in the specified group. b. n1=number of participants meeting the endpoint definition. c. Total surveillance time in 1000 person-years for the given endpoint across all participants within each group at risk for the endpoint. Time period for COVID-19 case accrual is from 7 days after dose 2 to the end of the surveillance period. d. n2=number of participants at risk for the endpoint. e. CI for vaccine efficacy is derived based on the Clopper and Pearson method adjusted for surveillance time. f. Includes participants who had ≥1 Charlson Comorbidity Index (CMI) category or obesity (body mass index [BMI] ≥30 kg/m^2 [≥16 years old] or BMI ≥95th percentile [12–15 years old]). g. Participants who had BMI ≥30 kg/m^2 (≥16 years old) or BMI ≥95th percentile (12–15 years old; refer to the CDC growth charts at https://www.cdc.gov/growthcharts/html_charts/bmiagerev.htm).

Figure S1 | Local Reactions and Systemic Events Reported within 7 Days after Receipt of BNT162b2 or Placebo by Baseline SARS-CoV-2 Status. Local reactions and systemic events and medication use were collected with electronic diaries for 7 days after each vaccination from ≥16-year-old participants in the reactogenicity subset (n=9839; ie, participants who used an electronic diary for reporting local reactions and systemic events). **A.** Solicited injection-site (local) reactions. Pain at the injection site scale: mild, does not interfere with activity; moderate: interferes with activity; severe, prevents daily activity; Grade 4, emergency room visit or hospitalization). Redness and swelling scale: mild, 2.0 to 5.0 cm in diameter; moderate, >5.0 to 10.0 cm in diameter; severe, >10.0 cm in diameter; Grade 4, necrosis or exfoliative dermatitis for redness and necrosis for swelling. **B.** Systemic events and medication use. Fever scale as indicated in the key. Medication use is not graded. Fatigue, headache, chills, new or worsened muscle pain, new or worsened joint pain scale: mild, does not interfere with activity; moderate, some interference with activity; severe, prevents daily activity; Grade 4, emergency room visit or hospitalization. Vomiting scale: mild, 1 to 2 times in 24 hours; moderate, >2 times in 24 hours; severe, requires intravenous hydration; Grade 4, emergency room visit or hospitalization. Diarrhea scale: mild, 2 to 3 loose stools in 24 hours; moderate, 4 to 5 loose stools in 24 hours; severe, 6 or more loose stools in 24 hours; Grade 4, emergency room visit or hospitalization. Whiskers represent 95% CIs. Numbers above the whiskers are the overall percentage of participants in each group reporting the specified local reaction or systemic event. One participant who received BNT162b2 reported a fever of >40.0ºC, but this is not visible on the graph. Local reactions and systemic events for 12-15-year-old participants have been reported previously (Frenck RW, et al. *N Engl J Med* 2021;385(3):239-250).



B.



From: (b)(6)
Sent: Sun, 22 Aug 2021 23:58:53 -0600
To: Janet.Woodcok@fda.hhs.gov;Marks, Peter (FDA/CBER);Hinton, Denise (FDA/OC);asmonto@umich.edu;Walensky, Rochelle (CDC/OD);sean.mccluskie@hhs.gov;Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: RE: Approval of Pfizer COVID "Vaccine"

I am not a medical professional, just a very concerned citizen about the news reports that the Pfizer COVID "vaccine" is being fast tracked for approval. My question is WHY? To me it appears that it is purely political and financially motivated and not about the safety of the people being vaccinated. It is still a mystery as to why a "vaccine" that is supposedly has a 95% efficacy is needed for a virus that has a 99+% survival rate. It is being seen that the efficacy of these "vaccines" has dropped dramatically and the vaccinated are experiencing reinfection and experiencing antibody dependent enhancement and spreading the spike protein to the non-vaccinated. These "vaccines" are not effective and causing more harm than good. I don't know how you can morally approve any of the COVID "vaccines". To understand what is happening to the vaccinate you need to watch the videos that are being posted on-line by those that have been permanently harmed and those that have lost loved ones to the "vaccines". I personally know of a young woman that has had her menstrual cycles totally messed up after being vaccinated and an older gentleman that has been vaccinated and is in the hospital fighting for his life.

You in the FDA knew this would happen. In an FDA presentation on slide 16 on October 22, 2020 the following potential adverse reactions to the vaccinations were listed as: Guillain-Barre Syndrome, Acute disseminated encephalomyelitis, transverse myelitis, encephalitis/myelitis/encephalomyelitis/meningoencephalitis/meningitis/encephalopathy, convulsions/seizures, stroke, narcolepsy and cataplexy, anaphylaxis, acute myocardial infarction, myocarditis/pericarditis, autoimmune disease, death, pregnancy and birth outcome, other acute demyelinating disease, thrombocytopenia, disseminated intervascular coagulation, venous thromboembolism, arthritis and arthralgia/joint pain, Kawasaki disease, multi-symptom inflammatory syndrome in children and vaccine enhance disease.

The August 8, 2021 VAERS report shows the following data: Deaths-12,791 (more deaths than the last 30 years combined), Life Threatening-13,140, Permanently Disabled-16,044, Hospitalizations-51,242, Anaphlyzxis-5,282, Bells Palsey-4,461, Miscarriages-1,505, Heart Attacks-5,590, Severe Allergy-24,305 and Shingles-6,784. People know that the VAERS report represents 1% to 10% of what is actually happening. If you approve Pfizer or any of the COVID "vaccines", you are not following your own protocols at shutting down the use of a vaccine at 50 deaths.

People know who the major donors to the non-governmental health agencies are and what the donors' political motivations are. People know about what the "vaccines" are about by doing patent searches. People also know that written protocols are not being followed by allowing the fast track approval.

You have an obligation to protect the health of the citizens of the United States, not implement a death sentence.

Thank you for allowing to express my opinion.

From: Collins, Francis (NIH/OD) [E]
Sent: Mon, 24 May 2021 16:05:06 +0000
To: Wholley, David (FNIH) [T];Schuchat, Anne MD (CDC/OD)
Cc: Walensky, Rochelle (CDC/OD);Berger, Sherri (CDC/OCOO/OD);Mahon, Barbara (CDC/DDID/NCIRD/OD);Melencio, Cheryl (FNIH) [T]
Subject: RE: CDC representative for ACTIV Leadership Team?

Thanks, Anne!

From: Wholley, David (FNIH) [T] <dwholley@fnih.org>
Sent: Monday, May 24, 2021 9:52 AM
To: Schuchat, Anne MD (CDC/OD) <acs1@CDC.GOV>; Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Cc: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Mahon, Barbara (CDC/DDID/NCIRD/OD) <bdm3@cdc.gov>; Melencio, Cheryl (FNIH) [T] <cmelencio@fnih.org>
Subject: RE: CDC representative for ACTIV Leadership Team?

Thank you, Dr. Shuchat. By copy to our administrative manager Cheryl Melencio, we will see that Barbara is added to the meeting invitation and documents distribution list going forward.
David Wholley

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Monday, May 24, 2021 9:35 AM
To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Mahon, Barbara (CDC/DDID/NCIRD/OD) <bdm3@cdc.gov>
Subject: FW: CDC representative for ACTIV Leadership Team?

Francis:
CDC proposes Dr. Barbara Mahon join the Leadership Team for ACTIV on behalf of our agency. I've added her to the email and let her know about the two dates for the next meetings. Barbara has a wealth of vaccine and product development expertise, with longtime experience at CDC and prior appointments in academia, industry, and foundations. She is based in the National Center for Immunization and Respiratory Diseases within the Office of the Director.

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From: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Sent: Sunday, May 23, 2021 7:09 PM
To: Walensky, Rochelle (CDC/OD)
Cc: Wholley, David (FNIH) [T]
Subject: CDC representative for ACTIV Leadership Team?

Dear Rochelle,

With Nancy Messonnier's departure from CDC , I am writing to ask whether you would like to name someone else from CDC to join the Leadership Team for our ACTIV (Accelerating Covid-19 Therapeutic Interventions and Vaccines) public-private partnership.

You may have heard me speak about ACTIV, which we've been engaged in for over a year with 8 government agencies, 20 biopharmaceutical companies, and several non-profits, including the Foundation for the NIH, who provides program management for the entire effort. The attached deck outlines some of the top line activities. ACTIV has pretty much represented the core of the USG response to COVID on the therapeutics front, prioritizing over 1000 different potential therapies for COVID and testing the most promising candidates in nine different master protocol clinical trials run in both government and CRO networks. Our Vaccines Working group has been essential in advising the field, and particularly FDA, on issues like harmonizing protocols across multiple vaccine trials, establishing standards for EUAs, and evaluating approaches to possible disease enhancement and the need for human challenge trials. Most recently, ACTIV has been the home for TRACE (Tracking Resistance and Coronavirus Evolution), a relatively new initiative that is working with multiple NIH Institutes and HHS agencies (including CDC) to help monitor and test emerging viral variants for their functional consequences, making the results broadly and quickly available to the scientific community.

ACTIV is led by a Leadership Team (LT) co-chaired by me and Paul Stoffels at Janssen. The team meets monthly to review progress and tackle any obstacles to progress that may arise. Until recently CDC was represented on both the LT and the Vaccines Working Group by Nancy Messonier. I personally think having CDC continue to be a part of our conversations is essential. Is there someone from your team who could take Nancy's role? The next two meetings are May 28 and June 28; I'll be happy to have FNIH send an invitation to whomever you deem suitable.

Warm personal regards,
Francis

From: Walensky, Rochelle (CDC/OD)
Sent: Mon, 24 May 2021 13:44:53 +0000
To: Schuchat, Anne MD (CDC/OD)
Subject: RE: CDC representative for ACTIV Leadership Team?

Awesome, thank you, Anne!
R

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Monday, May 24, 2021 9:35 AM
To: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Cc: Wholley, David (FNIH) [T] <dwholley@fnih.org>; Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Mahon, Barbara (CDC/DDID/NCIRD/OD) <bdm3@cdc.gov>
Subject: FW: CDC representative for ACTIV Leadership Team?

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From: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Sent: Sunday, May 23, 2021 7:09 PM
To: Walensky, Rochelle (CDC/OD)
Cc: Wholley, David (FNIH) [T]
Subject: CDC representative for ACTIV Leadership Team?

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Warm personal regards,
Francis

From: Walensky, Rochelle (CDC/OD)
Sent: Mon, 24 May 2021 12:26:49 +0000
To: Berger, Sherri (CDC/OCOO/OD);Schuchat, Anne MD (CDC/OD)
Subject: RE: CDC representative for ACTIV Leadership Team?

Yes please, that would be terrific…
Thanks much, Anne.
R

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Sent: Monday, May 24, 2021 8:19 AM
To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Subject: RE: CDC representative for ACTIV Leadership Team?

Yes please and can you reply directly to Collins (unless RW disagrees)

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Sent: Monday, May 24, 2021 8:16 AM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>
Subject: RE: CDC representative for ACTIV Leadership Team?

Suggest Barbara Mahon – has the right type of vaccine, product development, and covid expertise and has position in NCIRD OD. If ok with you I can check w her if those dates are ok given timing of her (b)(6)

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Sent: Sunday, May 23, 2021 7:12 PM
To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>
Subject: Fwd: CDC representative for ACTIV Leadership Team?

Thoughts on who would be best?

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From: Collins, Francis (NIH/OD) [E] <collinsf@od.nih.gov>
Sent: Sunday, May 23, 2021 7:09 PM
To: Walensky, Rochelle (CDC/OD)
Cc: Wholley, David (FNIH) [T]
Subject: CDC representative for ACTIV Leadership Team?

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Warm personal regards,
Francis

From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Mon, 28 Jun 2021 14:01:07 +0000
To: Walensky, Rochelle (CDC/OD);Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI)
Subject: RE: Monday TODAY'S NEWS

Following up now

-----Original Message-----
From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Sent: Monday, June 28, 2021 10:00 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>
Subject: FW: Monday TODAY'S NEWS

Any details on this?

CDC reportedly probing Michigan teen's death after COVID-19 vaccination

By Shen Wu Tan - The Washington Times

Federal health officials are investigating the case of a Michigan teenager who died days after he received a COVID-19 vaccine, Fox News reported Friday.

The 13-year-old boy died three days after getting a second dose of a COVID-19 vaccine, the Saginaw County Health Department told the news agency in a statement. The department learned of the teenager's death on June 17.

"The investigation as to whether there is a correlation between his death and vaccination is now at the federal level with [the Centers for Disease Control and Prevention," the health department said. "Meanwhile, the health department continues to encourage families to speak with their physicians to weigh their own risks and benefits of vaccination."

It is unknown whether the teenage boy had previous health problems. The news report did not specify whether the teenager received the two-dose Pfizer-BioNTech COVID-19 vaccine or the Moderna vaccine. The death has been supposedly reported to the Vaccine Adverse Event Reporting System (VAERS), a national surveillance system.

Neither the CDC nor the Saginaw County Health Department immediately responded to requests for comment.

CDC officials say deaths following COVID-19 vaccinations have been rare. More than 318 million COVID-19 doses were administered in the U.S. from Dec. 14 through June 21, and about 5,400 deaths, or 0.0017%, among those vaccinated were reported to VAERS during that time.

"Reports of adverse events to VAERS following vaccination, including

deaths, do not necessarily mean that a vaccine caused a health problem. A review of available clinical information, including death certificates, autopsy and medical records, has not established a causal link to COVID-19 vaccines," the CDC says on its website.

However, there could be a "plausible causal relationship" between the one-shot Johnson & Johnson COVID-19 vaccine and a rare, serious blood clotting condition, which has caused deaths.

Health care providers are required by the Food and Drug Administration to report any death after a COVID-19 vaccination to VAERS.

-----Original Message-----
From: Mike Cooper <mcooper@panix.com>
Sent: Monday, June 28, 2021 9:51 AM
To: cdc@panix.com
Subject: Monday TODAY'S NEWS

TODAY'S NEWS

MONDAY, JUNE 28, 2021

CDC Director Rochelle Walensky On Coronavirus Variants And Vaccinations, National Public Radio

Half of public health workers experiencing mental health strain: study; TheHill.com

CDC says roughly 4,100 people have been hospitalized or died with Covid breakthrough infections after vaccination, CNBC.com

U.S. FDA adds warning about rare heart inflammation to Pfizer, Moderna COVID vaccines; Reuters

Vaccine-associated myocarditis tends to resolve quickly, Reuters

CDC reportedly probing Michigan teen's death after COVID-19 vaccination, WashingtonTimes.om

Bipartisan senators ask CDC, TSA when they will update mask guidance for travelers; TheHill.com

U.S. Senate Republicans press CDC to end mask mandate on airplanes, transit; Reuters

Ted Cruz joins forces with other GOP lawmakers to call for an end to mask mandates for vaccinated travelers, ahead of Independence Day; BusinessInsider.com

Senate Republicans urge CDC to lift public transportation mask mandate, TheHill.com

Ted Cruz Urges Joe Biden to 'Follow the Science' and End Travel Mask Requirement, Newsweek.com

Georgia State Looks To Boost Vaccine Rate Among Refugees, AP Georgia

U.S. average daily COVID-19 vaccination drops by over 50 pct: CDC; Xinhua

U.S. reaches 323 million doses of COVID-19 vaccine administered -CDC, Reuters

CDC reports 4,115 breakthrough COVID-19 cases involving hospitalizations or deaths, FoxNews.com

Some fully vaccinated people may still get sick if exposed to variants, CDC warns; CNN.com

Booster may be needed for J&J shot as Delta variant spreads, some experts already taking them; Reuters

'Please get your second shot,' top health official urges as Delta variant remains a pressing threat; CNN.com

States Hesitant To Adopt Digital Covid Vaccine Verification, Associated Press

`A tough slog': White House struggles to increase vaccination rates as Delta variant surges; Politico.com

Wisconsin's Johnson To Tout Claims Of Vaccine Side Effects, AP Wisconsin

Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic, research finds; CNN.com

1st Post-Pandemic Cruise Ship From US Sails Away, Associated Press

How the first cruise of the Covid era got ready to safely set sail, CNN.com

Virus-Origin Review Likely to Be Unclear, Wall Street Journal

What We Know About the Origins of Covid-19, WSJ.com

The US is concealing its research on deadly viruses -- while criticizing China's secrecy over the Wuhan lab, BusinessInsider.com

Why US labs need to be investigated for COVID-19 origins, Global Times

Celebrity Cruises to Be First to Resume Sailing From U.S., New York Times

Harris Seeks Nuance On Migration Debate During Tour of Border, New York Times

Harris views immigration problems up close, Los Angeles Times

CDC director Robert Redfield 'prayed' Trump would understand how serious COVID-19 was after contracting it, a book excerpt says; BusinessInsider.com

How Trump's blunders fueled our coronavirus nightmare, Washington Post

Hospitals Strain Under Surge in Mental-Health Cases, Wall Street Journal

ACIP approves dengue vaccine for endemic areas, tweaks flu vaccine advice; CIDRAP News

CDC Gives Maine $7M To Prep For Future Public Health Crises, AP Maine

CDC: `Don't kiss or snuggle the birds;' Salmonella outbreak linked to more than 400 infections; SILive.com

Backyard poultry Salmonella outbreak grows to 474 cases, 1 death; CIDRAP News

Avanti Frozen Foods recalls several shrimp products linked to salmonella outbreak, CNN.com

Competing events make their marks on LGBTQ+ Pride Day in New York, Reuters

HIV SOS: Action Sought For Spike In Cases In West Virginia; AP West Virginia

ACLU In West Virginia Sues Over Needle Exchange Law, AP West Virginia

Johnson & Johnson to Pay $230 Million as Part of Exit From Opioid Industry, New York Times

Johnson & Johnson settles New York opioid suit in $230 million deal, CNN.com

J&J to pay $263 mln in New York opioid settlements, avoids trial; Reuters

For Native Americans, clean water is rare; Los Angeles Times

Correction, New York Times

National Public Radio
Friday, June 25, 2021

CDC Director Rochelle Walensky On Coronavirus Variants And Vaccinations

NPR's Audie Cornish checks in with Centers for Disease Control and Prevention Director Dr. Rochelle Walensky about vaccinations, variants and the current state of the pandemic.

AUDIE CORNISH, HOST:

Fifty thousand baseball fans showed up to see the Dodgers play the Phillies last week. The Foo Fighters drew a full-capacity crowd, all vaccinated, to New York's Madison Square Garden on Sunday. And tomorrow, the first major cruise ship will set sail from Fort Lauderdale. Even as the nation returns to life as it once was, thousands of people are still dying of COVID every week. And in unvaccinated pockets of the country, the delta variant of the virus is taking hold. So here to talk about the challenges that remain, Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention. Welcome back to ALL THINGS CONSIDERED.

ROCHELLE WALENSKY: Thanks so much, Audie. Great to be here.

CORNISH: I want to talk about that delta variant. It's more contagious - potentially more dangerous strain of the coronavirus. But more importantly, it makes up to 20% of cases nationwide at this point. And that's doubled in just a few weeks. So what's your concern as this is beginning to spread?

WALENSKY: Yeah, that's exactly right. So we have been doing genomic surveillance now for a while and have a really good window as to the variants that are circulating here in the United States. About a month ago, we were seeing the delta variant at about 2- to 3%. Two weeks ago, we were seeing it at about 9- to 10%. And this last...

CORNISH: And this is assuming that we're - the testing is good enough that we know the true infection rate. I mean, do you think that's the case?

WALENSKY: Oh, that's a really good point. We have scaled up our genomic sequencing in an extraordinary fashion just in the last six months. So I do believe that we're sequencing enough to have quite a good window

as to what's going on here in this country. And more recently, our - we're seeing that the delta variant makes up about 20% of virus circulating and up to 30-, 40-, 50% in some regions of the United States.

As you noted, the things that we worry about with this variant specifically is not only how quickly it is scaling up - and what we've seen in the U.K. is, you know, it really has taken over as the predominant variant, which I expect to happen - but it really is more transmissible. And early data actually suggest it may actually lead to more severe disease as well.

CORNISH: So what's your concern when you look at, say, vaccination rates among people under the age of 25? How do you convince those groups in particular that they're still vulnerable?

WALENSKY: Well, you know, anybody is vulnerable to coronavirus. And so we really do need to make sure that we get vaccine to people who are unvaccinated. We do know that younger people have not had as long of an opportunity to be vaccinated as our older people who were eligible first. And what we really do need to do is figure out ways to talk to these young folks and ensure that they understand, not just about the severity of the disease, about the morbidity and mortality related to the disease, but about the implications of long COVID.

You know, what we have seen and the data have shown us is that the young folks are not getting hospitalized or die at the same rate of older people. But young people shouldn't die at the same rate of older people. And we do have - we have seen, for example, just in the last month that there have been over 300 deaths among people ages 20 to - 12 to 29. And that is - that shouldn't happen in that demographic, which is why we really want to get people vaccinated.

CORNISH: I want to jump in here because it's not just about the vaccinated people. Studies in England - the unvaccinated, I mean. Because there are studies in England that have shown one shot isn't enough to give full protection against the delta variant. And there's some - I think I'm reading 27 million people in the U.S. who are still only half vaccinated; either still waiting for their second shot or who maybe decided one shot was enough. What's your message to them?

WALENSKY: Right. So thank you for raising that. My message is to please get your second shot. So what we do know is you get some protection from the first shot. But really, that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this delta variant and other variants as well. And as you note, data from the U.K. show that one shot is really not working as well to stave off, especially, the delta variant and you really do need that second shot. So we are really encouraging people not only to get their first, but to get their second. And if you didn't, if you missed your second within the time window, get it whenever - get it now. But do get that second shot.

CORNISH: Is it clear how helpful that is? When you look at a country like Israel, where the variant accounts for 90% of new cases there - in cases where people had been fully vaccinated with the Pfizer vaccine. I

mean, they reimposed indoor mask requirements. Looking at our map, we've got states that aren't doing that now. So what are your concerns?

WALENSKY: So I do think we have more to learn about this delta variant, but here's what I'll say. It is the case that if you're vaccinated, we believe you actually have quite good protection against the delta variant. But nothing is foolproof. What we do know is that if you have been vaccinated, you are far less likely to have severe disease, to have - to result in death and also to be able to transmit to others. So yes, perhaps we're seeing breakthrough infections at a higher rate than we would like to see, but we're also seeing that if you've been vaccinated, you have less severe disease, less transmission and less death.

CORNISH: President Biden has said the variant is unlikely to force the U.S. into another lockdown situation. Looking at a state like, say, Missouri that has low vaccination numbers and climbing cases, are you guys going to be urging local leaders to put mask mandates back in place or social distancing requirements back in place?

WALENSKY: Right. So that's a really great question. We are encouraging all local areas to look at their vaccination rates, to look at the case rates and to make their policies that - with those both in mind. It may very well...

CORNISH: So if they've got no mask mandate or no social distancing and they're like, we've only got a few people in the hospital but a low vaccination rate, is that a recipe that you want?

WALENSKY: Well, that would be - if you have low cases, then the answer there is to make sure you scale up your vaccination rates. If you also have high cases, then we might encourage states to take the mitigation strategies that we know work to decrease the number of cases and increase the vaccination rate. For the most part, CDC has said since its initial mask guidance for fully vaccinated people that if you are not vaccinated, you should continue the standard mitigation strategies - distancing, handwashing and masking - that we know work to protect people.

CORNISH: In our final few seconds - even if you wanted to, do you think you could convince anyone to go back into lockdown? I mean, politically, it was tough.

WALENSKY: Yeah. I think my job is to make sure that the public is safe. And so we have many strategies, many tools in our toolbox now to be able to do that. Vaccine is certainly one of them. And I think we have continued work ahead of us to get into these communities and to let people - give people the information they need so that they know vaccine is the best protection for them.

CORNISH: That's Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention. Thank you for your time.

WALENSKY: Thanks so much.

(SOUNDBITE OF NATIONAL AIR AND SPACE MUSEUM, DIPLO, AND HRISHIKESH

HIRWAY'S SONG, "MOTION MMXX -- I")

TheHill.com
Friday, June 25, 2021

Half of public health workers experiencing mental health strain: study

By Reid Wilson

More than half of public health workers reported experiencing symptoms of mental health conditions, according to a new study, a toll that disproportionately falls on those who spent most of their time treating patients suffering from COVID-19.

The study, to be published in the Centers for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report, found nearly a third of the 26,000 health care workers polled suffered from symptoms of depression in the last two weeks. Three in 10 reported suffering from anxiety, and more than a third say they have experienced symptoms of post-traumatic stress disorder (PTSD).

Eight percent, or about one in twelve, told researchers they experienced suicidal ideation.

All of the mental health conditions were more prevalent among public health workers under the age of 29, among those who worked more than 60 hours per week and among those who reported they were unable to take time off work.

The symptoms were particularly pronounced among those who spent most of their time in COVID-19 wards. Among public health workers who spent three-quarters of their time responding to the pandemic, nearly half reported symptoms of PTSD within the last two weeks alone and more than a third reported signs of depression and anxiety.

The CDC researchers said stress-inducing events like the coronavirus pandemic can undermine the public health workforce at exactly the time when they are most essential.

"Increases in adverse mental health symptoms among workers have been linked to increased absenteeism, high turnover, lower productivity, and lower morale, which could influence the effectiveness of public health organizations during emergencies," the researchers wrote.

The report found nearly three-quarters of all public health workers felt overwhelmed by work. One in 8 reported receiving job-related threats, in an echo of abuse hurled at health care workers early on in the pandemic. And almost a quarter said they had felt bullied, harassed or threatened because of their work.

Public health care workers are more likely to have experienced traumatic events or stressors during the pandemic than are members of the general population. More than a quarter reported losing a loved one, and more than 10 percent reported they had been diagnosed with

COVID-19 themselves.

The CDC researchers surveyed 26,174 public health workers from state, tribal, local and territorial health departments over a three-week period in late March and early April of 2020, as the pandemic began.

CNBC.com
Friday, June 25, 2021

CDC says roughly 4,100 people have been hospitalized or died with Covid breakthrough infections after vaccination

Rich Mendez@richmendezcnbc

More than 4,100 people have been hospitalized or died with Covid-19 in the U.S. even though they've been fully vaccinated, according to new data from the Centers for Disease Control and Prevention.

So far, at least 750 fully vaccinated people have died after contracting Covid, but the CDC noted that 142 of those fatalities were asymptomatic or unrelated to Covid-19, according to data as of Monday that was released Friday.

The CDC received 3,907 reports of people who have been hospitalized with breakthrough Covid infections, despite being fully vaccinated. Of those, more than 1,000 of those patients were asymptomatic or their hospitalizations weren't related to Covid-19, the CDC said.

"To be expected," Dr. Paul Offit, a top advisor to the Food and Drug Administration on children's vaccines told CNBC. "The vaccines aren't 100% effective, even against severe disease. Very small percentage of the 600,000 deaths."

Breakthrough cases are Covid-19 infections that bypass vaccine protection. They are very rare and many are asymptomatic. The vaccines are highly effective but don't block every infection. Pfizer and Moderna's phase three clinical studies found that their two-dose regimens were 95% and 94% effective at blocking Covid-19, respectively, while Johnson & Johnson's one-shot vaccine was found to be 66% effective in its studies. All three, however, have been found to be extremely effective in preventing people from getting severely sick from Covid.

The CDC doesn't count every breakthrough case. It stopped counting all breakthrough cases May 1 and now only tallies those that lead to hospitalization or death, a move the agency was criticized for by health experts.

Most Americans have received at least one shot of the two currently authorized mRNA vaccines. The U.S. has administered 178.3 million shots and fully vaccinated 46% of its population.

"You are just as likely to be killed by a meteorite as die from Covid after a vaccine," Dr. Peter Chin-Hong, an infectious disease expert at

the University of California San Francisco, told CNBC. "In the big scheme of things, the vaccines are tremendously powerful."

Efficacy rates decrease slightly for variants like alpha and delta, with studies indicating 88% efficacy against the delta strain after two doses of the Pfizer vaccine. It was unclear if any of the reported breakthrough cases were caused by variants.

In Israel and the United Kingdom, concerns about the delta variant are rising after growing reports of breakthrough infections.

Even with 80% of adults vaccinated, Chezy Levy, director-general of Israel's Health Ministry, said the delta variant is responsible for 70% of new infections in the country. Levy also said that one-third of those new infections were in vaccinated individuals.

In the U.K., Public Health England released a report that found 26 out of 73 deaths caused by the delta variant occurred in fully vaccinated people from June 8 to June 14. Most of the deaths occurred in unvaccinated individuals.

"Determination of whether hospitalizations and deaths are more represented in immunocompromised patients and the type of vaccine received will be important for future guidance," Chin-Hong said.

On June 7, the CDC received reports of 3,459 breakthrough cases that led to hospitalization or death. On June 18, that number was updated to 3,729, an increase of 270 cases. Today, the number stands at 4,115.

An overwhelming majority, 76%, of the hospitalizations and deaths from breakthrough cases occurred in people over the age of 65.

"We do not have the years and years of data we have for vaccines against other airborne pathogens -- and therefore it is really essential that the CDC provides up to date reporting on breakthrough cases," David Edwards, aerosol scientist and Harvard University professor, told CNBC.

The CDC says its numbers are "likely an undercount" of all Covid infections in vaccinated people because the data relies on passive and voluntary reporting.

-- CNBC's Berkeley Lovelace Jr. contributed to this report.

Reuters
Friday, June 25, 2021

U.S. FDA adds warning about rare heart inflammation to Pfizer, Moderna COVID vaccines

(Reuters) - The U.S. drug regulator on Friday added a warning to the literature that accompanies Pfizer Inc/BioNTech and Moderna vaccine shots to indicate the rare risk of heart inflammation after its use.

For each vaccine, the fact sheets have been revised to include a warning about myocarditis and pericarditis, FDA said.

The latest update follows an extensive review of information and the discussion by CDC's Advisory Committee on Immunization Practices meeting on Wednesday.

(Reporting by Maria Ponnezhath in Bengaluru; Editing by Chris Reese)

Reuters
Friday, June 25, 2021

Vaccine-associated myocarditis tends to resolve quickly

By Nancy Lapid

Cases of an inflammation of the heart muscle known as myocarditis have been reported after receiving COVID-19 shots, mostly in young men after the second dose of the mRNA vaccines. When myocarditis symptoms, such as chest pain and rapid or irregular heartbeats, do occur after vaccination, they usually resolve quickly, suggests a report of a small study published in the journal Circulation. Doctors tracked seven male patients, ages 19 to 39, who were hospitalized for myocarditis-like illness not long after receiving a COVID-19 vaccine manufactured by either Pfizer and BioNTech, Moderna - the two mRNA vaccines - or Johnson & Johnson. All recovered and left the hospital after two to four days of treatment. Study co-author Dr. Christopher deFilippi of the Inova Heart and Vascular Institute in Fairfax, Virginia, noted that in his health system, which represents about 2 million patients, myocarditis after COVID-19 vaccination has been a "rare event" and "fortunately so far associated with a benign outcome." The U.S. Centers for Disease Control and Prevention this week said reports of the heart condition occurred at a rate of 12.6 cases per million people who received either the Pfizer/BioNTech or Moderna vaccines, a higher rate than would be expected in the general population. However, deFilippi's team advised that given the dangers of COVID-19, even for younger adults, "the risk-benefit decision for vaccination remains highly favorable." (https://bit.ly/35NyLRv)

WashingtonTimes.om
Friday, June 25, 2021

CDC reportedly probing Michigan teen's death after COVID-19 vaccination

By Shen Wu Tan - The Washington Times

Federal health officials are investigating the case of a Michigan teenager who died days after he received a COVID-19 vaccine, Fox News reported Friday.

The 13-year-old boy died three days after getting a second dose of a COVID-19 vaccine, the Saginaw County Health Department told the news

agency in a statement. The department learned of the teenager's death on June 17.

"The investigation as to whether there is a correlation between his death and vaccination is now at the federal level with [the Centers for Disease Control and Prevention," the health department said. "Meanwhile, the health department continues to encourage families to speak with their physicians to weigh their own risks and benefits of vaccination."

It is unknown whether the teenage boy had previous health problems. The news report did not specify whether the teenager received the two-dose Pfizer-BioNTech COVID-19 vaccine or the Moderna vaccine. The death has been supposedly reported to the Vaccine Adverse Event Reporting System (VAERS), a national surveillance system.

Neither the CDC nor the Saginaw County Health Department immediately responded to requests for comment.

CDC officials say deaths following COVID-19 vaccinations have been rare. More than 318 million COVID-19 doses were administered in the U.S. from Dec. 14 through June 21, and about 5,400 deaths, or 0.0017%, among those vaccinated were reported to VAERS during that time.

"Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. A review of available clinical information, including death certificates, autopsy and medical records, has not established a causal link to COVID-19 vaccines," the CDC says on its website.

However, there could be a "plausible causal relationship" between the one-shot Johnson & Johnson COVID-19 vaccine and a rare, serious blood clotting condition, which has caused deaths.

Health care providers are required by the Food and Drug Administration to report any death after a COVID-19 vaccination to VAERS.

TheHill.com
Sunday, June 27, 2021

Bipartisan senators ask CDC, TSA when they will update mask guidance for travelers

By Olafimihan Oshin

A bipartisan group of senators has asked the Centers for Disease Control and Prevention (CDC) and Transportation Security Administration (TSA) when they will update their mask guidance for travelers.

In a letter, Sens. Brian Schatz (D-Hawaii), Roger Wicker (R-Miss.), Amy Klobuchar (D-Minn.), Susan Collins (R-Maine), and Jerry Moran (R-Kan.) requested information about the agency's process for updating the mask guidelines for vaccinated people, adding that they want answers by July 12.

"As there has not yet been any change in the requirement for masks while traveling, we request an update on the CDC's and TSA's process for updating the mask requirement for fully vaccinated individuals and what the science is showing about the transmission of COVID-19 for fully vaccinated individuals while traveling," the senators said in their letter.

The letter asked five questions including whether removing mask mandates for fully vaccinated people would encourage others to get vaccinated and whether lifting mask mandates for fully vaccinated people would create administrative challenges.

The senators noted they understand social distancing can be difficult on public transportation conveyances and public transportation hubs.

"If the requirement for wearing masks while traveling can be safely lifted and would serve the public health interest, then we believe it would benefit the traveling public. We appreciate your prompt attention to this matter and hard work in responding to the COVID-19 pandemic," the letter said.

The letter comes days after Democratic lawmakers on Wednesday shot down a bill from Republican Sens. Rick Scott (Fla.) and Mike Lee (Utah) that would have revoked the Biden administration's mask requirement on public transportation.

The Hill has reached out to the CDC and the TSA for comment.

Reuters
Friday, June 25, 2021

U.S. Senate Republicans press CDC to end mask mandate on airplanes, transit

By David Shepardson

June 25 (Reuters) - A group of Senate Republicans urged the Centers for Disease Control and Prevention (CDC) on Friday to stop requiring fully vaccinated Americans to wear masks on public transportation, including airplanes, trains and buses but also in airports and train stations.

Roger Wicker, the most senior Republican on the Senate Commerce Committee, and Ted Cruz, top Republican on an aviation subcommittee, along with Susan Collins, Jerry Moran, Cynthia Lummis and Marsha Blackburn introduced a resolution urging the CDC to lift mask requirements in place since Feb. 1.

"Over 150 million people in the United States are fully vaccinated and mask mandates have been lifted across the country. But the CDC inexplicably still hasn't lifted the mask mandate for public transportation," Cruz said. "It's long past time for President Biden and the CDC to follow the science."

The lawmakers argued the change "would incentivize a greater number of

individuals to receive the COVID-19 vaccine."

A CDC spokeswoman declined to comment.

In May, the CDC said fully vaccinated Americans could stop wearing masks in nearly all indoor spaces - with transportation one of the few exceptions.

The Transportation Security Administration on April 30 extended orders to enforce face mask requirements through Sept. 13.

Sara Nelson, international president of the Association of Flight Attendants-CWA, representing nearly 50,000 Flight Attendants at 17 airlines, said the union supported the mandate to help stop the spread of the virus and protect those who don't have access to the vaccine, such as children under 12.

Since January, the Federal Aviation Administration has received 3,100 reports of unruly behavior on airlines, including 2,350 reports of passengers refusing to comply with federal face mask requirements.

On June 10, the CDC said it would no longer require travelers to wear masks in outdoor transit hubs and in outdoor spaces on ferries, buses and trolleys but left indoor requirements unchanged.

(Reporting by David Shepardson Editing by Sonya Hepinstall)

BusinessInsider.com
Saturday, June 26, 2021

Ted Cruz joins forces with other GOP lawmakers to call for an end to mask mandates for vaccinated travelers, ahead of Independence Day

Kevin Shalvey

A group of Republican senators led by Ted Cruz on Friday announced a bill seeking an end to federal mask mandates for vaccinated travelers on planes, trains, and other public transport.

Mask requirements from the Centers for Disease Control & Prevention (CDC) and Transportation Security Administration (TSA) have outlasted their purpose, the lawmakers said.

The CDC in February recommended that travellers stayed home until they were fully vaccinated, but still required everyone to wear a mask while on public transport. The same was true for the TSA, which extended its requirement until September. Airlines have their own requirements, too.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," Sen. Ted Cruz said in a statement accompanying the bill.

In addition to Cruz, the GOP effort involved Susan Collins, Jerry

Moran, Roger Wicker, Cynthia Lummis, and Marsha Blackburn. It came as states across the country continued loosening restrictions on daily life.

TSA mask mandates have led to altercations in airports and on flights, where cabin crews have had to deal with unruly passengers. Flight attendants have described "unprecedented" violence. The TSA in July will restart its self-defense training for flight crews.

A frequent flier last week sued seven airlines, saying vaccinated travelers should be able to fly without masks.

The resolution, introduced in the Senate on Thursday, said the CDC could incentivize more people to get vaccines by dropping the mask requirement.

The three-page text said that getting rid of the mask mandate "would be instrumental in helping the economic recovery of the United States by boosting travel and benefitting the travel and tourism industries without sacrificing public health."

In late May, the transportation secretary, Pete Buttigieg, said the mask requirement on public transit was a "matter of safety, but it's also a matter of respect" for flight crews.

The World Health Organization in a Friday press briefing said vaccines alone won't end the pandemic. The organization urged fully vaccinated people to continue wearing masks.

Collins in a statement said she'd spoken with flight attendants about the mandate. The senator said she'd heard about "horrendous and unthinkable violence" on recent flights.

If vaccinated people on the ground no longer need masks indoors, then fliers don't need them either, Collins said.

"It makes no sense that someone can go to a restaurant without wearing a mask, but they cannot fly on an airplane without one, even though it has a far better ventilation system," she said.

TheHill.com
Saturday, June 26, 2021

Senate Republicans urge CDC to lift public transportation mask mandate

By Celine Castronuovo

A group of GOP lawmakers led by Sen. Ted Cruz (R-Texas) on Friday introduced a resolution formally calling on the Centers for Disease Control and Prevention (CDC) to lift its mask mandate for fully vaccinated individuals on public transportation.

Cruz, along with Republican Sens. Susan Collins (Maine), Jerry Moran (Kan.), Roger Wicker (Miss.), Cynthia Lummis (Wyo.) and Marsha

Blackburn (Tenn.), argued that the CDC's guidance that fully vaccinated individuals do not have to wear masks in most settings should also apply when traveling on commercial planes, buses, trains and other forms of public transit.

President Biden on his first full day in office signed an executive order directing federal agencies to "immediately take action" to require masks on public transportation.

While the federal mask mandate was initially set to expire May 11, the Transportation Security Administration (TSA) has since extended it to Sept. 13.

However, Cruz and his colleagues said in their resolution Friday that "science shows that individuals fully vaccinated against COVID-19 are protected against asymptomatic infection, and thus very unlikely to spread the disease," adding that Americans "have sacrificed immensely" throughout the coronavirus pandemic.

In a press release announcing the resolution, Cruz said, "It's long past time for President Biden and the CDC to follow the science and end this mask mandate for fully vaccinated individuals.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," he added.

Collins in a statement included in the release said she had spoken with flight attendants who had expressed fears on enforcing the federal mask mandate amid multiple viral incidents showing passengers attacking or threatening workers over the safety restrictions.

"It makes no sense that someone can go to a restaurant without wearing a mask, but they cannot fly on an airplane without one even though it has a far better ventilation system," Collins argued.

The resolution comes just days after Democrats blocked a bill from Senate Republicans that would have revoked Biden's mask requirement on public transit.

GOP Sens. Rick Scott (Fla.) and Mike Lee (Utah), who had introduced the bill, cited the nation's vaccination rates in arguing against the need for a face mask requirement.

However, Sen. Patty Murray (D-Wash.), chair of the Senate Health, Education, Labor and Pensions Committee, said when blocking the bill, "This virus is still spreading, it is still mutating, it is still costing lives, and it is still leaving survivors with long-haul symptoms."

"We cannot pretend this pandemic is over," she added.

Newsweek.com
Saturday, June 26, 2021

Ted Cruz Urges Joe Biden to 'Follow the Science' and End Travel Mask Requirement

By Darragh Roche

Senator Ted Cruz (R-TX) has called on President Joe Biden to end the requirement for people who are fully vaccinated to wear face masks while traveling on trains, airplanes, buses and other vehicles.

Cruz is leading a group of Republican senators who are introducing a bill calling on the Centers for Disease Control and Prevention (CDC) to end the mask requirement for travelers.

The CDC issued updated guidance on COVID-19 mask-wearing in May, saying that fully vaccinated people could go without face coverings in most indoor and outdoor settings but masks continue to be required on forms of transportation.

Cruz issued a statement on Friday to accompany the lawmakers' resolution.

"Over 150 million people in the United States are fully vaccinated and mask mandates have been lifted across the country," Cruz said.

"But the CDC inexplicably still hasn't lifted the mask mandate for public transportation. It's long past time for President Biden and the CDC to follow the science and end this mask mandate for fully vaccinated individuals.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," Cruz said.

Biden had previously set July 4 as the deadline for the administration's goal of having at least 70 percent of Americans with one shot of the COVID vaccine but recently admitted it will not now meet that goal. However, around 65 percent of adults have been at least partially vaccinated, according to CNBC.

The CDC issued a sweeping mask mandate for public transport following Biden's executive order on the pandemic on January 21 - the day after he took the oath of office. That order came into effect on February 1.

Though CDC advice has been updated since the order on public transport was issued, the mask-wearing requirements for buses, airplanes, trains and other forms of transport remain in place.

Marty Cetron, director for CDC's Division of Global Migration and Quarantine, explained the rationale behind the decision in the 11-page written order on January 29.

"Requiring masks on our transportation systems will protect Americans and provide confidence that we can once again travel safely even during this pandemic," Cetron said.

The CDC updated its advice on June 10 to say that fully vaccinated people no longer needed to wear masks while outdoors at transportation hubs such as bus stations but that unvaccinated people should continue to do so.

Cruz, who is the ranking member of the Senate Subcommittee on Aviation Safety, Operations, and Innovation, called legal requirements for mask-wearing on airplanes "performative theater" on June 16.

Newsweek has asked the White House, Senator Ted Cruz and the CDC for comment.

AP Georgia
Saturday, June 26, 2021

Georgia State Looks To Boost Vaccine Rate Among Refugees

CLARKSTON, Ga. (AP) -- Researchers at Georgia State University will use a $500,000 grant to try to increase COVID-19 vaccination rates among refugees and other groups in the Atlanta area city of Clarkston -- one of the largest refugee resettlement communities in the U.S., the university announced.

The money from the U.S. Centers for Disease Control and Prevention will help train and deploy six outreach workers to address residents' concerns about coronavirus vaccines and encourage them to get jabbed. The workers will represent major refugee groups living in Clarkston, including the Burmese, Congolese, Afghan and Somali communities, as well as the African American community, the university said in a news release.

The school plans to use workers who are known and trusted in their respective communities and send them out within a month, Michael Eriksen, a public health professor at Georgia State who is leading the effort, said during a phone interview Wednesday. Thousands of refugees live in the Clarkston area.

"We're really pushing this as quickly and as hard as we can," Eriksen said, citing the need for urgency because of the ongoing pandemic.

Vaccination rates in Georgia and elsewhere in the South have lagged behind the rest of the country. In some Clarkston neighborhoods, the percentage of people fully vaccinated as of June was below 30, according to researchers at Georgia State. That was lower than the state's vaccination rate.

Eriksen said many refugees receive additional conspiracy theories and false information about vaccines from people in their home countries.

They may also be struggling to overcome traumatic events that brought them to the U.S. and face language and cultural barriers -- all of which can hamper vaccine uptake.

The outreach workers will also help local clinics and the DeKalb County

Board of Health schedule vaccine appointments, arrange transportation and follow up with residents to make sure they get a second dose. The goal is to increase vaccine rates in Clarkston by 50 percent by spring 2022.

The one-year grant was awarded to the Prevention Research Center located on the Clarkston campus of Perimeter College -- a two-year school in the Georgia State system.

Xinhua (China)
Saturday, June 26, 2021

U.S. average daily COVID-19 vaccination drops by over 50 pct: CDC

WASHINGTON, June 26 (Xinhua) -- The latest 7-day average number of administered vaccine doses per day decreased by 55.3 percent from the previous week, according to a weekly report of the U.S. Centers for Disease Control and Prevention (CDC).

As of June 24, the 7-day average number of administered vaccine doses reported to the CDC per day was 0.37 million, according to the report released on Friday.

About 45.8 percent of the U.S. population was fully vaccinated against COVID-19, and 53.9 percent of the population received at least one shot as of Saturday, CDC data showed.

Roughly 152.2 million people were fully vaccinated. But some states, such as Alabama, Arkansas, Louisiana, Mississippi, Tennessee and Wyoming, had low vaccination rates.

A new CDC study showed adults aged 18 to 24, as well as non-Hispanic Black adults and those with less education, no insurance, and lower household incomes, had the lowest reported vaccination coverage and intent to get vaccinated.

The White House confirmed earlier this week that the country would not hit U.S. President Joe Biden's goal of getting 70 percent of American adults to receive at least one COVID-19 vaccine shot by July 4, the Independence Day.

Reuters
Sunday, June 27, 2021

U.S. reaches 323 million doses of COVID-19 vaccine administered -CDC

(Reuters) - The United States has administered 323,327,328 doses of COVID-19 vaccines in the country as of Sunday morning, and distributed 381,282,720 doses, the U.S. Centers for Disease Control and Prevention (CDC) said.

Those figures are up from the 322,123,103 vaccine doses the CDC said

had gone into arms by June 26 out of 381,276,030 doses delivered.

The agency said 179,261,269 people had received at least one shot, while 153,028,665 in the United States are fully vaccinated as of Sunday.

The CDC tally includes two-dose vaccines from Moderna Inc and Pfizer/BioNTech, as well as Johnson & Johnson's one-shot vaccine as of 6 a.m. EDT (1000 GMT) on Sunday.

(Reporting by Maria Ponnezhath in Bengaluru; Editing by Matthew Lewis)

FoxNews.com
Monday, June 28, 2021

CDC reports 4,115 breakthrough COVID-19 cases involving hospitalizations or deaths

Cases reflect small percentage of 150 million people who are fully vaccinated

By Alexandria Hein | Fox News

The Centers for Disease Control and Prevention (CDC) has received reports of 4,115 patients with COVID-19 vaccine breakthrough cases who were hospitalized or died. Of those cases, 26% of hospitalizations were reported as asymptomatic or not related to COVID-19, and 19% of the 750 fatalities were reported as asymptomatic or not related to COVID-19.

The data, which includes information through June 21, is amid a backdrop of 150 million people who are fully vaccinated in the U.S. Nearly half of the breakthrough cases, or 49%, involve females, and 3,124, or 76%, occurred in patients ages 65 years and older.

Officials have long predicted vaccine breakthrough cases would be reported, as "no vaccines are 100% effective at preventing illness in vaccinated people." The agency has also warned there would be a "small percentage" of vaccinated people who get sick, require hospitalization or even die from COVID-19.

"The number of COVID-19 vaccine breakthrough infections reported to CDC likely are an undercount of all SARS-CoV-2 infections among fully vaccinated persons," the agency noted. "National surveillance relies on passive and voluntary reporting, and data might not be complete or representative. These surveillance data are a snapshot and help identify patterns and look for signals among vaccine breakthrough cases."

The agency noted that "no unexpected patterns" have been identified in the reported breakthrough infections. It also states that vaccines remain effective and everyone ages 12 and older who have not received it should get one as soon as possible.

CNN.com
Saturday, June 26, 2021

Some fully vaccinated people may still get sick if exposed to variants, CDC warns

By Madeline Holcombe and Jacqueline Howard, CNN

(CNN)The US Centers for Disease Control and Prevention told CNN Friday that the agency is tracking the Delta coronavirus variant, among others -- and warned that there is a small chance a fully vaccinated person could still get infected if they're exposed.

"Current data suggest that COVID-19 vaccines authorized for use in the United States offer protection against most variants currently spreading in the United States. However, some variants might cause illness in some people even after they are fully vaccinated," CDC spokesperson Jade Fulce told CNN in an email on Friday.

While Covid-19 vaccines are effective, Fulce said no vaccine is "100% effective at preventing illness."

And with millions of people getting vaccinated against the virus, some who are fully vaccinated "will still get sick if they are exposed," Fulce said.

"However, people with breakthrough infections may get less severely ill or have a shorter illness than they would have if they had not been vaccinated."

That's why experts are especially worried about people who have not yet gotten their Covid-19 shots.

More than 53% of the US population has received at least one Covid-19 vaccine dose and more than 45% is fully vaccinated, CDC data shows.

'Please get your second shot'

As officials urge more people to get their shots, the US surgeon general warns a big obstacle stands in their way: Misinformation.

"There is so much misinformation out there about the vaccine, coming through so many channels -- a lot of it being spread on social media," Dr. Vivek Murthy told CNN's Erin Burnett. "It's inducing a lot of fear among people."

"Two-thirds of those who are unvaccinated in polls say that they either believe the myths about Covid-19 or think that they might be true," he added.

Experts, including Dr. Anthony Fauci, have estimated that 70 to 85% of people in the US will need to become immune to the virus through vaccination or infection in order to control community spread. But after initial surges, vaccination rates have now slowed across the country.

And more than 1 in 10 people who have received one dose of the Pfizer/BioNTech or Moderna vaccine have missed their second dose, according to data shared with CNN by the CDC.

That statistic is especially concerning to experts because studies have shown that the vaccines are much more effective against the Delta variant after the two-dose series is completed.

"Please get your second shot," CDC Director Dr. Rochelle Walensky said in a Friday NPR interview. "What we do know is you get some protection from the first shot, but really that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this Delta variant and other variants as well.

"If you missed your second within the time window, get it whenever, get it now, but do get that second shot," Walensky added.

Officials worried about unvaccinated Americans

The Delta variant is believed to be more transmissible and cause more severe disease than other strains. Murthy said he is worried for those who are unvaccinated as the variant spreads.

In Los Angeles County, the impact is already clear. Nearly all of the Covid-19 cases, hospitalizations, and deaths in Los Angeles County are occurring among people who are unvaccinated, county health officials said Thursday.

Out of nearly 437,000 positive coronavirus cases reported in L.A. County since December 2020, 99.6% of those were among individuals who were unvaccinated, health officials said in a press release.

"The virus is still with us," Los Angeles County Public Health Director Barbara Ferrer said at a press conference. "Even now, we need to be careful to mask and maintain distance from people outside of our households, especially if they're not yet vaccinated."

Missouri hospitals stretched thin

Missouri is the state with the largest proportion of the Delta variant of Covid-19 infections, according to the CDC. And hospitals in the state are feeling the stress of managing Covid-19 patients on top of their regular intake, one hospital leader told CNN's Ana Cabrera on Thursday.

"Both hospitals here in town are stretched," said Erik Frederick, chief administrative officer at Mercy Hospital Springfield in Springfield, Missouri.

"We saw a very rapid escalation in our in-patient census starting June 1, we went from 26 to 90 in about three weeks. To go back to last year when our peak started, it took us six to seven weeks to escalate that quickly. Today to hit 97, it really took us almost two months to hit that level which we've done in under a month."

Frederick said a return of typical hospital patients is exacerbating

the issue.

"The difference between last year and this we have traditional business back we didn't have last year during the initial surge. The demand for beds is higher for both Covid and non-Covid patients. It's definitely a stretch."

Frederick said there is also a high amount of pressure on available labor.

"The staff are right back into the mix of it, and I don't think they were fully recovered from last year," he said.

Smell and taste come back, studies show

In a bit of good news, researchers reported Thursday that those who did not regain their sense of taste and smell when they cleared their Covid-19 infections should get them back after a year.

Studies confirm that many, if not most, Covid-19 patients say their sense of smell is affected -- a condition called anosmia or hyposmia.

Because smell and taste are closely linked, many people feel their ability to taste food normally is also affected when their sense of smell is disrupted.

An ongoing experiment of about 100 people who lost their sense of smell in early 2020 showed it can take months for it to come back, but it does. Some patients didn't realize or appreciate it, however, the international team of researchers reported in the Journal of the American Medical Association's JAMA Network Open.

"At eight months, objective olfactory assessment confirmed full recovery in 49 of 51 patients (96.1%)," they wrote. Two continued to have an abnormal sense of smell a year later -- one who couldn't smell much and another who had an abnormal smell sense.

"Our findings suggest that an additional 10% gain in recovery can be expected at 12 months, compared with studies with 6 months of follow-up that found only 85.9% of patients with recovery," they wrote.

CNN's Lauren Mascarenhas, Deidre McPhillips, Alexandra Meeks, Maggie Fox and Virginia Langmaid contributed to this report.

Reuters
Sunday, June 27, 2021

Booster may be needed for J&J shot as Delta variant spreads, some experts already taking them

By Michael Erman

NEW YORK (Reuters) -Infectious disease experts are weighing the need for booster shots of the Pfizer/BioNTech or Moderna mRNA-based vaccines

for Americans who received Johnson & Johnson's one-dose vaccine due to the increasing prevalence of the more contagious Delta coronavirus variant.

A few say they have already done so themselves, even without published data on whether combining two different vaccines is safe and effective or backing from U.S. health regulators. Canada and some European countries are already allowing people to get two different COVID-19 shots.

The debate centers on concerns over how protective the J&J shot is against the Delta variant first detected in India and now circulating widely in many countries. Delta, which has also been associated with more severe disease, could quickly become the dominant version of the virus in the United States, Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky has warned.

There is no substantial data showing how protective the J&J vaccine is against the new variant. However, UK studies show that two doses of either the Pfizer/BioNTech or AstraZeneca vaccines are significantly more protective against the variant than one.

Andy Slavitt, former senior pandemic advisor to U.S. President Joe Biden, raised the idea this week on his podcast. At least half a dozen prominent infectious disease experts said U.S. regulators need to address the issue in short order.

"There's no doubt that the people who receive the J&J vaccine are less protected against disease," than those who get two doses of the other shots, said Stanford professor Dr. Michael Lin. "From the principle of taking easy steps to prevent really bad outcomes, this is really a no brainer."

The CDC is not recommending boosters, and advisors to the agency said at a public meeting this week there is not yet significant evidence of declining protection from the vaccines.

Jason Gallagher, an infectious diseases expert at Temple University's School of Pharmacy, recently received a Pfizer dose at the Philadelphia vaccine clinic where he has been administering shots. He got the J&J vaccine in a clinical trial in November.

Gallagher said he was concerned about the UK data https://www.gov.uk/government/news/vaccines-highly-effective-against-b-1-617-2-variant-after-2-doses showing lower efficacy against the Delta variant for people who received one vaccine dose.

"While the situation has gotten so much better in the U.S., the Delta variant that's spreading ... and really quickly taking over in the U.S. looks a little more concerning in terms of the breakthrough infections with the single-dose vaccines," he said. "So I took the plunge."

Cases, hospitalizations and deaths have plummeted in the United States with 56% of the adult population fully vaccinated.

J&J said it is testing whether the immune response from its vaccine is

capable of neutralizing the Delta variant in a laboratory setting, but no data is available yet.

Both mRNA vaccines showed efficacy rates around 95% in large U.S. trials, while J&J's vaccine was 66% effective in preventing moderate-to-severe COVID-19 globally when more contagious variants were circulating.

Dr. Angela Rasmussen, a researcher at the University of Saskatchewan's Vaccine and Infectious Disease Organization, said on Twitter she had gotten a dose of Pfizer's vaccine this week after receiving J&J's in April.

Rasmussen, who declined to be interviewed, encouraged Americans who received the J&J vaccine to talk to their doctors about a possible second shot.

"If you live in a community with overall low vaccination, I'd suggest you strongly consider doing so," she tweeted.

Vaccine expert Dr. Peter Hotez from Baylor College of Medicine in a tweet said adding a second J&J dose or one of the mRNA vaccines might provide broader protection, "but we need data and CDC-FDA guidance."

The U.S. National Institute of Allergy and Infectious Diseases (NIAID) is running a trial to determine the need for boosting all currently authorized shots with another dose of Moderna's vaccine. NIAID scientist Dr. John Beigel told Reuters the agency hopes to have that data by September to help inform regulators' decisions on boosters.

As long as case counts remain low in the United States, J&J recipients should wait for more data, he said.

If Delta variant-driven infections and hospitalizations increase significantly, he said, "then decisions might need to be made with an absence of data. But right now, I do think it's appropriate that they wait."

(Reporting by Michael Erman; Editing by Caroline Humer and Bill Berkrot)

CNN.com
Saturday, June 26, 2021

'Please get your second shot,' top health official urges as Delta variant remains a pressing threat

By Aya Elamroussi, CNN

(CNN)America is in a far better place now than it was six months ago in its fight against the coronavirus pandemic, with overall cases and deaths down, according to the latest data.

It shows that vaccines are effective, experts say, although they have

some protection limitations when faced with more aggressive virus variants.

The Delta variant, which can spread more easily and cause even more severe disease than other strains, has been a major concern for health experts who are worried about those who remain unvaccinated.

That variant, first identified in India, has been found in 49 states and Washington, D.C., according to GISAID, an independent data sharing initiative, and the Hawaii Department of Health. South Dakota did not report cases of the variant as of Wednesday, a state health department spokesperson told CNN.

To be sure, the US Centers for Disease Control and Prevention has said there's a low chance people who are fully vaccinated may get infected with virus variants.

And any illness could be shorter or milder if one is fully vaccinated--but the keyword is "fully" because a second shot is essential for optimal protection against variants.

"Please get your second shot," CDC Director Dr. Rochelle Walensky said Friday in an interview with the National Public Radio.

"What we do know is you get some protection from the first shot, but really that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this Delta variant and other variants as well."

More than one in 10 people in the US who received one dose of the Pfizer/BioNTech or Moderna vaccine have missed their second dose, according to CDC data.

"If you missed your second within the time window, get it whenever, get it now, but do get that second shot," Walensky added.

In Los Angeles County, 99.8% of the 12,234 people who died from Covid-19 since December 2020 were unvaccinated, local health data shows.

"The virus is still with us," Los Angeles County Public Health Director Barbara Ferrer said at a news conference Thursday. "Even now, we need to be careful to mask and maintain distance from people outside of our households, especially if they're not yet vaccinated."

President Joe Biden took note of the variant's dangerousness in remarks Thursday, warning that the variant is "now the most common variant in America."

"And unvaccinated people are incredibly vulnerable," he said, underscoring that the Delta variant is "more easily transmittable," and "potentially deadlier and especially dangerous to young people."

In the US overall, the Delta variant has accounted for about 21% of cases in the two weeks ending June 19, according to CDC data.

More than 151.6 million Americans are fully vaccinated, according to CDC data on Friday, which is nearly 45.7% of the total US population.

Nearly 65.8% of adults in America have had at least one dose of a vaccine as of Friday, according to the CDC. Biden's goal of 70% of adults with at least one dose by July 4 is all but likely to fall short, as officials are currently targeting mid-July.

Distribution of some antibody treatments are paused due to variants

It's not only the Delta variant that is complicating matters for health care providers.

The increase of cases due to the Gamma or P.1 variant first identified in Brazil, and the Beta or B.1.351 variant first identified in South Africa, are being cited as the reason for a pause in nationwide distribution of certain monoclonal antibody treatments from Eli Lilly, according to an announcement on Friday from the US Health and Human Services Department (HHS).

The monoclonal antibody treatment of etesevimab, as well as a combination treatment of etesevimab and bamlanivimab, don't work as well with the variants, according to the HHS statement.

In May, federal regulators had paused the distribution of these treatments to eight states where there were a high number of variant cases. Eli Lilly's single monoclonal antibody treatment bamlanivimab was put on pause in March. In April, the company had asked the FDA to revoke its emergency use authorization of the single antibody treatment, so it could focus on its combination treatment.

The Beta and Gamma variants now make up at least 11% of the cases in the US, and case numbers are increasing, according to CDC data.

Rare heart risk warning is added to 2 vaccine fact sheets

Meanwhile, the US Food and Drug Administration added a warning about the risk of the heart inflamations known as myocarditis and pericarditis to fact sheets for Moderna and Pfizer-BioNTech Covid-19 vaccines Friday.

The warning notes that reports of adverse events following vaccination suggest increased risks of both types of inflammation, particularly after the second dose.

Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of tissue surrounding the heart.

Vaccine advisers to the CDC met Wednesday and said there is a likely association between the mRNA Covid-19 vaccines and rare cases of heart inflammation in adolescents and young adults.

However, the risk is rare: Following about 300 million administered doses of Pfizer and Moderna vaccines through June 11, the CDC has received roughly 1,200 preliminary reports of myocarditis and pericarditis.

Advisers urged that the benefits of vaccination outweigh the risks, and almost all the cases resolved with little treatment and patients recovered quickly.

The FDA is advising those who receive one of the two vaccines to seek immediate medical attention if they experience "chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after vaccination."

Both the FDA and CDC are monitoring reports of these adverse events and will follow up to assess longer-term outcomes, the FDA noted.

CNN's Lauren Mascarenhas, Jen Christensen, Jacqueline Howard, Deidre McPhillips, Jamie Gumbrecht and Travis Caldwell contributed to this report.

Associated Press
Saturday, June 26, 2021

States Hesitant To Adopt Digital Covid Vaccine Verification

By DAVID A. LIEB
Associated Press

Customers wanting to wine, dine and unwind to live music at the City Winery's flagship restaurant in New York must show proof of a COVID-19 vaccination to get in. But that's not required at most other dining establishments in the city. And it's not necessary at other City Winery sites around the U.S.

If City Winery tried doing such a thing at its places in Atlanta and Nashville, "we would have no business, because so many people are basically against it," said CEO Michael Dorf.

Across the U.S., many hard-hit businesses eager to return to normal have been reluctant to demand proof of vaccination from customers. And the public and the politicians in many places have made it clear they don't care for the idea.

In fact, far more states have banned proof-of-vaccination policies than have created smartphone-based programs for people to digitally display their vaccination status.

The Centers for Disease Control and Prevention still recommends masks when dining or gathering indoors for those who aren't fully vaccinated. But few states require it, and most businesses rely on voluntary compliance -- even in places with low vaccination rates where COVID-19 cases are climbing.

Digital vaccine verification programs could make it easier to enforce safeguards and tamp down new outbreaks.

"But that only works when you have mass adoption, and mass adoption

requires trust and actual buy-in with what the state health department is doing, which is not necessarily present in all states," said Alan Butler, executive director of the Electronic Privacy Information Center, a Washington-based nonprofit organization.

Hawaii is the only state enforcing some version of a vaccine passport. It requires travelers to upload a photo or PDF of their Hawaii vaccination document or pass a pre-arrival COVID-19 test to avoid having to quarantine for 10 days.

Earlier this month, California became just the third state -- behind New York and Louisiana -- to offer residents a way to voluntarily display digital proof of their COVID-19 shots. None of those states requires the use of their digital verification systems to access either public or private-sector places.

By contrast, at least 18 states led by Republican governors or legislatures prohibit the creation of so-called vaccine passports or ban public entities from requiring proof of vaccination. Several of those -- including Alabama, Florida, Iowa, Montana, North Dakota and Texas -- also bar most businesses from denying service to those who aren't vaccinated.

"Texas is open 100%, and we want to make sure that you have the freedom to go where you want without limits," Gov. Greg Abbott said in signing a law against vaccine passports.

The prohibition doesn't apply to the demands employers make on their employees. Earlier this month, a federal judge in Texas threw out a lawsuit from 117 Houston hospital employees who challenged a workplace requirement that they get vaccinated. More than 150 were later fired or resigned for not getting their shots.

In Louisiana, under a Republican-passed bill facing a potential veto from Democratic Gov. John Bel Edwards, public facilities would not be allowed to bar unvaccinated people until the COVID-19 vaccines have received full approval from the Food and Drug Administration. The vaccines for now are being dispensed under emergency FDA authorization.

In May, Louisiana launched a program allowing residents using the state's digital driver's license, LA Wallet, to add a record of their COVID-19 vaccination.

But its reach is still limited. About 105,000 people have activated the COVID-19 verification function. That's about 14% of those with a digital license and less than 4% of Louisiana's 3.1 million people with valid driver's licenses.

Democratic state Rep. Ted James, who wrote the bill creating the digital driver's license, said he has used the feature just once -- to show an Uber driver in Nevada that he didn't need to wear a mask. But James said he has never been asked to show it in Louisiana and doubts he ever will.

"Earlier in the year, I felt that at some point we would be limited in travel, going to certain places, unless we had the vaccine," James

said. Now, "I don't foresee us ever having some type of requirement."

As a step in reopening, New York in March launched its Excelsior Pass, the first state system to provide digital proof of COVID-19 vaccination or a recent negative test. As of early June, more than 2 million people had gotten the digital pass -- about one-fifth of those who have been vaccinated.

At the City Winery, most customers bypass the Excelsior Pass and instead show their paper CDC vaccination cards to gain entry, according to Dorf, who said patrons at the 1,000-person capacity venue "appreciate going into a bubble of safety, knowing that everyone around them is vaccinated."

Though larger ticketed events, like concerts at Madison Square Garden, require proof of vaccination, most businesses don't ask.

"Think of a bar," said Andrew Rigie, executive director of the New York City Hospitality Alliance. "You have four friends that go in -- maybe two of them have it, the other two don't. You're going to turn the other two away when small businesses are struggling so much?"

Though most states have shied away from creating digital vaccination verification systems, the technology may soon become widespread nonetheless.

Vaccine providers such as Walmart and major health care systems already have agreed to make digital COVID-19 vaccination records available to customers. Apple also plans to incorporate the vaccination verification function into a software update coming this fall.

Within months, hundreds of millions of people across the U.S. will be able to access digital copies of their COVID-19 vaccination records, said Brian Anderson, chief digital health physician at the nonprofit MITRE Corp., part of a coalition of health and technology organizations that developed such technology.

People will receive QR codes that can be stored on smartphones or printed on paper to be scanned by anyone seeking vaccine verification. Those who scan the codes won't retain any of the information -- a protection intended to address privacy concerns.

The California Chamber of Commerce said it welcomes the state's new vaccine verification system as a way for employers to check on their employees. California regulations require most employees who aren't fully vaccinated to wear masks when dealing with others indoors.

Digital vaccine verification "allows an employer who really wants to make sure the workplace is vaccinated to require that without having the impossible problem of `John says he's vaccinated but he lost his vaccine card. What do we do?' This solves that issue," said Rob Moutrie, a policy advocate at the California Chamber of Commerce.

Friday, June 25, 2021

`A tough slog': White House struggles to increase vaccination rates as Delta variant surges

By ERIN BANCO and DAVID LIM

Top Biden administration health officials trying to slow the spread of the Covid-19 Delta variant have largely given up on the possibility of reinstating mask and social-distancing rules in favor of a grassroots vaccine education campaign.

The Centers for Disease Control and Prevention, the Department of Health and Human Services and the White House Covid-19 Task Force have discussed whether to press mayors and governors in the Midwest and South, where the highly transmissible Delta variant is spreading quickly, to once again require mask mandates, according to three senior Biden health officials. But the administration ultimately concluded that many people who are not vaccinated are also those who have resisted wearing masks.

Instead, the federal government will try to convince hesitant Americans to get vaccinated by working with state officials and trusted community members to communicate the benefits of the shots, the three senior officials said. The president's team is not confident that the new campaign will change hearts and minds, the two officials said, but it is falling back on old messaging in part because top administration officials are unsure what other tactics will work.

Only about 46 percent of the U.S. population is vaccinated, and the number of doses administered has fallen by almost 300,000 per day since June 7, according to the Centers for Disease Control and Prevention.

The plateauing vaccination rate underscores the extent to which the White House is struggling to find new and better ways to convince Americans to get Covid-19 shots -- while much of the rest of the world struggles to secure a steady supply of vaccines. And it raises questions about how the federal government will manage increasing Covid-19 cases associated with the Delta variant in the months ahead, with businesses and schools returning to normal operations.

"This is the door-to-door campaign, this is the church-to-church, this is going into the community and meeting people where they are. We're not going to convince everybody," said Scott Becker, CEO of the Association of Public Health Laboratories. "The Delta variant and its explosive growth -- I wish there was a better way to articulate the damage that it is doing and will do in those communities, but it is going to be a tough slog."

New Covid-19 infections have increased by more than 50 percent over the last two weeks in under-vaccinated states such as Missouri and Oklahoma. Many of the cases are tied to the Delta variant, which the CDC says now accounts for one-fifth of new infections nationwide.

"Based on the data that we have right now, the Delta variant is more transmissible than Alpha," the strain that has predominated in the U.S.

this spring, said Summer Galloway, a senior adviser at the agency.

Preliminary data from the U.K. suggests that unvaccinated people infected with the Delta variant have an increased risk of hospitalization, she added. The CDC is studying whether the variant leads to more severe infections in undervaccinated communities. But there is good news: recent data shows the Pfizer vaccine is nearly 90 percent effective against Delta, making vaccination one of the most effective ways to stop the variant's march across the U.S.

"We really just want to encourage everyone ... to get vaccinated. What we don't want to have happen is we have a significant proportion of the population that's unvaccinated and you see an increase in the number of cases and the number of hospitalizations, the number of deaths," Galloway said. "It could lead to another surge."

In the meantime, the CDC is still encouraging people who are unvaccinated to wear masks and avoid crowded indoor gatherings, an agency spokesperson said.

The number of U.S. adults who say they will definitely not take a Covid-19 vaccine has remained steady at 13 percent, according to a Kaiser Family Foundation survey released last month. Twelve percent say they are waiting to decide if they will get vaccinated, while 7 percent say they will only opt for immunization if it is required for work or other activities.

The Biden administration in March rolled out a $1 billion advertising campaign, relying on radio and television spots to educate Americans on the benefits of vaccination and on where and when they could receive the shot. The administration partnered with 275 groups, including the Christian Broadcasting Network and Nascar, to reach areas where hesitancy or outright opposition to the vaccines is high.

The federal government has also joined up with the Ad Council -- a nonprofit organization that often partners with the federal government on public service announcements -- and the Covid Collaborative, a group of organizations working together to combat the virus, on ads promoting Covid-19 vaccines. The CDC Vaccine Task Force is also offering "vaccine confidence consultations" to interested jurisdictions. The consultations include briefings between CDC officials and local leaders about how states can build trust in their communities around vaccination.

The three senior Biden health officials said the administration is pushing more of the responsibility of convincing the unvaccinated to get the jab to local officials, who can tap trusted community leaders to spread the word. The hope is that those local leaders will be more effective messengers than national ad campaigns or top federal officials.

Over the last two weeks, officials from the CDC, HHS and the White House Covid-19 Task Force have formulated a plan to work with local officials, including mayors, to knock on doors in areas with low vaccination rates to talk with people about signing up for the shot. Officials like President Joe Biden's chief medical adviser, Anthony

Fauci, and CDC Director Rochelle Walensky also are increasing their appearances on national TV programs and with local press in the South where the Delta variant is spreading.

Fauci, for instance, has visited vaccine sites in New York and Florida this month with First Lady Jill Biden. He spent the Juneteenth holiday going door-to-door with Washington, D.C., Mayor Muriel Bowser, urging city residents to get vaccinated.

But the Biden team is still unsure how many people could be swayed by these more local appeals. The White House is now planning for what top officials see as inevitable Covid-19 surges in several states with low vaccination rates later this summer and into the fall.

Many states have already tried on their own to encourage people to get Covid-19 shots -- often through lotteries and other financial incentives. But that strategy has largely failed, and Delta Covid-19 cases continue to rise.

The CDC is now considering whether to update guidelines for schools and for domestic and international travel. Federal and state health officials are debating how and whether to recommend proof of vaccination for everything from restaurants to movie theaters to office buildings. The fear, Fauci recently told POLITICO, is that recommending proof of vaccination could cause an uproar among unvaccinated people. While federal health officials have pledged so-called vaccine passports will not be implemented at the national level, some states and private businesses have explored using vaccine passes to support safe reopening.

European Union officials have recently put pressure on U.S. diplomats overseas to open up travel to the U.S. with proof of vaccination, according to a U.S. official with direct knowledge of the matter. Germany recently issued an order that allows all U.S. residents to fly into the country if they can prove vaccination or a negative Covid-19 test.

For now, Biden administration officials say the increasing number of Delta cases is cause for worry but not overwhelming dread. The Pfizer vaccine in wide use in the U.S. works well against the variant; Moderna's vaccine uses similar technology, so the hope is that it will be similarly effective in warding off Delta. The CDC is currently in the midst of conducting studies to pin down just how well the current vaccines protect against Delta and what impact it has on the unvaccinated population, particularly children.

"We have to stay vigilant. We see this strain is affecting how much protection people get from the first dose dramatically," said Phil Febbo, chief medical officer of DNA sequencing company Illumina, which is working with the CDC to study the spread of Covid-19 variants in the U.S. "I don't think we're that far away from a different variant that goes beyond the Delta and decreases significantly the efficacy of both doses."

AP Wisconsin
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Wisconsin's Johnson To Tout Claims Of Vaccine Side Effects

By SCOTT BAUER
Associated Press

MADISON, Wis. (AP) -- Republican U.S. Sen. Ron Johnson, a vocal critic of COVID-19 vaccine mandates, announced plans Friday to hold a news conference bringing together people who claim to have had adverse reactions to the vaccine, including the wife of a former Green Bay Packer player.

Johnson, who has also advocated for alternative and unproven treatments for COVID-19, said the Monday event in Milwaukee will allow people from across the country to tell their stories and concerns he said have been "repeatedly ignored" by the medical community.

Johnson, who has no medical training or expertise, hasn't been vaccinated, saying he doesn't think he has to because he had the virus last year and formed natural antibodies. He has said he's "just asking questions" and isn't against vaccines, but doctors and other critics have blasted him for spreading misinformation.

Dr. Jeff Huebner, a family doctor in Madison, said Johnson was "promoting dangerous and unfounded claims about COVID-19 vaccines" that contradict medical data and evidence.

"As a member of the Wisconsin medical community I'm gravely concerned about the impact his event and remarks will have on our ability to return to normal and protect Wisconsinites from COVID-19.," Huebner said in a statement.

Nearly all COVID-19 deaths in the U.S. now are in people who weren't vaccinated, with "breakthrough" infections in fully vaccinated people accounting for fewer than 1,200 of the more than 853,000 COVID-19 hospitalizations in May, based on an Associated Press analysis.

YouTube this month removed an interview Johnson did with the Milwaukee Press Club during which he touted the benefits of alternative treatments for COVID-19 and suspended Johnson for a week, saying his comments violated the company's "medical misinformation policies."

Johnson, during the June 3 event, criticized the administrations of President Joe Biden and former President Donald Trump for "not only ignoring but working against robust research (on) the use of cheap, generic drugs to be repurposed for early treatment of COVID."

Johnson said Monday's event at the federal courthouse in Milwaukee will include former Green Bay Packers offensive lineman Ken Ruettgers, a member of the Packers Hall of Fame, and his wife Sheryl. Johnson said Sheryl Ruettgers will detail "severe neurological reactions that still inhibit her ability to live a normal life, including muscle pain, numbness, weakness and paresthesia" that she experienced after getting the COVID-19 vaccine this month.

Other speakers with similar stories are from Ohio, Missouri, Utah, Michigan and Tennessee.

The medical community has been consistent in stressing that the risk of side effects is exceedingly low and the benefits of getting vaccinated for the virus far outweigh the risks. Earlier this week, top U.S. government health officials, medical organizations, laboratory and hospital associations and others issued a statement touting the overriding benefit of the vaccines.

Still, certain elected officials in some states continue to push back against the vaccination recommendations.

On the same day the government and medical experts issued their statement on the vaccines' benefits, Republican attorneys general in Louisiana, Alabama and Montana wrote to a Centers for Disease Control and Prevention COVID-19 task force leader requesting a pause in recommending that children and healthy young adults get vaccinated against the disease.

The letter accused the CDC of providing "dismissive, misleading, and deadly advice" regarding incidents of heart inflammation among young people who get the vaccines.

U.S. health officials paused the Johnson & Johnson's single-dose shot for 11 days earlier this year, after 15 vaccine recipients developed a highly unusual kind of blood clot out of nearly 8 million people given the J&J shot. Experts said Wednesday that there also seems to be a link between the Pfizer and Moderna shots and some cases of heart inflammation.

Johnson's seat is up for election in 2022 and he has not yet said whether he will seek a third term.

Associated Press writer Kevin McGill in New Orleans contributed to this report.

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Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic, research finds

By Lauren Mascarenhas, CNN

(CNN)Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic at one Louisiana hospital, according to research presented Friday. The researchers say the cases increased in severity, too.

Dr. Daniel Hsia, an associate professor at Pennington Biomedical

Research Center in Baton Rouge, Louisiana, and colleagues looked at the hospitalization rate for new onset type 2 diabetes among children at Our Lady of the Lake Children's Hospital.

From March to December 2019, the rate was .27% -- 8 cases out of 2,964 hospitalizations. During the same period in 2020, the rate jumped to .62% --17 cases out of 2,729 hospitalizations.

"These are very small numbers," Hsia told CNN. "We're a single hospital, but we think that we may be a microcosm of what's happening across the country."

Type 2 diabetes is by far the most common type of diabetes, and it's associated with obesity, poor diet and a lack of exercise.

Among the 25 cases of type 2 diabetes over both years, 23 were in Black children, the team noted. Black, Latinx, Asian, Native American, Alaska Native and Pacific Islander children may be at increased risk for type 2 diabetes, according to the US Centers for Disease Control and Prevention. Hsia said these existing health disparities may have worsened over the course of the pandemic.

"Risk factors for type two diabetes may worsen even more during a time like this, where they have to stay home, and they don't have access to healthy foods and physical activity, and there are sleep disturbances," Hsia said.

Children who were admitted for type 2 diabetes in 2020 had more severe symptoms than children admitted in 2019, the team said. They had higher blood sugar levels and signs of more severe dehydration -- caused when the body tries to get rid of excess glucose through urination.

Dr. Lily Chao, interim medical diabetes director at Children's Hospital Los Angeles, said she's seen the same trend in her hospital, particularly in cases of ketoacidosis, a severe complication of diabetes that occurs when the body does not have enough insulin.

"Historically, in people with type 2 diabetes, the rates vary from 5 to 10% in our hospital," said Chao. "In this past year, our rates went up to 20% of new type 2 diabetes cases presenting in that severe state." Chao noted that her hospital serves a primarily Latinx population.

"There are reports of new-onset diabetes that occur after someone's been infected with the SARS-CoV-2 virus," said Chao. "We know the Covid pandemic disproportionally affected people of color. What we don't know is how many of these cases are related to prior exposure to the virus."

A new lifestyle

Andrew Aparicio, a 17-year-old patient of Chao's, said it was about a year ago when he started experiencing stomach cramps and fatigue. At first, he thought it could be coronavirus.

"I wasn't eating. I would be sleeping most of the day and not doing anything," Aparicio said.

His father took him to the hospital, where he stayed for a week and was diagnosed with type 2 diabetes. Aparicio said the news came as a shock.

"I left the hospital pretty traumatized," Aparicio said. "What happened to me really scared me."

Aparicio said he weighed around 257 pounds at the time, "Being stuck at home all day, I would just eat. Covid kind of messed me up."

He started taking medication, scheduling workouts and eating healthier.

"Andrew's case is really inspirational," said Chao. "It is extremely difficult for many of our young people to really accomplish what he has in terms of motivation to stay as physically active as he has and to exercise that discipline."

A year later and about 120 pounds lighter, Aparicio is ready to take on his senior year of high school. He no longer needs the same level of medication to manage his diabetes and says that in a few months, he may be able to stop taking some medication completely -- a sign that he is doing much better.

"Overall, I'm both mentally and physically happy with the change I've been able to accomplish," he said. "I have a whole new lifestyle."

A growing problem

Children and teens almost never got type 2 diabetes until recently, according to the CDC, which now says the condition is a growing problem among pediatric patients.

"Getting diabetes at this age is very different than getting diabetes as an adult," said Chao. "The complications occur sooner. It is a much more progressive condition."

Hsia says additional research is needed to understand the factors driving the increase in cases, but the lifestyle changes associated with the pandemic -- including less physical activity and more screen time -- could drive weight gain in children.

"The little weight changes and small amounts of weight gain can certainly tip the scale and cause someone to develop type 2 diabetes," Hsia said.

Doctors say symptoms to look out for include increased fatigue, thirst, urination, and sudden, unexplained weight loss.

The CDC says having a family member with type 2 diabetes, being born to a mother with diabetes while pregnant, and having conditions related to insulin resistance can place children at increased risk. The agency advises that children who are overweight and have a combination of risk factors check with their doctor about getting their blood sugar tested.

Associated Press

Saturday, June 26, 2021

1st Post-Pandemic Cruise Ship From US Sails Away

By ADRIANA GOMEZ LICON and MARTA LAVANDIER
The Associated Press

FORT LAUDERDALE, Fla. (AP) -- The first cruise ship to leave a U.S. port since the coronavirus pandemic brought the industry to a 15-month standstill sailed away on Saturday with nearly all vaccinated passengers on board.

Celebrity Edge departed Fort Lauderdale, Florida, at 6 p.m. with the number of passengers limited to about 40% capacity, and with nearly all 1,100 passengers vaccinated against COVID-19. Celebrity Cruises, one of Royal Caribbean Cruise's brands, says 99% of the passengers are vaccinated, well over the 95% requirement imposed by the Centers for Disease Control and Prevention.

A giant greeting was projected on a wall of one of the port buildings: "Someday is here. Welcome back."

Passengers arrived with matching T-shirts that read phrases such as "straight outta vaccination" and "vaccinated and ready to cruise."

"Words can't describe how excited we are to be a part of this historic sailing today," said Elizabeth Rosner, 28, who moved from Michigan to Orlando, Florida, in December 2019 with her fiance just to be close to the cruise industry's hub.

To comply with both the CDC's requirement and a new Florida law banning businesses from requiring customers to show proof of vaccination, Celebrity Cruises asked guests if they would like to share their vaccination status. Those who did not show or say they are vaccinated face additional restrictions.

Saturday's sailing kicks off the cruise lines' return to business with Carnival vessels already scheduled to depart from other ports next month.

"This is an emotional day for me. When I stepped on board the ship, I was proud. It's a beautiful ship," said Royal Caribbean Cruises' CEO Richard Fain, after expressing condolences to the victims of the Surfside building collapse, less than 15 miles (about 24 kilometers) south of the port.

Celebrity Cruises had unveiled the $1 billion boat in December 2018 -- betting on luxury cruising, offering a giant spa and multifloor suites. The seven-night cruise will sail for three days in the Western Caribbean waters before making stops in Costa Maya, Cozumel and Nassau.

The ship is led by Capt. Kate McCue, the first American woman to captain a cruise ship, who has more than 1 million followers on TikTok.

"You can truly feel the palpable sense of excitement and energy amongst the group as we prepare for our welcoming of our first guests," McCue

said. "I've never honestly seen a group so excited to get back to work."

Industry officials are hoping all goes smooth to move past a chapter last year of deadly outbreaks on cruise ships that prompted ships to be rejected at ports and passengers to be forced into quarantine. Some passengers died of COVID-19 at sea while others fell so ill they had to be carried out of the vessels on stretchers.

The CDC extended no-sail orders repeatedly last year as the pandemic raged, and came up with strict requirements for the industry that have already been contested in court by the state of Florida. Florida Gov. Ron DeSantis says the industry generates billions for the state's economy.

On Saturday, officials at Port Everglades in Fort Lauderdale said only that port lost more than $30 million in revenue in fiscal year 2020 from the cruise shutdown.

During that hiatus, Carnival, Norwegian and Royal Caribbean, the three largest cruise companies, have had to raise more than $40 billion in financing just to stay afloat. Collectively they lost $20 billion last year and another $4.5 billion in the first quarter of 2021, according to Securities and Exchange Commission filings.

The pandemic forced Kurt and Carol Budde to cancel their beach celebration wedding aboard the world's largest ship, Symphony of the Seas, in March 2020. COVID-19 halted cruising six days before they were scheduled to tie the knot in St. Maarten. Kurt Budde's part-time gig as a travel agent also dried up.

"It's a honeymoon make-up cruise," said Kurt Budde, sporting matching shirts with the phrase "On Cruise Control."

"We are living our best lives post COVID today," he said.

CNN.com
Saturday, June 26, 2021

How the first cruise of the Covid era got ready to safely set sail

By Andrea Kane and Nadia Kounang, CNN

(CNN)It's anchors aweigh and full steam ahead for the Celebrity Edge. On Saturday, the cruise ship, owned by the Royal Caribbean Group, will become the first to sail from a U.S. port since the US Centers for Disease Control and Prevention brought the industry to a halt more than 15 months ago with a no-sail order that was ultimately extended a number of times. It is scheduled to sail from Fort Lauderdale on a seven-night trip that will take it around the Caribbean, with ports of call in Mexico and the Bahamas.

CNN Chief Medical Correspondent Dr. Sanjay Gupta got an exclusive early look at the procedures and safety features in place to make cruising in

the Covid era possible. The question is, will they be enough to keep passengers and crew coronavirus-free?

Smooth sailing or troubled waters?

For die-hard cruise fans, this event, after several false starts, has been a long time coming. For the more skeptical, the event is tempting fate to once again reveal that cruise ships are floating petri dishes for one infectious disease or another. It will be a long while before the world forgets the high-profile saga of the Diamond Princess, which saw more than 700 coronavirus infections on board, and others like it -- a situation made worse and more dramatic by nationwide lockdowns and travel bans that left some ships literally racing toward any welcoming port.

For cruising to be possible in the Covid era, leaders in the industry convened the Healthy Sail Panel -- which included experts in the public health, infectious diseases, biosecurity, maritime and hospitality industries -- to come up with recommendations to make the experience healthier and safer for guests and crew. These wide-ranging recommendations, developed before vaccines became available, dovetail with the Covid-19 Member Policy of the industry's largest trade group, Cruise Lines International Association, and with the requirements and guidelines for cruise ships set forth by the CDC, which has been -- up to now -- deciding the circumstances under which ships can sail from the United States.

Dr. Calvin Johnson, the chief medical officer for Celebrity, told CNN neither he nor the crew are apprehensive. "I think everyone really believes in -- because they were part of it -- the protocols that we've developed, the processes we put in place," he said.

"This has been over a year of consistent, methodical, science-based, operational examinations to look at the business, how it operates, and how we can do it safely. Putting in place protocols to protect our crew, and then looking at what it will look like when our guests come back to protect them -- and so it's been a process that brought us to this place," he said.

The industry battens down the hatches

So, what's the plan to make sailing safer? This summer at least, there will be fewer people on board; the Edge is sailing at 40% of its capacity. Because the coronavirus is spread through airborne particles, fewer people, less crowding and good ventilation can make a big difference.

"For this start-up period, we're sailing with a reduced capacity to give us all a chance to get used to the protocols and to really allow for natural social distancing," said Susan Lomax, head of global public relations at Celebrity Cruises. She said the cruise line does not plan to exceed 50% capacity on any of its trips this summer. Because of the reduced capacity, cabin occupancy will be spaced out and people will be put into cabins with windows that face outward. Crew members will get their own cabins.

Lomax said filtration experts from the University of Nebraska were asked to evaluate the ventilation/HVAC system and pronounced it "better than what hospitals have."

Linsey Marr, an environmental engineer and professor at Virginia Tech, agrees the Edge's ventilation system is more than adequate. "The combination of high air change rates and high-quality filters ... will greatly reduce the amount of virus that can build up in the air. Thus, it is unlikely that people will be exposed to elevated levels of virus in cabins and public indoor spaces," she told CNN. "If this is the case, then the biggest risk comes from being in close proximity, within the exhaled respiratory plume of an infected individual."

Yuguo Li, from the department of mechanical engineering at The University of Hong Kong, sides with Marr.

"Taking all evidence so far, I highly believe that SARS-CoV-2 is predominantly transmitted by the short-range inhalation route in inadequately ventilated spaces. We have studied about 20 outbreaks of SARS-CoV-2, and performed ventilation measurement for 10 of them, all supporting this hypothesis," Li wrote in an email. His study on the Diamond Princess was published online in April in the journal Building and Environment and his editorial appeared in the journal Indoor Air in mid-May.

"For the Diamond Princess outbreak, we showed that their cabin ventilation might be sufficient, and suspect that infections occurred in the public areas. There are two major factors in these public areas: First, in gyms and dancing floors, people perform high [energy] activities with more droplet release and higher inhalation flow, hence infection risks are high ... Second, if occupancy is not controlled in these public spaces, the ventilation per person can be even lower. In some spaces such as restaurants, people cannot wear masks," he explained.

On the Edge, other procedural changes include staggered arrival and departure times to prevent large crowds, and a muster drill -- the mandatory safety exercise done at the start of every trip -- done virtually instead of in person, again to avoid large crowds. And, food lovers need not fear: the all-you-can-eat buffets will still be a staple of the dining experience, but instead of self-serve, crew members will lend a hand.

In the unfortunate event of an outbreak, the Edge has the capacity to manage 33 patients, and there are four ICU beds. The entire medical area is on a separate ventilation system.

Contact tracing plans that make use of the ship's CCTV have been drawn up, there are protocols for isolation and quarantining, and disinfection procedures following positive cases.

Importantly, Royal Caribbean has agreements with a number of countries to act as disembarkation ports, should there be a need to get people off the ship.

"There's no longer any 'Oh my gosh, we're sailing for days and no one

will take us,' " said Lomax. "There's no reason to wait till the end of the cruise; we have the ability to go to those disembarkation ports if and as needed."

Vaccines are game changers

But everyone, from those in the cruise industry to health experts, says the real game changers are vaccines, which offer up to 95% protection against symptomatic Covid-19. Even if there are breakthrough infections, vaccines reduce the amount of virus in the body, making people less infectious to others.

"It's really the vaccines that have enabled us to return to cruising with a low enough level of risk of transmission," said Marr.

On the Edge, 100% of the crew and at least 95% of passengers are vaccinated, which considerably lowers the risk of people getting infected and sparking an outbreak.

However effective vaccines are, it's unclear whether, when and where they can be mandated on future cruises. The CDC currently advises unvaccinated people against going on a cruise -- but that's just guidance. Additionally, Florida is one of several states that has banned businesses from requiring customers to provide proof of vaccination, although upcoming cruises leaving from ports in Washington state and Alaska are expected to have vaccination requirements.

And to top it off, a federal district judge in Tampa recently concluded the CDC's restrictions on the cruise industry are likely unconstitutional and the agency is overstepping its legal authority.

So, starting July 18, the agency will no longer be able to enforce its sailing rules, including requirements that either 95% of passengers be vaccinated or that the ship successfully conduct a simulated voyage.

The judge gave the CDC until July 2 to propose more modest guidelines.

In navigating these murky, fluctuating rules, Lomax said that the Edge capped at 5% the number of cabins for people who choose not to disclose their vaccination status. They are counted as unvaccinated. People presumed to be unvaccinated will have to wear masks in public areas and will also have to undergo additional Covid-19 testing -- both to board and midway through the cruise -- at their own expense. Everybody has to be tested before disembarking in the United States.

"With 95% of passengers vaccinated, that's far more than we have in any country. And we know that the higher vaccination rates have really brought down cases. So I think it's probably reasonable for healthy vaccinated people to go on a cruise," said Marr. "The risk of an outbreak on a cruise ship, together with the measures that they're taking requiring unvaccinated people to wear masks, the overall risk of an outbreak should be quite low. And I'd be surprised if we saw something like the Diamond Princess again."

But, despite all the precautions, the experience is still not guaranteed to be 100% coronavirus-free, if the Celebrity Millennium is

any example. That ship, carrying the first North American paying passengers, set sail in early June out of St. Maarten, and made several ports of call. The crew were all fully vaccinated as were more than 95% of passengers. Nonetheless, two passengers tested positive for coronavirus at the end of the trip.

"In term of vaccination, the protection is not 100%. Sufficient vaccination protects us from developing a chain of infection, i.e. sustained infection in a large population but ... that means sporadic outbreaks can still occur particularly with the new variants of concern," Li noted.

Johnson, Celebrity's CMO, said the incident was unfortunate but it shows the system is working. "It certainly got my attention," he said.

"But we also know that, if we look [at] the world around us, in every venue infections are happening every day. And so we fully anticipate that... as thorough as our efforts are and as much as we do prevent, on the front end, virus from coming on board the ship, that it can happen," he said. "It's why we have protocols, we have a process; we've trained our folks to know what to do when we do identify this. We work very quickly to identify and isolate that, and prevent and stop the spread."

But perhaps the most reassuring statement for would-be cruise goers comes from Marr, who said that she would not stop her healthy, vaccinated, 70-year-old cruise-loving mother from taking one.

CNN Health's Keri Enriquez and Michael Nedelman contributed to this story

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Virus-Origin Review Likely to Be Unclear

Biden administration warns that the hunt for clues is a challenge for U.S. spy agencies

By Michael R. Gordon and Warren P. Strobel

Biden administration officials are cautioning that a 90-day review into the origins of the Covid-19 virus may not produce a definitive explanation as intelligence agencies take on the challenge of unraveling the global pandemic.

Spy agencies conducting the review have yet to find conclusive evidence that would settle the debate over whether the virus came from human contact with an infected animal or was leaked from a Chinese government virology lab, a person familiar with the efforts said.

President Biden is due to receive a 45-day update in mid-July, and administration officials said that even partial progress might narrow differences among scientists, politicians and intelligence experts and

turn up clues for further investigation.

Mr. Biden "is mindful of the fact that after 90 days we may not have an absolutely definitive answer, but he wanted a focused, intense, time-bound effort," a senior administration official said.

Experts say that knowing the origins of Covid-19 could be important in preparing for future pandemics. The virus has killed more than 600,000 Americans and nearly four million people world-wide, and disrupted the global economy.

The review is being overseen by Director of National Intelligence Avril Haines, a lawyer and former deputy director of the Central Intelligence Agency. It requires the vast intelligence community to train its resources on an area it has long treated as far less of a priority than spying on the Russian military, terrorist dangers or China's weapons buildup: the detection and analysis of global pandemics.

Ms. Haines told lawmakers this spring she had hired additional personnel to work on pandemic threats.

Absent a breakthrough, the review faces many obstacles, chief among them China's refusal to provide further access to data and scientists from the Wuhan Institute of Virology, a biosecurity lab that has studied coronaviruses. China has said the search should turn to other countries and cited the conclusion of a World Health Organization-led team of experts early this year that a lab leak was "extremely unlikely."

A daily intelligence briefing Mr. Biden received in the Oval Office in February showed the difficulties the intelligence community has had in identifying the source of the virus. Intelligence officials told Mr. Biden during that session they had numerous questions about the origin of the virus but didn't have "high confidence" in any particular explanation, more than a year after the virus was first detected in the Chinese city of Wuhan.

Mr. Biden instructed national security adviser Jake Sullivan to follow up, which he did in a meeting with intelligence officials in early March. The White House ordered a written assessment from intelligence officials. Delivered to Mr. Biden in May, the assessment showed one intelligence agency leaning toward the hypothesis that the virus leaked out of a lab and two intelligence agencies leaning toward the view that it arose naturally -- all with low or moderate confidence.

That inconclusive assessment and China's statement to the WHO that it considered the Covid-19 origins investigation in its country to be complete, led to Mr. Biden's order to mount what a senior administration official called an "all hands on deck effort" over a 90-day period.

Within Ms. Haines's office, officials said, the review is being coordinated by the National Counterproliferation Center, which oversees intelligence efforts to combat nuclear, chemical and biological proliferation.

The National Security Agency, the officials said, will look for clues in its vast stores of intercepted foreign electronic communications, most of which aren't analyzed in real time. The effort is being aided by experts from government labs, the Centers for Disease Control and Prevention, the National Institutes of Health and other parts of the Department of Health and Human Services. Experts outside the government are being consulted, as are allied intelligence agencies.

One outcome, Mr. Biden said in May, could be a list of specific questions that the U.S. would put to China as well as recommendations on what additional inquiries might be needed.

Given the possibility that the intelligence review might be inconclusive, there are already calls by leading lawmakers, some experts outside government and a grass-roots group of people affected by Covid-19 for an independent national commission.

"There has not yet been a properly organized, independent, scientific evaluation of all of the available evidence," said Philip Zelikow, the former executive director of the commission on the 9/11 terror attacks. Mr. Zelikow is heading a planning group, backed by prominent foundations, for a possible commission to investigate how Covid-19 emerged and how to prepare for future pandemics.

The Trump administration didn't organize an intensive governmentwide review into Covid-19's origins, though intelligence agencies and the Lawrence Livermore National Laboratory probed the matter, former Trump administration officials said.

WSJ.com
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What We Know About the Origins of Covid-19

Key findings from The Wall Street Journal's investigation into how the global pandemic began

By Drew Hinshaw, Jeremy Page and Betsy McKay

It is among the world's most consequential mysteries: Where did the coronavirus that killed millions of people and shattered the global economy come from?

The Wall Street Journal has covered the global quest for answers, tracking the World Health Organization, doctors and scientists in China and around the world, the U.S. intelligence community and the vast network of disease specialists, all struggling to piece together a puzzling set of disparate clues. Here are some of the key findings:

1. A WHO-led inquiry into the origins of the virus was stymied from the start.

A Journal investigation found China resisted international pressure for an investigation it saw as an attempt to assign blame, delayed the

probe for months, secured veto rights over participants and insisted its scope encompass other countries as well. The WHO-led team that traveled to China in early 2021 to investigate the origins of the virus struggled to get a clear picture of what research China was conducting beforehand, faced constraints during its monthlong visit and had little power to conduct thorough, impartial research without the blessing of China's government. In their final report, the investigators said insufficient evidence meant they couldn't yet resolve when, where and how the virus began spreading.

2. China withheld data on potential early cases and delayed sharing information on animals sold at a market where the first cluster was found.

Chinese authorities refused to provide WHO investigators with raw data on confirmed and potential early Covid-19 cases that could help determine how and when the coronavirus first began to spread in China. Chinese researchers also directed a U.S. government archive to delete gene sequences of early Covid-19 cases , removing an important clue.

For months before the WHO investigators arrived, Beijing declined to disclose information about samples authorities took in the first weeks of the pandemic from animals sold at the Wuhan market linked to many early cases . During their visit, the investigators found no proof of live mammals being sold at that market and quoted market authorities saying there was no illegal wildlife traded there. A study later suggested the Wuhan market was the site of widespread trading in illegal caged wildlife , providing evidence that the virus could have spread naturally from market animals to humans.

3. The question of whether a lab accident was the cause of the pandemic remains unanswered.

Since the early days of the pandemic, questions have surrounded the Wuhan Institute of Virology and whether an accident at one of its labs could have caused the pandemic . The WHO-led team declared that a lab accident was an extremely unlikely cause of the pandemic. But afterward, WHO Director-General Tedros Adhanom Ghebreyesus called for further investigation into the lab-leak hypothesis.

A group of leading scientists also published an open letter saying the lab hypothesis was plausible enough to merit serious consideration. Other scientists sought more information about the WIV's role in investigating a mysterious respiratory illness that afflicted six people clearing bat guano from a mine in southwest China in 2012. Three of them died, and samples the WIV took from bats in the mine were later found to contain the closest known virus on earth to the one that causes Covid-19.

Unanswered questions about the miners' illness, the viruses found at the site and the research done with them elevated into the mainstream an idea once dismissed as a conspiracy theory: that SARS-CoV-2, the virus that causes Covid-19, might have leaked from a lab in Wuhan. China denies that the virus came from the Wuhan Institute of Virology or any other Chinese laboratory.

4. International pressure for a fuller inquiry into the origins of the virus grows.

The WHO-led investigators have pushed for a second phase of research into the origins of the virus, warning that time was running out to examine blood samples and other important clues in China . Meanwhile, the Journal disclosed a U.S. intelligence report asserting that three WIV researchers became sufficiently ill in November 2019 to seek hospital care. In late May, President Biden ordered that U.S. intelligence agencies report to him within 90 days on how the virus emerged , with a focus on two scenarios--whether the coronavirus came from human contact with an infected animal or from a laboratory accident.

Meanwhile, China said further investigations should now turn to other countries, suggesting that the virus might have originated outside its borders and spread via frozen food.

5. Other efforts to trace the path of the pandemic continue.

As part of an international effort to pinpoint the origin of the Covid-19 pandemic and prevent future disease outbreaks, scientists around the world and organizations such as the American Red Cross and the U.S. Centers for Disease Control and Prevention are looking for new clues in frozen blood , searching for SARS-CoV-2 antibodies or signs of infection.

Other independent scientists are also trying to piece together a picture of how the virus could have been evolving before it exploded in late 2019. Many scientists believe that the most likely explanation is that the virus evolved and jumped from an animal to humans naturally, given evidence that two other coronaviruses spilled over to humans that way in the past two decades and signs of ample opportunity for that to occur.

At least four recent studies have identified coronaviruses closely related to the pandemic strain in bats and pangolins in Southeast Asia and Japan, a sign that these pathogens are more widespread than previously known and that there was ample opportunity for the virus to evolve.

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The US is concealing its research on deadly viruses -- while criticizing China's secrecy over the Wuhan lab

Mattathias Schwartz

In January 2020, an obscure government panel met at the Hyatt Regency in Bethesda, Maryland, to discuss a branch of virology known as "gain of function." The goal of such research is to take infectious diseases -- including the viruses that can cause pandemics -- and alter them in ways that make them deadlier or more transmissible, in the hope of

getting a jump on outbreaks. It was two days after the United States had its first confirmed case of COVID-19, but the empty seats in the Hyatt conference room were due to lack of interest, not social distancing.

The gathering "couldn't be more timely," said David Christian Hassell, a career official at the Department of Health and Human Services, as he began loading slides for his presentation. "We're seeing this virus reassort and mutate as it spreads. It's just pointing out the need for doing this kind of work."

In fact, many critics would soon be pointing to the COVID pandemic as the ultimate proof that gain-of-function research needs to be shut down. At the time, the virus was still widely viewed as a problem confined to China, where it originated. Later, as the US went into lockdown, President Trump would try to rebrand the pandemic as the "China virus." The city of Wuhan was home to a laboratory conducting "experimental investigations" into what it called the "origin, diversity, capacity to cause illness, and risk of spillover" from bat coronaviruses. If an altered virus escaped from the lab, then gain-of-function research might have accidentally caused the very sort of pandemic it's intended to prevent.

Trump's national-security adviser accused the Chinese government of engaging in a "cover-up" of what happened in Wuhan. But as the meeting in Bethesda demonstrated, the Chinese have nothing on the US when it comes to keeping secrets about dangerous viral research.

Discussion at the meeting focused on the government committee that recommends which studies get funded -- and which are too dangerous to perform. Its formal name is the P3CO Review Group. The group is cloaked in an opacity even more impenetrable than the one surrounding the military's drone-strike program or FISA's wiretapping court. Until that morning at the Hyatt, when Hassell identified himself as chair of P3CO, no one beyond a handful of officials knew who served on the panel. Only federal employees are permitted to take part in its proceedings, which are kept confidential; neither academia nor industry is represented. Even as Trump accused the Chinese of a cover-up, Americans had no way of knowing what their own government was doing to protect them from some of the riskiest science since the development of the atomic bomb.

"This lack of transparency is unacceptable," two scientists from Harvard and Johns Hopkins argued in The Washington Post. "Making decisions to approve potentially dangerous research in secret betrays the government's responsibility to inform and involve the public when approving endeavors, whether scientific or otherwise, that could put health and lives at risk."

Officials insist that the near-total secrecy surrounding P3CO is necessary "to preserve confidentiality and to allow for candid critique and discussion of individual proposals." A spokesperson for Health and Human Services told Insider that the review group meets "as needed," and that its membership varies depending on the proposal under review.

At the Hyatt meeting, which was prompted by scientists sounding the alarm over the apocalyptic risks of gain-of-function studies, Hassell

said he was open to broadening P3CO's authority and defended the integrity of its process. "This isn't some rubber-stamp group," Hassell said. "Right now, you don't see evidence of that. But it is a very tough group."

At the moment, unfortunately, we have little choice but to take Hassell's word for it. What we do know is that the group weighed in on -- and approved -- at least one gain-of-function study conducted on American soil. The research, which took place at the University of Wisconsin-Madison in 2019, sought to make the deadly H5N1 bird flu transmissible between mammals. Another study, conducted at the University of North Carolina at Chapel Hill in 2015, created a new "chimeric" hybrid that combined elements from bat and mouse coronaviruses.

We may never know for certain how the coronavirus made the jump from animals to humans. But even the slightest possibility of a lab leak should be worrisome enough to warrant a hard look at whether the benefits of gain-of-function research outweigh the risks, and who gets to make the call about which experiments move forward. Billions of people, after all, would suffer if a risky experiment inadvertently starts the next pandemic. "It is unethical to put the general public at risk," David Relman, a microbiologist at Stanford, said in a Nature roundtable, "and then minimize inclusion of the public in discussions about the appropriateness and oversight of such research."

Uncalculated risks

There's no question that tinkering with infectious diseases in the lab has saved lives. It was passing the yellow-fever virus through chicken cells, for example, that enabled researchers to create a vaccine for humans. And herpes viruses have been altered in the lab to create a treatment for cancer. Today, according to one of the funders of the Wuhan bat studies, hybrid viruses developed in the lab were used as reagents to test possible vaccines.

Michael Imperiale, a professor of microbiology and immunology at the University of Michigan, says that gain-of-function studies have made important contributions to biomedical research. The studies on H5N1 bird flu, he told me, provided vital insights into protein changes that could allow for human-to-human transmission. "The better we get at making these kinds of correlations," he said, "the further ahead we'll be in the game of anticipating dangerous pathogens."

There aren't many scientists who conduct gain-of-function research. "It's a very small part of virology," Richard Ebright, a critic of gain-of-function research who teaches molecular biology at Rutgers University, told me. "Less than 1%." And it would be wrong to suggest that biomedical research as a whole is unregulated. The federal government has a number of regulations that cover the conduct of scientific research, including special rules for 67 "select agents and toxins." Among them is SARS-CoV-2, the virus that causes COVID-19.

But what biomedicine lacks is anything approaching a consensus about risk. The potential dangers of gain-of-function research were apparent long before the events in Wuhan drew attention to them. One

comprehensive survey found that over a period of 75 years, there were 1,267 documented cases of "laboratory-acquired infections," or LAIs, caused by exposure to the kind of pathogens used in gain-of-function experiments, which resulted in 22 deaths. Infections by the deadliest agents in high-security labs appear to be far less frequent -- there were only 11 self-reported LAIs over a period of seven years.

There is sharp disagreement among scientists about the risk that a deadly gain-of-function pathogen could escape from a lab. Marc Lipsitch, a professor of epidemiology at Harvard, has estimated that it would take only one year of experimenting on a flu virus to put the risk of infecting a single person at 1 in 1,000. But Ron Fouchier, who induced mutations in H5N1 avian flu to make it transmissible between ferrets, calculated that under the safety measures in his own lab, it would take a million years of research to infect a single person -- and 33 billion years before an infected lab worker spread the disease to others. "This probability," he wrote, "could be assigned the term 'negligible,' given that the age of our planet is only 5 billion years."

Whatever the overall risks, there have already been some close calls. In 2014, fears of a lab-spawned pandemic, along with the Ebola outbreak in West Africa, spurred the Obama administration to impose a two-year moratorium on government funding for gain-of-function studies. Unsecured vials of smallpox from the 1950s turned up in a storage room at the Centers for Disease Control. In another incident, the CDC mistakenly sent samples of the virulent H5N1 flu to a lab in Athens, Georgia. And in a third mishap, as many as 75 CDC employees were accidentally exposed to anthrax when they handled samples they thought were inactive.

While none of the incidents involved gain-of-function studies, they underscore the risks inherent to cutting-edge biomedical research and the difficulty of solving for human error. At the time the moratorium was imposed, 19 studies identified as possible gain-of-function research were underway in 11 states. Health and Human Services set about devising a framework for evaluating the risks, which led to the establishment of the P3CO review group.

But even after the moratorium was lifted in 2017, the lab accidents kept coming. In 2019, the CDC briefly shut down the Pentagon's biodefense lab at Fort Detrick after numerous containment failures. And in April 2020, as the nation went into lockdown, a scientist at the University of North Carolina in Chapel Hill was forced to self-quarantine for two weeks after being bitten by a mouse that had been infected with a strain of the virus that causes COVID-19. Research at UNC -- some of which was carried out with the assistance of Shi Zhengli, who led the experiments on bat coronaviruses at the Wuhan Institute of Virology -- resulted in four incidents of potential human exposure to SARS coronaviruses. UNC confirmed to ProPublica that the viruses had been created in a lab.

Ralph Baric, who helped lead the UNC research, has denied that it involved gain of function. Zhengli, meanwhile, told The New York Times that the Wuhan lab "never conducted or cooperated in conducting GOF

experiments that enhance the virulence of viruses." (She did not comment on whether the lab was trying to enhance the transmissibility of viruses, which is another key criterion for gain of function.) Dr. Anthony Fauci and the National Institute of Health, which provided funding for the Wuhan experiments, also insisted that the work did not involve any gain-of-function research. The study was "subjected to rigorous peer review and was judged to be very high priority, given how SARS-CoV had already emerged in this bat population," an NIH spokesperson told Insider.

Experts I spoke with were skeptical of the NIH's claim that the Wuhan study didn't involve gain of function, noting that the term is subject to competing definitions. But when it comes to oversight, the NIH's definition -- which is extremely narrow -- is the one that counts. The agency told The Washington Post that the Wuhan study was determined to be "outside the scope" of oversight by the P3CO committee.

It's a telling admission: What turned out to be one of the most controversial and perhaps consequential experiments in history was deemed not to require government oversight. As a result, the grant proposal was never even passed along to the P3CO review group. And there's no way to know the reasoning behind the decision, or the identities of the officials who made it.

Made in the USA

After much obstruction and foot dragging, most scientists now agree that there is a need to investigate what happened in Wuhan. At the end of May, President Biden ordered the intelligence community to conduct a 90-day review of what they know about COVID-19's origin.

It's possible, of course, that the lab-leak scenario will turn out to be wrong. If, as many scientists believe, the virus had a natural origin, then the Wuhan lab -- now vilified by everyone from Mike Pompeo to Jon Stewart -- was actually conducting critical, prescient research into a soon-to-emerge disease. The lab would be held up as a shining example of the need for gain-of-function research, which proponents view as the last line of defense in humanity's arms race against nature. Unless we know what could be headed our way, they argue, we won't have enough time to stop it.

But the relentless focus on China-based research, and what may have gone wrong there, misses a deeper and more disturbing truth. The vast majority of virology -- including the Wuhan study and other gain-of-function research conducted outside the US -- is supported by American funding. The training, ethical guidelines, and standards for bioscience adhered to by top researchers worldwide are dominated by US institutions. If it becomes demonstrably true that a cutting-edge laboratory caused a pandemic, either now or in the future, America would deserve the blame, regardless of which country happens to be hosting those experiments. And much like the international regulatory regime around nuclear weapons, any effort to create an independent authority capable of overseeing dangerous biomedical experiments would need to be spearheaded by the US.

At the moment, though, we have no way of knowing the number or nature

of studies working to change viruses in ways that could lead to the deaths of millions. Even more striking, the public has no way to know who is responsible for reviewing those studies, or how they are making their decisions about funding. Regardless of how COVID-19 emerged, we are being kept in the dark about scientific work that seeks, as its primary objective, to make the most frightening diseases more frightening.

"Everyone on earth has now experienced a pandemic in their lifetimes," Ebright told me. "Nobody wants to see another. If there's even a possibility that this category of work caused this pandemic, or could result in the next pandemic, then it needs to be regulated."

Global Times (China)
Monday, June 28, 2021

Why US labs need to be investigated for COVID-19 origins

Suspect No.1: Why Fort Detrick lab should be investigated for global COVID-19 origins tracing

By Fan Lingzhi, Huang Lanlan and Zhang Hui

The lab-leak theory, that COVID-19 was leaked from a laboratory, has once again caused a clamor since the beginning of this year, months after the argument was thrown into the trash can of conspiracy theories by an overwhelming number of scientists.

Observers found that things only get more complicated when the origins of the coronavirus - an already difficult scientific issue - is entangled in political manipulation tricks. Combing through more than 8,000 pieces of news reports related to the lab-leak theory, the Global Times found that as many as 60 percent of the coverage was from the US alone.

It is worth noting that many media outlets in the US-led Western world, which hyped the lab-leak theory, are only willing to focus on the Chinese labs though they have been thoroughly investigated by the World Health Organization (WHO), while turning a blind eye to the more suspicious American biological research institutions, such as the infamous US Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, Maryland.

The USAMRIID was temporarily shut down in 2019 after a Centers for Disease Control and Prevention (CDC) inspection. Although this mysterious lab reported the reason for the closure as "ongoing infrastructure issues with wastewater decontamination," the explanation was not persuasive enough. The Global Times found that the lab's failure to control toxins seemed to have alarmed the Countering Weapons of Mass Destruction related institutions in the US.

Resurgence of lab-leak theory

A joint study into the origins of COVID-19 by Chinese experts and the WHO in March dismissed the "lab-leak" conspiracy theory. More evidence

pointed to the fact that the virus had probably jumped from bats to humans via another intermediary animal, and it was "extremely unlikely" that it leaked from a lab, the study report said.

Nonetheless, the lab-leak theory has not disappeared; instead, especially from the beginning of May, it has been largely promoted by some US politicians and media outlets as a "plausible science." In an article published on Bulletin of the Atomic Scientists on May 5, without any evidence, science writer Nicholas Wade claimed that "proponents of lab escape can explain all the available facts about SARS2 considerably more easily than can those who favor natural emergence."

Days later, The Wall Street Journal reported on May 23 that three researchers at Wuhan Institute of Virology (WIV) "became sick enough in November 2019 that they sought hospital care," and they had "symptoms consistent with both Covid-19 and common seasonal illness." The WSJ report quoted a "previously undisclosed US intelligence report."

On May 26, President Biden stated that he had ordered the US intelligence community to "redouble" its efforts to investigate the origins of COVID-19. The US national security adviser Jake Sullivan even claimed on June 20 that China will face "isolation in the international community" if it doesn't cooperate with a further probe into the origin of the COVID-19 pandemic, Bloomberg reported that day.

Pressure from politicians and the media seems to have affected some authoritative medical scientists in the US, including Director of the US National Institute of Allergy and Infectious Diseases (NIAID), Anthony Fauci. On May 11, after Rand Paul, a Republican to the Senate, accused Fauci of helping the Wuhan lab "create" the virus, Fauci strongly denied the accusation but said he is "fully in favor of any further investigation of what went on in China."

This sudden change in attitude of some US experts is due to the political pressure they have received, a Chinese virologist told the Global Times. "Western media like to ask the experts misguiding questions, like, 'is (lab leak) absolutely impossible?'" said the virologist who requested anonymity.

It's very difficult for experts to answer a question like that, as the possibility, although very little, still exists, the virologist said. "All they can say is, 'it's possible,'" he told the Global Times. Actually, most experts usually add "but it's highly unlikely" after "it's possible," but the media only presents the part which confirms their own bias, he said.

Big data shows the US is pushing the narrative of the COVID-19 lab-leak theory. Among the 8,594 pieces of news report related to "lab leak" that database GDELT collected since 2020, 5,079 were from the US, accounting for 59 percent. Following the US was the UK (611 pieces) and Australia (597 pieces). Almost all the coverage targeted the WIV lab.

While the US is solely focused on Chinese labs, the US seldom pays attention to the fault in its own domestic labs, some of which have even triggered virus-related accidents before. According to an August

2020 article by ProPublica, an independent newsroom that produces investigative journalism, the University of North Carolina at Chapel Hill reported 28 lab incidents involving genetically engineered organisms to safety officials at the National Institutes of Health between January 2015 and June 2020. "Six of the incidents involved various types of lab-created coronaviruses," ProPublica said in the article. "Many were engineered to allow the study of the virus in mice."

Weirdly, very few US mainstream media outlets have raised the question whether there is the possibility that COVID-19 was leaked from US labs, said the Chinese virologist. "They dare not ask that," he said.

In an article published on the independent political blog site Moon of Alabama on May 27, the author pointed out that some Westerners' hyping of the Wuhan lab leak conspiracy is similar to the trick the US played in pushing the Iraq War in 2002 - the US claimed "Saddam Hussein will soon have nuclear weapon," which was "obvious nonsense," the author said.

"The 'lab leak' theory is similar to the WMD claim - evidence-free speculation long promoted by a neoconservative leaning administration that was extremely hostile to the 'guilty' country in question," said the author.

The lab-leak theory, therefore, "isn't just about an implausible, evidence free tale of a SARS-CoV-2 lab escape," the author noted. "It is a campaign launched to depict China as an enemy of humankind."

Intl concerns on US bio-labs

The US has many bio-labs in 25 countries and regions across the Middle East, Africa, Southeast Asia and the former Soviet Union states, with 16 in Ukraine alone. Some of these labs have seen large-scale outbreaks of measles and other dangerous infectious diseases, according to media reports.

The international community has frequently expressed concern over US' biological militarization activities in other countries.

In October 2020, Deputy Chairman of the Security Council of Russia, Dmitry Medvedev, said that the US research activities in bio-labs in members of the Commonwealth of the Independent States have caused grave concern. The US not only builds bio-labs in these countries, but also tries to do so in other places across the world. However, its research lacks transparency and runs counter to the rules of the international community and international organizations.

Anatoly Tsyganok, a corresponding member of the Russian Academy of Military Sciences and associate professor of Faculty of World Politics at Lomonosov Moscow State University, told the Global Times that biological and bacteriological weapons tests on US territory are prohibited by the US Congress. He said that the US military has been and is still carrying out tests of biological and bacteriological weapons in Georgia.

This is done under the guise of providing sick people with various

therapeutic vaccines conducted by the US military and American private contractors at the Richard Lugar Center for Public Health Research, Tsyganok said. Related tests have been exposed by various media outlets.

In December 2015, 30 patients at the research center who were being treated for hepatitis C died. Twenty-four of them died on the same day, and their cause of death was listed as "unknown," according to Tsyganok and Russia news outlet.

Residents of neighborhoods around these labs often complain about health problems.

Bulgarian journalist Dilyana Gaytandzhieva published a story about the Lugar center in early 2018. In her interviews for the report, most residents who lived nearby the labs complained of headaches, nausea and high blood pressure. They also said there was black smoke coming from the lab.

USA Today reported that since 2003, hundreds of incidents involving accidental contact with deadly pathogens occurred in US bio-labs at home and abroad. This may cause the direct contacts to be infected, who can then spread the virus to communities and start an epidemic.

A member of the Russian Academy of Sciences, Armais Kamalov said in an interview with TASS in early June that development of genetically-engineered viruses as biological weapons should be subject to the same worldwide ban as the testing of nuclear weapons. He mentioned US labs in Georgia and Armenia as reference.

"There are a lot of labs, which are bankrolled today by the United States Department of Defense. It's no secret that they are in Georgia, Armenia and other republics. It's surprising that access to such labs is off-limits, and we don't understand what they are doing there," he said.

What had happened in July 2019?

The terrible safety records of American biological labs around the world shows a possibility of a virus escaping from an American lab. Many point to the shutdown of Fort Detrick lab in July 2019.

In July 2019, six months before the US reported its first COVID-19 case, Army laboratory at Fort Detrick that studies deadly infectious material like Ebola and smallpox was shut down after the US Centers for Disease Control and Prevention issued a cease-and-desist order. CDC officials refused to release further information after citing "national security reasons."

The USAMRIID in Fort Detrick said in August 2019 that the shutdown was because the center did not have "sufficient systems in place to decontaminate wastewater" from its highest-security labs, the New York Times reported.

What exactly happened at Fort Detrick in the summer of 2019? Some US media previously turned to CDC to get answers, but many key contents in

the report had been redacted.

In early June, a Virginia-based Twitter user got the CDC documents on the inspection of the Fort Detrick under The Freedom of Information Act (FOIA). Global Times found that most of the documents were emails between CDC officials at various departments and USAMRIID from 2018 to 2019. Although some of the emails were covered by an ABC-affiliated television station in Washington, the report did not catch much attention.

The emails revealed several violations at the Fort Detrick lab during

CDC's inspections in 2019. Four of which were labeled serious violations.

One of these serious violations, the CDC said, was one inspector who entered a room multiple times without the required respiratory protection while other people in that room were performing procedures with a non-human primate on a necropsy table.

This deviation from entity procedures resulted in a respiratory occupational exposure to select agent aerosols, the CDC said.

In another serious violation, the CDC said the USAMRIID had "systematically failed to ensure implementation of biosafety and containment procedures commensurate with the risks associated with working with select agents and toxins."

Other violations included lack of proper waste management where waste wasn't transported in a durable leak proof container, which creates the potential for spills or leaks.

The CDC documents show that it sent a letter of concern to USAMRIID, which resulted in a temporary shutdown of the Fort Detrick lab in 2019.

In an email on July 12, 2019, the CDC said the USAMRIID reported two breaches of containment on July 1 and July 11, 2019, and this demonstrated a "failure of USAMRIID to implement and maintain containment procedures sufficient to contain select agents or toxin generated by BSL-3 and BSL-4 laboratory operations."

"Effective immediately, USAMRIID must cease all work involving select agents and toxins in registered laboratory areas until the root cause investigation has been conducted for each incident and the results have been submitted to FSAP for review," the CDC said.

The FSAP (Federal Select Agent Program) is jointly comprised of the Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Division of Agricultural Select Agents and Toxins. The program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to cause a severe threat to the public, animal or plant health or to animal or plant products. Common examples of select agents and toxins include the organisms that cause anthrax, smallpox, and the bubonic plague.

Three days later, the Fort Detrick replied the email by saying that it had submitted messages in response to the immediate action, but the messages were deliberately blotted out.

The message was submitted by a director for Strategic Studies (Countering Weapons of Mass Destruction) at the USAMRIID whose name was also blotted out.

The Fort Detrick's public statement released in August 2019 said the shutdown was due to problems in decontaminating wastewater. But it's not clear whether the statement was consistent with CDC's inspection results.

The management of such high-level labs in general must be very strict with regular inspections. Various systems should be able to ensure that no potential risks can occur, and equipment failure and wastewater leakage certainly should not occur, a Chinese scientist from the WHO-China virus origins tracing team who requested anonymity told the Global Times.

The wastewater problems revealed major loopholes in the management at the Fort Detrick lab, and one has to wonder what else was leaked with the mismanaged wastewater.

"Some highly pathogenic pathogens in the laboratory were likely released. And the US military never told the public about what they were doing," the scientist said.

It is highly likely that researchers at Fort Detrick may have been infected accidentally but showed no obvious symptoms. In this way they could have brought the virus to the outside world, the scientist said.

"Under the circumstances of no obvious symptoms, 9 of the 10 individuals may not have known that they were infected and it's possible that more than 90 percent of the transmission routes had been lost when the virus was finally detected. This is also why the tracing of virus origins is difficult to conduct," he said, noting only serological survey on a large scale could find some of the early infections.

Why not open Fort Detrick lab

Several virologists and analysts interviewed by the Global Times urged the Fort Detrick lab to open its doors for an international investigation, since international experts have already visited the Wuhan Institute of Virology.

Many Western politicians and media outlets pinned the blame of the pandemic on Wuhan, saying that Wuhan was where the virus was first detected and where the virus came from despite mounting evidence that it's not the case.

In a recent example in June, a research study run by the National Institutes of Health's All of Us Research Program found evidence of COVID-19 infections in the US as early as December 2019, weeks before the first documented infection in the country.

Wuhan recorded the earliest COVID-19 symptoms from a patient on December 8, 2019.

When asked to give more details on the study, a media person with the All of Us Research Program told the Global Times that the program "has nothing further to add" from the information it had already released.

As for why the virus was first detected in Wuhan, the anonymous scientist said that the virus was difficult to be detected at an early stage, especially in autumn and winter with more cold cases. And it would not attract attention until a large number of people were infected. That's what happened in densely populated Wuhan, the scientist said.

China's public health system is very sensitive especially after the SARS outbreak in 2003, but this is not always the case abroad, especially when the population density is low and the virus does not spread so fast, the expert said.

"The novel coronavirus was first discovered by three Chinese companies at the same time. It is very simple to detect these things, and China has lots of such third-party companies with strong medical detection ability," he said.

Without going back to earlier serum samples elsewhere now, it is going to be difficult to find the source of the virus. The retrospective studies that have been done in China have not found any evidence. It's important for the world to work together now to sort through the evidence and do early serological investigations where necessary, he said.

Zeng Guang, former chief epidemiologist of the Chinese Center for Disease Control and Prevention, told the Global Times that laboratory leak is easy to identify, as infections are bound to show signs, whether it is an operational problem or an infection of a lab staff.

The WHO experts assessed the lab-leak hypothesis when they visited Wuhan and found no evidence, and the speculation on its possibility in a Wuhan lab should have ended by now. In the meantime, we should put a question mark on other hypotheses, such as other labs around the world, Zeng said.

Zeng said the US is afraid of WHO's inspection in the same way it was done in China, Zeng said.

The US, the only country obstructing the establishment of a Biological Weapons Convention (BWC) verification mechanism, has systematic problems, Zeng said, adding that the US is afraid that the investigation into its labs would lead to more of its dirt being dug out.

Xia Wenxin contributed to this story

New York Times
Saturday, June 26, 2021, page B6

Celebrity Cruises to Be First to Resume Sailing From U.S.

By Ceylan Yeginsu

The Celebrity Edge will depart from Fort Lauderdale, Fla., on Saturday with 95 percent of its passengers all crew members vaccinated.

The Celebrity Edge is poised to set sail out of Fort Lauderdale, Fla., on Saturday, becoming the first major cruise ship to restart operations from a United States port since the pandemic all but hobbled the industry over a year ago.

The ship will sail at 35 percent capacity, with at least 95 percent of passengers and all crew members fully vaccinated, its owner, Celebrity Cruises, said in a statement. Vaccines are not mandated for the cruise because of a new Florida state law banning businesses from requiring proof of immunization, but unvaccinated guests will face more stringent coronavirus protocols.

All guests over the age of 16 who do not show proof of vaccination will be required to wear masks on board and take a series of antigen tests during the cruise at an additional cost. (Testing for vaccinated guests will be free of charge.)

"We're definitely finding that cruisers prefer to be vaccinated and to share this information with us," said Susan Lomax, associate vice president for global public relations at Celebrity Cruises.

The sailing is a major milestone for the $150 billion global cruise industry, which has been decimated by the pandemic and spent months in a battle with the Centers for Disease Control and Prevention over its requirements for the safe resumption of cruising.

Earlier this month, Celebrity Cruises tested its Covid protocols during a seven-day sailing in the Caribbean, the line's first international cruise with American passengers. All adult passengers and crew members were fully vaccinated, and they were not required to wear masks or socially distance during the sailing.

Halfway through the cruise and following two shore excursions on the islands of Barbados and Aruba, a vaccinated couple tested positive for the virus and were immediately put into isolation. Other passengers who had come into contact with them were required to quarantine and get tested.

Before the ship reached its final destination, all passengers on board were tested, and no further positive cases were identified. Celebrity said the handling of the incident demonstrated that the company's virus protocols worked in preventing the spread of the virus.

Other major lines, including Carnival Cruise Line and Royal Caribbean, are preparing to restart U.S. operations in July. As of July 18, cruise ships departing from and arriving in Florida will not be required to

follow C.D.C. guidance, after a judge ruled last week that the order was based on "stale data" and failed to take into account the prevalence of effective vaccines.

New York Times
Saturday, June 26, 2021, page A18

Harris Seeks Nuance On Migration Debate During Tour of Border

Advocates pushed the vice president to end Title 42, a Trump-era rule that allows the government to expel migrants for public health reasons.

By Katie Rogers

WASHINGTON -- Vice President Kamala Harris on Friday made her first visit to the southern border since she took office, hitting back at Republican criticism and meeting with advocates who pushed her on why the Biden administration had not yet ended restrictive Trump-era policies on migration.

"We can take all of these perspectives into account and have meaningful good public policy if we just stop the rhetoric," Ms. Harris told reporters after a four-hour visit to El Paso. "You can't just react to a problem without solving it at its roots. Let's just agree to that."

During her trip, she confronted an issue that has bedeviled the administration for months and is now tied to her own political future after President Biden put her in charge of addressing the root causes of migration. But for all of the questions she took from reporters, immigration advocates and even a group of detained migrant children -- whom she met behind closed doors -- the vice president had few answers.

In one private meeting, she heard from immigration advocates who said they did not understand why the Biden administration had yet to deliver on promises to roll back Trump-era policies like Title 42. Several pressed Ms. Harris to end that rule, which allows the government to expel migrants, including asylum seekers, for public health reasons.

"We were very forceful about that," Fernando Garcia, the executive director of the Border Network for Human Rights, who attended the meeting, said in an interview. "She asked how we think it could happen. She was looking for some answers."

The Biden administration is working to phase out Title 42, but on Friday, Alejandro N. Mayorkas, the secretary of homeland security who accompanied Ms. Harris to El Paso, told reporters that the Centers for Disease Control and Prevention would ultimately decide.

"It's a public health decision," Mr. Mayorkas said. "It's based on the well-being of the American public."

The agency, however, has directed questions about the policy to the White House.

In some ways, the trip was notable for what Ms. Harris did not do: visit a tent complex at nearby Fort Bliss, where migrant children are being held. (As she traveled to Texas, the Biden administration announced that Xavier Becerra, the secretary of health and human services, would head there next week.)

"She'll check off the box of going down to the border," Representative Henry Cuellar, a Texas Democrat who wrote a letter to the vice president last week urging her to visit the border, said in an interview. Mr. Cuellar said his letter went unanswered.

Ms. Harris stopped at Customs and Border Protection's processing center, where she received a briefing from officials and asked questions about the technology used to process people who crossed the border illegally.

She also said she had met with young girls detained at the Paso del Norte port of entry, a meeting that had not been announced and was kept private. Ms. Harris said the girls reminded her that the issue should not be reduced to partisan politics.

"They were asking me questions: 'How do you become the first woman vice president?'" Ms. Harris said. "It also reminds me of the fact that this issue cannot be reduced to a political issue. We're talking about children, we're talking about families, we are talking about suffering."

Human rights and immigration advocates have assailed the Biden administration for not doing enough in its first six months to reopen the border to asylum seekers, reunite unaccompanied children with families and provide the appropriate facilities to hold detained migrants. In a report released last week, the human rights group Amnesty International said that the Biden administration had failed to fulfill some of its early pledges.

"Rebuilding an immigration system takes time, but nearly half a year in, the administration still needs to deliver promised change," the report read. "No matter the situation or who heads the administration, the government cannot get out of its human rights obligations."

Still, some Democrats praised Ms. Harris, saying her trip showed a dedication to finding solutions, including a push for bipartisan immigration overhaul, an effort that has eluded modern presidents.

"Her attendance today in El Paso is an indication of her caring and commitment to meaningful immigration reform," said Senator Richard J. Durbin, the chairman of the Judiciary Committee, who stood next to her on the tarmac in El Paso. "And I want to join her in saying that Congress needs to do its part."

The visit came together quickly after Ms. Harris was criticized on her trip to Mexico City and Guatemala, where Lester Holt of NBC grilled her about why she had not been to the border. She responded by calling the visit a "grand gesture" and pointed out that she had not been to Europe yet, either -- answers that confounded her critics and members of the

administration.

Though her office denied politics played a part, the El Paso stop does carry some significance. The city is a major port of entry and has complicated ties to former President Donald J. Trump, who will travel to the border with Gov. Greg Abbott of Texas days after Ms. Harris.

As president, Mr. Trump called El Paso "one of our nation's most dangerous cities," castigating it as overrun by immigrants and crime. It typically ranks among the safest cities in the United States. In 2019, after 22 people were killed at a Walmart and the white suspect warned of a "Hispanic invasion," Mr. Trump was greeted with protests when he met with the victims' families.

On Wednesday, a group of House Republicans said they would join Mr. Abbott and Mr. Trump on their trip, a move intended to add more pressure on the Biden administration, which has struggled to chip away at Mr. Trump's "zero tolerance" immigration policies while warning migrants not to make the journey to the United States.

The number of unaccompanied minors crossing the border has hit a record high under the Biden administration, and officials have struggled to quickly move them out of cramped facilities and into the care of family members. A surge in the apprehensions of single adults -- some 121,000 last month -- has offset a small decline in the number of unaccompanied minors and families traveling north, according to Customs and Border Protection data.

As she prepared to leave El Paso, Ms. Harris was asked about criticism that she had stopped by El Paso instead of the lower Rio Grande Valley, which is considered the center of the current surge in migration. The vice president, who spent her visit pleading for partisan politics to be omitted from the conversation about immigration, pointed to Mr. Trump to make her case.

"It is here in El Paso that the previous administration's child separation policy was implemented," she said. "We've seen the disastrous effects of that right here in this region."

Zolan Kanno-Youngs and Eileen Sullivan contributed reporting.

Los Angeles Times
Saturday, June 26, 2021, page A5

Harris views immigration problems up close

Criticism continues after she meets with border agents, migrant children in El Paso.

By Noah Bierman and Molly Hennessy-Fiske

Kamala Harris made her first trip as vice president to the U.S.-Mexico border Friday, meeting with border agents and migrant children as she toured a processing center in El Paso and became more closely tied to

one of the Biden administration's diciest political problems.

Her visit comes after months of Republicans' criticism that she and President Biden hadn't seen firsthand the effects of an immigration system overwhelmed by an increase in migrant families and unaccompanied children seeking entry into the United States.

Even as Harris traveled around the El Paso area, critics on both sides of the immigration debate lambasted her for avoiding some more problematic spots along the border, where children and families are experiencing long delays and often dangerous conditions as they wait to have their fates determined.

The migrant children she met "are filled with optimism," Harris said as she left Texas for a weekend at her Brentwood home. "But they are without their family -- young children. They're being processed through the system."

"This issue cannot be reduced to a political issue," she added. "We're talking about children. We're talking about families. We're talking about suffering. And our approach has to be thoughtful and effective."

Harris was accompanied by Homeland Security Secretary Alejandro N. Mayorkas, who has been to the border previously. Health and Human Services Secretary Xavier Becerra plans to visit a nearby facility Monday -- a federal tent city for hundreds of children at the Army's Ft. Bliss, where there have been outbreaks of COVID-19 and lice, reports of sexual abuse and other unsafe conditions.

During her visit, which lasted about four hours, Harris blamed the Trump administration for leaving her and Biden with "a tough situation," which she asserted was improving.

"We're not exactly where we want to be yet, but we've seen extreme progress," she said, noting that wait times for unaccompanied children in El Paso had been reduced.

Despite months of taunts from Republicans that she was avoiding the border, Harris told reporters that "it was always the plan to come here" as part of her work on immigration diplomacy with Central America. She had been to the U.S.-Mexico frontier numerous times as a senator and as California's attorney general.

"We have to deal with causes and we have to deal with the effects," she said. Her recent trip to Mexico and Guatemala, she added, was about probing the causes of residents' decisions to migrate north, while her border visit is intended to allow her to see "the effects of what we have seen happening in Central America."

Harris said the border stop reinforced her belief that deterring people from leaving their home countries will require long-term, consistent investment in Central American countries to reduce poverty there.

In addition to touring the processing center, Harris met privately with five migrant girls ages 9 to 16. Aides said the girls drew pictures and told the vice president what they wanted to be when they grew up.

Harris also went to a nearby inland entry port where asylum seekers arriving from Mexico, including unaccompanied children, are initially screened.

The Biden administration is facing tough policy decisions as it tries to balance efforts to deter migrants and to develop a more humane system of processing those who have made the journey.

Mayorkas told reporters traveling on Air Force Two that his office is still reviewing how quickly to rescind a Trump-era policy, initiated amid the pandemic, that allows agents to turn away migrants by citing a public health law known as Title 42.

Mayorkas said the decision on whether to end the policy would be based on the assessment of the Centers for Disease Control and Prevention, based on public health data and the threat of spreading COVID-19.

Harris' role in immigration policy dates to March, when Biden asked her to examine ways to reduce migration through Mexico from Honduras, Guatemala and El Salvador by attacking its root causes, including corruption, poverty and gang violence -- problems that have been exacerbated by devastating hurricanes and the pandemic.

The vice president visited the capitals of Guatemala and Mexico earlier this month to confer with their leaders, encourage investment and discourage corruption in the region. But those diplomatic activities were overshadowed by questions raised back in the United States about why she wasn't visiting the border.

On Friday, Sen. Ted Cruz (R-Texas) tweeted of Harris' trip: "93 days too late," adding: "It only took more than half a million illegal immigrants entering the U.S., more than 400,000 pounds of drugs seized, dozens of U.S. Senators and House members traveling to the southern border for Border Czar Kamala Harris to finally visit the southern border."

White House officials said Harris did not go to Texas in response to the partisan pressure, which includes former President Trump's recent announcement that he would visit a border site with GOP members of Congress next week.

Republicans say the Biden administration is looking at the wrong causes for the increase in migrants. They say the reason they're coming is because Biden has relaxed some of Trump's hard-line policies.

Republicans have decried Biden's early order to halt border wall construction while his administration reviews the legality of how Trump funded his signature project.

More than 200 miles of barrier were in some stage of construction in Texas, which is the least-fenced border state, when Trump left office, according to U.S. Customs and Border Patrol.

Texas Gov. Greg Abbott, a Republican who plans to host Trump next week, has vowed that his state will continue to build the wall, though it's not clear he has the authority to see that it's done.

Liberal groups and immigrant advocates have their own issues with the administration, complaining that officials have been too slow to roll back Trump's policies, including the use of Title 42, and to fix conditions for children at Ft. Bliss.

"There is a long way to go," said Shaw Drake of the ACLU of Texas in El Paso, a staff attorney and policy counsel for border and immigrants' rights.

From the administration's vantage, El Paso was an appealing destination for Harris. The largest city on the long Texas border, it's a military outpost but also a Democratic college town and a bastion of liberal activism for immigrant rights. It is also home to Democratic Rep. Veronica Escobar, who was traveling with the vice president.

El Paso also was the first place where the Trump administration began separating children and parents who crossed the border -- one of the former president's most reviled policies.

Rep. Henry Cuellar, a Texas Democrat who had urged Harris to visit the border, said El Paso is "politically safer to go to than the Rio Grande Valley, where you can see unaccompanied kids, family units, and where you get most of the single adults that are coming in."

Migrant numbers fell sharply in 2020 amid the pandemic, when the U.S., like many countries, restricted entry. This year the numbers began to increase.

Some progressive activists in the Rio Grande Valley also expressed disappointment that Harris and Mayorkas were visiting El Paso, where far fewer asylum-seeking families have been forced by U.S. policies to wait across the border in Mexico.

Karla Vargas, an attorney with the Texas Civil Rights Project, based in the Rio Grande Valley east of El Paso, said: "We would have hoped they would have tried to also visit this area to see how difficult it is for the families waiting here. We welcome them trying to address this. We hope it is not just showmanship."

Times staff writer Molly O'Toole contributed to this report.

BusinessInsider.com
Sunday, June 27, 2021

CDC director Robert Redfield 'prayed' Trump would understand how serious COVID-19 was after contracting it, a book excerpt says

Yelena Dzhanova

Robert Redfield, the director of the Centers for Disease Control and Prevention, prayed that former President Donald Trump would take the coronavirus more seriously after being diagnosed with it, according to a new book by two reporters from the Washington Post.

An excerpt of the book, "Nightmare Scenario: Inside the Trump Administration's Response to the Pandemic That Changed History," illustrates the White House's chaotic response to Trump's October 2020 COVID-19 diagnosis and hospitalization at the Walter Reed Medical Center. The book, written by Yasmeen Abultaeb and Damian Paletta, is due for release on June 29.

Over the weekend that Trump announced that he and then first lady Melania had the virus, Redfield prayed for a recovery, the excerpt says. Redfield also prayed that it would be a wake-up call for the president, who for months at this point had flouted or mocked COVID-19 safety restrictions like mask-wearing.

He also held giant rallies with thousands of mask-less people in attendance to drum up support for his 2020 re-election bid.

Redfield "prayed that Trump would tell Americans they should listen to public health advisers before it was too late," the excerpt says.

Just days after his hospitalization, Trump walked the White House South Lawn. Watching the event unfold on television, Redfield prayed again, this time that the former president would "show some humility" and "remind people that anyone could be susceptible to the coronavirus -- even the president, the first lady and their son. That he would tell them how they could protect themselves and their loved ones."

But Trump didn't do that. Instead, he took off his mask and gave the cameras a thumbs up, the excerpt says.

In a video taken just over the weekend while at Walter Reed, Trump appeared to be visibly paler than usual. He released a video from the hospital, saying he felt "much better now." In the video message, Trump appeared to have no trouble speaking and breathing.

During the moment he addressed the cameras on the South Lawn, he was likely still contagious.

"He made a military salute as the helicopter departed the South Lawn, and then strode into the White House, passing staffers on his way and failing to protect them from the virus particles emitted from his nose and mouth," the excerpt says.

That's when Redfield began to understand the hospitalization changed neither Trump nor his response to the coronavirus, according to the excerpt.

Washington Post
Sunday, June 27, 2021, page B1

How Trump's blunders fueled our coronavirus nightmare

Nightmare Scenario
Inside the Trump Administration's Response to the Pandemic That Changed

History
By Yasmeen Abutaleb and Damian Paletta
Harper. 478 pp. $30

By William Hanage

Early in the pandemic, an outbreak of the novel coronavirus on the Diamond Princess cruise ship had spread out of control. The passengers included many Americans, prompting urgent questions about whether they should be repatriated and where they should be quarantined. Among the most eye-popping and jaw-dropping revelations in a new book by Washington Post reporters Yasmeen Abutaleb and Damian Paletta, "Nightmare Scenario," is the claim that President Donald Trump suggested sending them to Guantanamo Bay.

It shouldn't need saying, but a military compound used to house terrorism suspects is not a suitable place for the quarantine, isolation and treatment of mostly elderly citizens, already known to be a group vulnerable to severe infection. The alleged reason for the suggestion was the president's obsession with keeping the numbers of cases in the United States low. While energies were consumed with the Diamond Princess and other cruise ships, the virus quietly entered the country and started to spread, even as the Centers for Disease Control and Prevention struggled to develop a test capable of establishing that fact.

This episode illustrates two of the common factors that tie together the many missteps documented in the book. One is the wasting of time and energy on narrow issues such as cruise ships, or the discredited treatment hydroxychloroquine, rather than accepting that the situation was bad and going to get much worse without the hard work of pandemic management. The other is the conviction that the negative press coverage was the problem, not the virus itself.

Over and over again, whenever public health and public relations came into conflict, public health lost out. Trump's complaints directed at "the Doctors" kept coming back to the same charge - negativity - including a remarkable, petulant presidential Oval Office outburst roughly halfway through the book. "I am sick and tired of how negative you all are. . . . I spend half of my day responding to what Tony Fauci has to say, and I'm the president of the United States!" Later in the same exchange, Trump told coronavirus response coordinator Deborah Birx: "Every time you talk, I get depressed. You have to stop that." As if the pandemic could be defeated by the power of positive thinking, and Birx should just cheer up and promote policies that she knew would lead to more illness and death than the alternatives.

In general, the book is not strong or detailed on the scientific nuts and bolts. This is not a place to come if you want to understand the nitty-gritty of why the CDC's test development went so very awry. But Abutaleb and Paletta are on the money when it comes to the challenges in formulating policy advice on the basis of science that was not fully settled. As they write, "The task force members . . . had to make the best decisions they could and update their guidelines as the scientific understanding grew."

The point is illustrated well by the politicization of masks. Amid early concerns about an exponential wave of infections flooding into the health-care system, experts including Fauci, director of the National Institute of Allergy and Infectious Diseases, argued against mask use, concerned that hoarding by the public would leave health-care workers deprived of vital personal protective equipment (PPE). This advice would later change as evidence accumulated showing that mask-wearing by a large fraction of the population is an effective intervention. This shift was interpreted as a political flip-flop, rather than science in progress, and adopted as ammunition by those adamantly opposed to masks. Mask use became irrevocably politicized, and attempts to convince doubters foundered amid an epidemic of cherry-picked evidence.

Shortages of PPE were in fact a serious concern early in the pandemic, because of an incoherent approach that set states and even individual health-care networks against one another. In just one example of many, the book alleges that the work of a "Shadow Task Force" run by Jared Kushner diverted "30 percent of 'key supplies' from the Strategic National Stockpile to operate forty-four drive through testing sites for five to ten days."

That the response was chaotic and dysfunctional will not be news, but according to this account there were opportunities to take a different course. Some officials emerge with credit, although it must be noted that, as with all tales of palace intrigue, the story is inevitably shaped by the sources. As time went on more efforts were put into finding ingenious reasons to deny the seriousness of the pandemic rather than to respond to it, with the nadir being the appointment of Scott Atlas as special coronavirus adviser to the president, to give the advice Trump wanted to hear.

This casting of reality as whatever you want to believe led to a sort of choose-your-own-pandemic, in which decisions were pushed ever downward to governors, mayors or individuals. Some of these were well resourced, others not, but all less well than they would have been with adequate federal support. Members of the coronavirus task force resorted to broadcasting their own advice as widely as possible, either in meetings with local officials or through the media, so those who were willing to hear and act on it could benefit. The divided, inconsistent messaging set up the disastrous fall and winter, when deaths peaked at well over 4,000 each day.

We will be examining the mistakes and missteps of 2020 for decades, probably centuries. This book will be one of the places future historians will start, if far from where they will finish. The epilogue expresses hopes that in the next pandemic, "the nation rallies together." Unfortunately the partisan divisions in the United States are deep, illustrated by reluctant vaccine uptake in Republican strongholds. This book will not change that, although it reminds us of the dangers of relying on policy-based evidence rather than evidence-based policy. You cannot intimidate an earthquake or bully a hurricane to do your bidding, and a virus cannot be fired.

Pandemics have a way of making history. From the Black Death to the 1918-19 flu to HIV, infectious-disease outbreaks convulse societies in

a way matched only by how readily humans forget them once they are over. Abutaleb and Paletta describe in sobering detail how the Trump White House chose to forget about the current pandemic while it was still going on.

William Hanage is an associate professor of epidemiology at the Center for Communicable Disease Dynamics at the Harvard T.H. Chan School of Public Health.

Wall Street Journal
Monday, June 28, 2021, page A7

Hospitals Strain Under Surge in Mental-Health Cases

By Robbie Whelan

PITTSBURGH -- Before the coronavirus pandemic took hold, psychiatrist Garrett Sparks usually treated about a dozen patients on his overnight shift in the emergency department at Western Psychiatric Hospital, this city's biggest mental-health hospital. On a recent Thursday evening, he saw 21 cases.

As the night began, an agitated man sitting on a couch in a space reserved for acute cases loudly demanded turkey sandwiches. Parents of a 7-year-old who had been kicked out of school for emotional outbursts came in, saying their child's behavior was spiraling and he was becoming more aggressive. A few hours later, police brought in a 17-year-old boy who had tried to commit suicide by jumping from a bridge.

"It seems like everyone has been holding their breath for a year, and now, it's just a total explosion of everything, both in terms of high volume but also the severity of cases," Dr. Sparks said. "You see a lot more people who were, pre-pandemic, kind of overwhelmed and stressed, and now they have full-on anxiety disorders or depression."

In the coronavirus pandemic, a wave of mental-health crises has grown into a tsunami. As the country appears to be emerging from the worst of the Covid-19 crisis, emergency departments say theyare overwhelmed by patients who deferred or couldn't access outpatient treatment, or whose symptoms intensified or went undiagnosed during the lockdowns.

Doctors say it could be years before we see the full impact of the pandemic on mental health, but a host of studies indicate how strained the system has become. Emergency visits for patients seeking help for overdoses and suicide attempts rose 36% and 26%, respectively, between mid-March and mid-October of last year, the U.S. Government Accountability Office said in March. U.S. Centers for Disease Control and Prevention surveys have found that 38% of respondents reported symptoms of anxiety or depression between April of last year and February, up from about 11% in 2019.

Children have been hit particularly hard. School closures have allowed serious mental-health issues to go unnoticed, because teachers and

school psychologists are a primary source of referrals, doctors say. Even before the pandemic, the country faced a shortage of mental-health professionals to serve juveniles; the American Academy of Pediatrics last year estimated the need for child psychiatrists at 47 per 100,000 people, roughly four times the number in practice.

Emergency-room visits for mental-health crises among 12- to 17-year-olds increased 31% between 2019 and 2020, the CDCreported in June. Among the same group, emergency-room visits for suspected suicide attempts rose 22% last summer compared with the previous year, and 39% this past winter compared with the previous winter.

At the University of Pittsburgh Medical Center, which includes Western Psychiatric, pediatric-outpatient volume surged 30% in the first four months of 2021 compared with the year earlier.

"We have more kids waiting for care than we ever have before," said Abigail Schlesinger, the hospital's chief of child and adolescent psychiatry. "We're in the mental-health emergency phase of this pandemic."

Mental-health crisis cases are ending up in emergency rooms in higher numbers in part because outpatient facilities, including private psychiatrists' offices, therapy practices and crisis centers, are saturated with patients whose mental-health problems have worsened during the pandemic, doctors and hospital administrators say.

"For us, it's definitely a lot of people who either had pre-existing conditions or have neglected to address their new onset of emotional imbalance," said Damir Huremovic, a psychiatrist at North Shore University Hospital on Long Island. "Many developed anxiety or insomnia, and they tried to see a provider but no one was taking new patients, and then things sort of just snowballed."

For patients dealing with depression, anxiety or eating disorders, physicians recommend getting out of the house, seeing people and establishing a normal routine, said Jeanne Noble, an emergency physician at the University of California, San Francisco.

"That's the exact opposite of what's happened with the school closures and lockdowns," Dr. Noble said.

The pandemic has taken its toll on mental-health providers, too. In his downtime, Dr. Sparks trains for marathons, listens to audiobooks, and sees a therapist to treat his own longstanding depression.

"You can only take so much when you're sleep-deprived, exhausted, and juggling other people's problems like balls on fire for so many nights in a row," he said.

CIDRAP News
Friday, June 25, 2021

ACIP approves dengue vaccine for endemic areas, tweaks flu vaccine advice

The vaccine advisory group to the Centers for Disease Control and Prevention (CDC) yesterday unanimously voted to recommend Sanofi's dengue vaccine (Dengvaxia) for children ages 9 to 16 years who live in areas such as Puerto Rico where the disease is endemic.

The vaccine is given in three doses and requires a test to confirm that a child has had a previous dengue infection. Vaccination in someone who has never been exposed to dengue before can lead to a more severe future infection through a phenomenon called antibody-dependent enhancement.

An Advisory Committee on Immunization Practices (ACIP) working group has been studying the issue and drafted the recommendation, which the whole group discussed and voted on yesterday, according to Stat. The experts acknowledged that the rollout of the vaccine would be challenging, owin to lab testing before vaccination. Also, members discussed challenges regarding provider access to tests to assess previous exposure to dengue and to ensure that kids receive all three doses. However, the group was swayed by the benefits and manageable risks.

The Food and Drug Administration (FDA) approved Dengvaxia in May 2019 for children ages 9 to 16 who have had at least one lab-confirmed dengue infection.

In separate discussions, ACIP fine-tuned its flu vaccine recommendations, according to American Academy of Pediatrics (AAP) News. The committee green-lighted co-administration with COVID-19 vaccines and added guidance about flu vaccine timing for certain groups--such as for children ideally by the end of October. Also, ACIP said nonpregnant adults should avoid immunization in July and August because of concerns over waning immunity, and women in their third trimester should be vaccinated as soon as the vaccine is available to protect their babies.

On another topic, the group said children receiving pre-exposure rabies vaccination can receive two rather than three doses, similar to a change recommended earlier this year for adults.

AP Maine
Sunday, June 27, 2021

CDC Gives Maine $7M To Prep For Future Public Health Crises

PORTLAND, Maine (AP) -- The federal government has given Maine a $7 million boost to help prepare for another public health crisis.

Republican Sen. Susan Collins and independent Sen. Angus King said the Maine Department of Health and Human Services has received the money from the U.S. Centers for Disease Control and Prevention. About $1.8 million of the money is for preventing and controlling emerging diseases and the rest is for preparing and responding to public health emergencies.

The senators said the state "must not lose sight of other public health initiatives that protect the health and safety of the community" while it continues responding to the coronavirus pandemic.

SILive.com
Monday, June 28, 2021

CDC: `Don't kiss or snuggle the birds;' Salmonella outbreak linked to more than 400 infections

By Joseph Ostapiuk | jostapiuk@siadvance.com

STATEN ISLAND, N.Y. -- The Centers for Disease Control and Prevention (CDC) said a salmonella outbreak linked to backyard poultry has now sickened nearly 500 people in the U.S.

The outbreak has caused 474 illnesses in 46 states, and more than 100 hospitalizations, the CDC announced late last week. One death has been reported in Indiana. Data from the agency shows that 15 people in New York have been sickened by salmonella germs.

Since May 20, the CDC said an additional 311 illnesses have been reported, and the agency said it is likely that the actual number of sick people is much higher, since many people recover without medical care and are not tested for salmonella.

About one-third of sick people are young children under the age of five, the CDC said.

Currently, backyard poultry is considered the "likely source" of the outbreak. Even if backyard poultry look clean, salmonella germs can spread in areas where the animals live and roam -- easily spreading from their environment to humans through physical contact.

To avoid infection, the CDC recommends washing your hands for 20 seconds after touching poultry or poultry supplies, and to also avoid letting children under the age of five touch the birds.

"Don't kiss or snuggle the birds, as this can spread germs to your mouth and make you sick," the CDC said.

Salmonella can cause a multi-day illness that includes diarrhea, fever and stomach cramps. Children under five and adults over the age of 65 are more susceptible to severe salmonella illness.

CIDRAP News
Friday, June 25, 2021

Backyard poultry Salmonella outbreak grows to 474 cases, 1 death

A US Salmonella outbreak linked to backyard poultry has grown by 311

cases, to 474 illnesses, and the CDC has reported the first outbreak death, according to a CDC update yesterday.

Three more states are affected (46 total) and a new serotype has been added (Salmonella Mbandaka) since the CDC's first notice of the outbreak on May 20, and 41% of isolates have shown some degree of antibiotic resistance, the agency noted. Of 334 people with information available, 103 (31%) have been hospitalized, up from 34 on May 20. An Indiana patient has died.

Illness-onset dates range from Dec 15, 2020, to Jun 4, 2021, and 58% of case-patients are female. Patient ages range from less than 1 to 97 years, with a median age of 31, and 139 patients (30%) are children younger than 5 years.

Of 271 people interviewed, 209 (77%) reported contact with backyard poultry before getting sick.

"Epidemiologic and laboratory data show that contact with backyard poultry is making people sick," the CDC says. "The true number of sick people in an outbreak is likely much higher than the number reported, and the outbreak may not be limited to the states with known illnesses."

The agency recommends no close contact, such as snuggling, with backyard poultry, and to buy the animals from hatcheries that take steps to reduce Salmonella. Those who raise backyard birds should always wash their hands with soap and water immediately after touching poultry, their eggs, or their surroundings.

Newsweek.com
Sunday, June 27, 2021

Whole Foods, Safeway and Other Stores Recall Shrimp for Salmonella Contamination

By Scott McDonald

Several lots of frozen cooked shrimp have been recalled nationwide at major grocers, including Whole Foods, Safeway, Meijer and Hannaford. The U.S. Food and Drug Administration (FDA) stated the recalled shrimp has been found to contain Salmonella contamination.

The eight recalled brands include Chicken of the Sea and the supermarket house brands.

The Centers for Disease Control and Prevention (CDC) stated that six people have been infected with the contamination so far--four in Nevada and two more in Arizona. There were two hospitalizations and zero deaths. The last onset illness was April 25.

All recalled shrimp were distributed by Avanti Frozen Foods of India, and the affected lots were distributed between December 2020 and February 2021.

Salmonella was first found in an import sample during January, the FDA stated. Though that particular sample was destroyed in March, illnesses began sprouting up in April from the contaminated lots sold three months earlier.

"As of (Friday, June 25), there are six clinical isolates from ill people that are genetic matches to the salmonella collected from the import sample. Five of the six ill people were interviewed to determine the foods they ate before becoming sick, and all five ill people report eating shrimp," the FDA stated.

The shrimp that caused the reported sicknesses have already passed their expiration dates and have been pulled from the shelves. Here are the affected products still on the shelves and their lot numbers:

* Censea, tail off -- 2-pound pouch; Codes 140313D, 140314D, 140315D, 140316D; expiration dates 5/7/2022 -- 5/10/2022.
* Chicken of the Sea, tail on -- 16-ounce tray; Codes 91AS/02UN/216 and 91AS/03UN/217; expiration dates 5/1/2022 and 5/2/2022.
* Honest Catch, tail on -- 1-pound pouch; Code 3150-GFF; expiration date 11/9/2022.
* CWNO, tail on -- 7-pound pouch; Codes 91AS/06UN/220D, 91AS/07UN/221C, 91AS/23HN/206B, 91AS/24HN/207; expiration dates 1/23/2022; 1/24/2022; 2/6/2022; and 2/7/2022.
* Hannaford, tail on -- 1-pound pouch; Codes. AVF 30920 EF and AVF 31020 EF; expiration dates 10/25/2022 and 10/26/2022.
* Waterfront Bistro (Safeway house brand), tail on -- 16-ounce tray; Codes 20305 and 20306; expiration dates 10/30/2022 and 10/31/2022.
* Open Acres, tail on -- 1-pound pouch; Code 02572 0307 11 and 02572 0308 11; expiration dates 11/2/2022 and 11/3/2022.
* 365 (Whole Foods store brand), tail on -- 2-pound pouch; Codes 91AS/29HN/212B and 91AS/30HN/213; expiration dates 4/29/2022 and 4/30/2022.
* Meijer, tail on -- 1-pound pouch; Codes 29720 49982, 29820 49982, 30220 50736, 30320 50736, 30520 49486, 30620 49486, 30920 50737, 31020 50737; expiration dates 10/22/2022, 10/23/2022, 10/27/2022, 10/28/2022, 10/30/2022, 10/31/2022, 11/3/2022, 11/4/2022.

Healthy people who come in contact with Salmonella could experience nausea, vomiting, diarrhea or bloody diarrhea, abdominal cramping and fever. More serious problems could include arterial infections, endocarditis, arthritis, muscle pain, eye irritation, and urinary tract symptoms.

Should any person have these symptoms after handling the product, they should contact their health care provider.

The CDC says that roughly 1.3 million people get sick on an annual basis from Salmonella contamination.. There are about 26,500 hospitalizations and 420 deaths annually.

CNN.com
Saturday, June 26, 2021

Avanti Frozen Foods recalls several shrimp products linked to salmonella outbreak

By Rachel Trent, CNN

(CNN)If you eat frozen cooked shrimp at home, you may want to check your freezer.

A salmonella outbreak has been linked to certain frozen cooked shrimp products distributed nationwide, according to the US Centers for Disease Control and Prevention.

Salmonella was found in a sample of Avanti Frozen Foods' shrimp collected as part of the FDA's Imported Seafood Compliance Program, the CDC said.

In a statement on the FDA website, Avanti said that out of "an abundance of caution" it recalled some of its frozen cooked shrimp products sold under the brand names 365, Censea, Chicken of the Sea, CWNO, Hannaford, Honest Catch, Meijer, Open Acres and Waterfront Bistro.

Six people got sick from this outbreak and two of those were hospitalized, according to the CDC. The agency says the illnesses happened in Nevada and Arizona, but the outbreak may have affected other states.

The products in question were distributed from late December to late February.

Only products bearing certain codes are affected by the recall. Anyone who has purchased one of those can return them to where they bought them for a refund.

Salmonella can cause fever, diarrhea, nausea, vomiting and abdominal pain, the FDA said. The organism can cause serious and sometimes deadly infections in young children, frail or elderly people, and others with weakened immune systems.

The CDC said symptoms usually start six hours to six days after swallowing the bacteria and most people recover without treatment after four to seven days.

Reuters
Sunday, June 27, 2021

UPDATE 1-Competing events make their marks on LGBTQ+ Pride Day in New York

By Peter Szekely

(Recasts to reflect that events have begun, adds details and comments)

NEW YORK, June 27 (Reuters) - For the second consecutive year, the

lingering pandemic consigned New York's annual Pride march to the virtual world on Sunday, even as its alter-ego, the Queer Liberation March, took its edgier message through the streets of Manhattan.

The NYC Pride march, the city's marquee LGBTQ+ event now in its 51st year, became a made-for-TV production as a cautionary measure to prevent coronavirus infections, which have dropped sharply as the number of people vaccinated has grown.

Only a small number of guests were invited to the group's three-block areas where floats and musical acts paraded for the cameras, but organizer Sue Doster said "something in the millions" of viewers were expected to tune in.

Guests included Brandon Wolf, a survivor of the June 2016 mass shooting at the Pulse, a gay nightclub in Orlando, Florida, who has since become an advocate for LGBTQ rights legislation.

"Six days after the shooting, we had a funeral service for my best friend and I made a promise to him that day that I would never stop fighting for a world that he would be proud of," he told ABC, which aired the event.

"We've made incredible progress in equality across the country, but trans people are under attack," he added.

HIV/AIDS expert Dr Demetre Daskalakis, one of the event's grand marshals, urged all LGBTQ+ community members to get tested frequently for the virus.

"At the end of the day, HIV is just a virus, and we have the ability to prevent it and to treat it," said Daskalakis, who is director of the Division of HIV/AIDS Prevention at the Centers for Disease Control and Prevention.

MARCHING FOR 'LIBERATION AND JUSTICE'

Meanwhile, thousands of people organized by the Reclaim Pride Coalition, whose parade began as a protest to the Pride march two years ago, marched more than 30 blocks down New York's Seventh Avenue with rainbow flags and signs that included "Liberation and Justice."

Coalition cofounder Jay W. Walker said the group was hoping to draw up to 70,000 marchers.

Under sunny skies with muggy conditions that felt like 90 degrees Fahrenheit (32 degrees Celsius), a racially mixed crowd of men and women chanted "No Justice, No Peace," and other slogans, some critical of the New York Police Department.

After linking last year's message to the Black Lives Matter movement, Walker said this year's theme is returning to the coalition's standard: "None of us are free until all of us are free."

Although the group had urged marchers to wear masks, few did. Last year's march produced no discernable spike in new coronavirus cases, he

said.

Both events commemorate the June 28, 1969, uprising at the Stonewall Inn, a gay bar in Manhattan's Greenwich Village, when patrons fought back during a police raid. The defiant stand gave birth to the modern LGBTQ rights movement.

The two groups have differed over their policies on police participation in their events, which the Reclaim Pride Coalition opposes. But Heritage of Pride last month also decided to bar uniformed police officers from its future parades. Doster said many of its Black, brown and trans members feel threatened by their presence. (Reporting by Peter Szekely in New York Editing by Grant McCool and Matthew Lewis)

AP West Virginia
Saturday, June 26, 2021

HIV SOS: Action Sought For Spike In Cases In West Virginia

By JOHN RABY
Associated Press

CHARLESTON, W.Va. (AP) -- Dozens of volunteers formed the letters "HIV SOS" at a health event Saturday as activists seek a public health emergency declaration in a city with one of the nation's highest spikes of such cases.

Kanawha County, which includes Charleston and has 178,000 residents, had two intravenous drug-related HIV cases in 2018. The number grew to 15 in 2019 and 39 last year, according to state data. There have been 14 such cases so far in 2021.

After volunteers wearing red T-shirts formed the plea for help along the Kanawha River near downtown Charleston, Joe Solomon, co-founder of the nonprofit group Solutions Oriented Addiction Response, called on the City Council and Mayor Amy Shuler Goodwin to act on the HIV crisis and overdoses from prescription pain pills.

"In Charleston and Kanawha County, there's a family butchered by the overdose crisis every other day," Solomon said. "All we're asking is for (them) to take one day to declare a public health emergency. We need to treat this like the emergency that it is."

Earlier this year, Dr. Demetre Daskalakis, the CDC's chief of HIV prevention at the Centers for Disease Control and Prevention, called Kanawha County's outbreak "the most concerning in the United States." He warned it could take years to address the surge and that the case count possibly "represents the tip of the iceberg."

Earlier this week the CDC presented preliminary findings of an investigatio n that showed emergency departments and inpatient medical personnel in Kanawha County rarely conducted HIV testing on intravenous drug users.

Republican Gov. Jim Justice in April signed a bill to introduce more stringent requirements to needle exchange programs like those offered by Solomon's group. The move came over the objections of critics who said it would restrict access to clean needles amid the spike in HIV cases.

The bill requires licenses for syringe collection and distribution programs. Operators would have to offer an array of health outreach services, including overdose prevention education and substance abuse treatment program referrals. Participants also must show an identification card to get a syringe. Advocates view the regulations as onerous.

The American Civil Liberties Union on Friday filed a lawsuit challenging the new law.

AP West Virginia
Friday, June 25, 2021

ACLU In West Virginia Sues Over Needle Exchange Law

CHARLESTON, W.Va. (AP) -- The American Civil Liberties Union of West Virginia on Friday filed a lawsuit opposing a law that would instate stringent requirements on needle exchange programs in the state.

Republican Gov. Jim Justice signed the bill in April over the objections of critics who said it will restrict access to clean needles amid a spike in HIV cases.

The bill requires licenses for syringe collection and distribution programs. Operators would have to offer an array of health outreach services, including overdose prevention education and substance abuse treatment program referrals. Participants also must show an identification card to get a syringe. Advocates see the regulations as onerous.

Supporters said the legislation would help those addicted to opioids get connected to health care services fighting substance abuse. Some Republicans lawmakers had said the changes were necessary because some needle exchange programs were "operating so irresponsibly" that they were causing syringe litter.

The ACLU-WV went to court to prevent it from taking effect on July 9.

The group called it "one of the most restrictive state laws governing syringe exchange services in the nation" and that it would likely lead to more HIV cases and the spread of other bloodborne illnesses.

The restrictions "will cost lives and deprive West Virginians of numerous constitutional rights, including due process and equal protection among others," ACLU-WV legal director Loree Stark said in a statement. "The bill should be declared unconstitutional and stopped."

The governor's office did not return an email seeking comment.

The law would take effect amid one of the nation's highest spikes in HIV cases related to intravenous drug use. The surge, clustered primarily around the capital of Charleston and the city of Huntington, is being attributed at least in part to the cancellation in 2018 of a needle exchange program.

It led to an investigation by the Centers for Disease Control and Prevention that this week found emergency departments and inpatient medical personnel rarely conducted HIV testing on intravenous drug users in Kanawha County.

Previously, city leaders and first responders complained that the program in Kanawha County led to an increase in needles being left in public places and abandoned buildings, and it was shut down.

The CDC describes syringe programs as "safe, effective, and cost-saving."

New York Times
Sunday, June 27, 2021, page A25

Johnson & Johnson to Pay $230 Million as Part of Exit From Opioid Industry

The settlement agreement came just days before opening arguments in a sweeping trial of several defendants, including the company.

By Sarah Maslin Nir

Johnson & Johnson will pay New York State more than $230 million in a settlement that also ensures the company will permanently stay out of the opioid business in the United States, the state attorney general's office announced on Saturday.

The settlement comes at a time when the opioid industry is facing over 3,000 lawsuits across the nation for its contribution to an epidemic of prescription and street opioid abuse that has killed more than 800,000 Americans in the last 20 years, according to the Centers for Disease Control and Prevention.

And it came just days before opening arguments in a sweeping New York trial in which the company was to be among the defendants. That trial will be the first of its kind to go before a jury, and the first to target the entire opioid supply chain, from the drugmakers who manufactured the pills to the distributors that supplied them to a pharmacy chain that filled prescriptions for them.

"The opioid epidemic has wreaked havoc on countless communities across New York State and the rest of the nation, leaving millions still addicted to dangerous and deadly opioids," Attorney General Letitia James said in a statement. "Johnson & Johnson helped fuel this fire, but today they're committing to leaving the opioid business -- not only in New York, but across the entire country."

In a statement, Johnson & Johnson said that the settlement was not an admission of liability or wrongdoing and that "the company's actions relating to the marketing and promotion of important prescription pain medications were appropriate and responsible."

It has not sold opioids in the United States since last year, when it ceased production of its last opioid product; and it stopped supplying opioid ingredients to other manufacturers in 2016.

Johnson & Johnson is the parent company of Janssen Pharmaceutical Companies, one of the defendants in the New York trial that will be removed from the case because of the settlement. The company will also pay an additional $33 million as reimbursement for New York's attorney fees and costs. The payments for the total will be made over nine years.

The money is not intended to compensate people harmed by the opioid crisis, but rather for what is known as abatement, mitigating harm and preventing future crises with things like education and addiction treatment programs.

The funds will be distributed to the counties subject to an allocation agreement with the state that is currently being finalized, according to Jayne Conroy, lawyer with Simmons Hanly Conroy, who is representing Suffolk County in the case.

The sprawling opioid case about to begin in New York was filed by the attorney general and by Nassau and Suffolk Counties on Long Island, and is being argued jointly. It includes claims that the companies, like Janssen, misled the public by initially denying the drugs were highly addictive, and aggressively marketed them as such, ignoring warnings of abuse as they chased profits.

The drugs that Janssen developed included a fentanyl patch and a tablet that was crush-resistant, marketed under names like Duragesic and Nucynta, which, according to Johnson & Johnson, accounted for less than one percent of total opioid prescriptions in the United States. It stopped marketing its opioids in 2016 in the United States and later discontinued the fentanyl patch. In 2020, it ceased production of the pill in the United States as well.

For years, Johnson & Johnson had supplied 60 percent of the ingredients that make opioids to companies that used them to make drugs like Oxycodone, contracting with poppy growers in Tasmania. In 2016, they sold the business that supplied the materials.

Johnson & Johnson has struggled under waves of bad publicity. It suffered a defeat in an opioid trial in 2019 when an Oklahoma judge ordered it to pay the state $465 million for its role in the public nuisance created by opioid addiction. It has been ordered to pay millions in courts that have found products like its talcum powder and hip implants to be harmful. Most recently, its coronavirus vaccine has been plagued by a troubled rollout.

The one-shot vaccine was initially seen as a vital tool in combating Covid-19, the disease caused by the coronavirus. But a host of concerns

with production and the drug itself has seen the company's product account for just about 12 million of the more than 320 million doses administered in the United States so far, according to C.D.C. data.

In April, federal health officials paused use of the Johnson & Johnson vaccine after cases of a rare blood-clotting disorder emerged as a side effect. In June, a mix-up in a Baltimore factory resulted in the government ordering the disposal of 60 million potentially contaminated vaccine doses.

The exit of Johnson & Johnson from the New York case means that two of the country's biggest drugmakers will now be absent from the trial when opening arguments begin on Tuesday. Purdue Pharma, the maker of OxyContin, owned by members of the billionaire Sackler family and the company most publicly linked to the opioid epidemic, is also no longer standing trial.

Though initially named in the case, as were some individual Sacklers, Purdue filed for bankruptcy nearly two years ago as it faced thousands of opioid-related lawsuits. The bankruptcy process has paused cases against the drugmaker and the Sacklers.

In addition, in the weeks before opening arguments were to be made before a six-person jury and a New York Supreme Court justice, Jerry Garguilo, three of the four pharmacy chains -- Walmart Inc., Rite Aid Corp. and CVS -- were severed from the case; one of them, CVS, confirmed it had reached a settlement agreement with the counties, the terms of which are not yet final and public. Walmart and Rite Aid did not respond to emails requesting comment.

Walgreens remains one of the defendants that will face a jury next week.

Ms. Conroy, who is representing Suffolk County, cautioned that Saturday's announcement did not mark the end of the case. "While this settlement is good news, there still remains a crucially important trial starting next week," she said in a statement.

"We remain focused on ensuring the other defendants who played a major role in creating the opioid crisis are held accountable for their actions," she said.

Jan Hoffman contributed reporting.

CNN.com
Saturday, June 26, 2021

Johnson & Johnson settles New York opioid suit in $230 million deal

By Danielle Wiener-Bronner, CNN Business

New York (CNN Business)Johnson & Johnson has agreed to a $230 million settlement with New York state, resolving complaints from the state's attorney general over the pharmaceutical company's role in the opioid

epidemic.

"Johnson & Johnson helped fuel this fire," New York Attorney General Letitia James said in a statement Saturday. "While no amount of money will ever compensate for the thousands who lost their lives or became addicted to opioids across our state ... these funds will be used to prevent any future devastation."

The settlement money will go toward opioid education, prevention and treatment, James added. Johnson & Johnson is set to pay out the funds over the course of nine years. The company may also be responsible for another $30 million if New York passes a law that creates an opioid settlement fund.

In a statement, Johnson & Johnson (JNJ) said that "the settlement is not an admission of liability or wrongdoing," adding that it "remains committed to providing certainty for involved parties and critical assistance for communities in need."

The settlement also prevents Johnson & Johnson from manufacturing or selling opioids in the state, or promoting opioids or opioid-related products. The company had already decided to discontinue the production and sale of pain medication in the United States last year, a spokesperson said.

About 247,000 people died from overdoses involving prescription opioids in the United States from 1999 to 2019, according to the Centers for Disease Control and Prevention. The crisis has had a financial toll, as well -- a notice of claim filed last summer in bankruptcy court by nearly every US state and many territories said that opioid manufacturers have cost the American economy $2.15 trillion.

A New York lawsuit against the makers and distributors of opioids is going to trial next week. Johnson & Johnson was set to be a defendant but will no longer be a part of the trial due to the settlement agreement.

News of the settlement comes as lawsuits against major pharmaceutical companies over their role in the opioid epidemic play out in court. In May, a landmark trial involving three major prescription opioid distributors began in federal court in West Virginia. California's trial against opioid manufacturers began in April.

-- CNN's Lauren del Valle contributed to this report.

Reuters
Saturday, June 26, 2021

UPDATE 1-J&J to pay $263 mln in New York opioid settlements, avoids trial

By Jonathan Stempel

(Adds details of settlements, upcoming trial, New York attorney general comment, background)

NEW YORK, June 26 (Reuters) - Johnson & Johnson said on Saturday it will pay $263 million to resolve claims it fueled an opioid epidemic in New York state and two of its largest counties.

The settlements remove the drugmaker from a jury trial scheduled to begin on Tuesday on Long Island, where several big opioid makers and distributors are also defendants.

Johnson & Johnson did not admit liability or wrongdoing in settling with New York state, and with Nassau and Suffolk counties. The $229.9 million state settlement also calls for J&J to stop selling the painkillers nationwide.

"The opioid epidemic has wreaked havoc" across the nation, New York Attorney General Letitia James said in a statement. "Johnson & Johnson helped fuel this fire."

She said her focus remains "getting funds into communities devastated by opioids as quickly as possible."

J&J said the settlements were consistent with its prior agreement to pay $5 billion to settle opioid claims by states, cities, counties and tribal governments nationwide.

The healthcare company and the largest U.S. drug distributors - AmerisourceBergen Corp, Cardinal Health Inc and McKesson Corp - have proposed paying a combined $26 billion to end thousands of opioid lawsuits.

J&J has also been appealing an Oklahoma judge's 2019 ruling that the New Brunswick, New Jersey-based company pay that state $465 million for its deceptive marketing of opioids.

Tuesday's opioids trial is one of several scheduled for this year, with others underway in California and West Virginia.

Drugmakers AbbVie Inc and Teva Pharmaceutical Industries Ltd and several distributors are among the defendants. Pharmacy chain Walgreens Boots Alliance Inc is also a defendant, though it was sued only by the counties.

Walmart Inc, Rite Aid Corp and CVS Health Corp were severed from the trial during jury selection. CVS has settled with Nassau and Suffolk counties. Settlement terms have not been disclosed.

The U.S. Centers for Disease Control and Prevention has said nearly 500,000 people died from opioid overdoses from 1999 to 2019. (Reporting by Jonathan Stempel in New York; Additional reporting by Nate Raymond in Boston; Editing by Bill Berkrot)

Los Angeles Times
Monday, June 28, 2021, page A2

For Native Americans, clean water is rare

Crumbling pipes and faulty sanitation systems leave many on reservations struggling for access

By Celina Tebor

When the clean water system failed last week at the Warm Springs Reservation in Oregon, thousands of residents relied on members of nearby communities to come to their aid with bottled water.

It was not the first time clean water had been difficult to find at Warm Springs, two hours southeast of Portland, or at many other Native American reservations across the United States.

The nonprofit U.S. Water Alliance says 58 out of every 1,000 Native American households lack access to indoor plumbing.

Many Native American communities don't have access to clean water because of faulty, outdated or nonexistent pipes or sanitation systems that result in residents being forced to use bottled water or to boil water to kill viruses, bacteria and parasites.

Sen. Ron Wyden (D-Ore.) in February introduced a bill aimed at funding facilities for drinking water and sanitation in tribal communities. The bill calls for the Environmental Protection Agency to connect, expand or repair public water systems on reservations, at a cost of about $150 million by 2026.

" 'Boil water' notices and crumbling pipes are not acceptable," Wyden said during Interior Secretary Deb Haaland's nomination hearing. "Congress must do more to bring urgently needed resources to build sustainable tribal water infrastructure that has been neglected for far too long."

About 130,150 out of 409,535 homes of Native Americans surveyed by the government organization Indian Health Service needed sanitation facility improvements involving water, sewer or solid waste systems at the end of fiscal year 2018. The cost to improve those systems is estimated at $2.67 billion, according to the IHS.

In the 1960s, the federal government funded sanitation programs for tribes after the general American public began to become aware of poor living conditions on reservations.

The Sanitation Facilities Construction Act, passed in 1959, led to a sharp decrease in gastrointestinal and infectious respiratory disease in both Native American infants and white infants who lived near reservations, according to a Journal of Public Economics study.

According to the U.S. Water Alliance, Native American households are 19 times more likely than white households to lack indoor plumbing. Black and Latino households are twice as likely as white households to lack indoor plumbing.

Federal funding for reservations is not meeting needs, said Randall

Akee, a UCLA professor of public policy and American Indian studies and chair of the university's America Indian Studies Interdepartmental Program.

"It's just woefully underfunded at the federal level, and tribes for a long, long time have not had the resources to fully develop these resources themselves," Akee said. "And frankly, it's a responsibility of the federal government -- a trust responsibility of treaties and hundreds of years of commitments. There has been a failure to fully live up to those commitments."

A problem for tribes across the U.S.

The Hopi tribe in Arizona has up to three times the amount of arsenic in its water that the EPA says is safe to drink. Many Native households in rural Alaska use a 5-gallon bucket as a toilet because they don't have running water. And the Navajo Nation, the biggest reservation in the U.S., faces a diabetes crisis because soda is more accessible and cheaper than clean drinking water.

Bidtah Becker is a member of the Navajo Nation, which spans northeastern Arizona, southeastern Utah and northwestern New Mexico. She helped lead a report on access to clean water for tribes in the Colorado River Basin and has studied its effects on her own community and other tribes. She estimates that 30% to 40% of homes on the Navajo Nation lack piped water.

The federal Centers for Disease Control and Prevention and the Alaska Native Tribal Health Consortium have found links between low water service and respiratory infections. Studies from the CDC, the consortium and the IHS have also found links between a lack of access to clean water and skin and gastric infections.

"The other thing that people often don't think of with access to clean water is that it affects the economics of your community," Becker said. "If you don't have pipes to go to homes, you don't have pipes to go to laundromats or gas stations or stores. Clean water is integral to creating a healthy economy."

The cost of new infrastructure

Almost one-quarter of Native Americans lived below the poverty level in 2019, and fixing or building water infrastructure isn't cheap, nor is it easy or quick.

The IHS determined that there were 130,153 homes needing sanitation improvements in Native American communities at the end of fiscal year 2018 and identified 1,837 communitywide projects to assist those homes. The agency aims to bring sanitation systems to a level that complies with laws for water supplies and pollution control while requiring only routine maintenance.

About 28% of these projects are considered "infeasible" by the government, because they're too expensive. The IHS estimates the cost of all feasible projects across the country at $985 million.

According to the IHS report, the cost to bring sanitation to this level in Alaska was higher than the cost in every other community combined, at nearly $1.4 billion (for feasible and infeasible projects). Alaska is home to two-thirds of the nation's federally recognized tribes, with 229. Almost 16% of the state's population is American Indian or Alaska Native.

Jackie Qatalina Schaeffer is the community development manager for the tribal health Consortium's Division of Environmental Health and Engineering. Her role at the nonprofit is to work with rural Alaskan tribes, helping them access water and sanitation services.

Communities that don't have those services typically have access to a central watering point consisting of a hose connected to a building that provides showers, utility sinks andsometimes commercial washers and dryers, Qatalina Schaeffer said.

Residents can collect clean drinking water at the watering point, she said. They then haul the water by ATV, snowmobile or hand to their homes. They use either an outhouse or a "honey bucket," a 5-gallon bucket with a lid, as a toilet.

The average rural Alaskan living without piped water uses 3 gallons of water a day for bathing, drinking and cooking, compared with 156 for the average American.

Alaska's rural villages present particular challenges when it comes to providing water and sanitation systems.

"In Alaska, rural is not just 'away from a city,' " Qatalina Schaeffer said. "Rural is disconnected by any road systems. The only access to these communities is via small aircraft."

The average rural Alaskan village has a population of 400 to 500. It costs $40 million to $60 million to implement a communitywide water and sanitation system. While the infrastructure is often funded by the government, the burden of operation and maintenance falls on the community -- a burden most cannot afford.

Community support when pipes fail

Dan Martinez, emergency manager at Warm Springs, said the reservation's entire water system needs to be overhauled, at a cost of about $40 million. And while the federal and state governments provide emergency funds to the reservation, those often cover only the cost of quick fixes to a water system that he said needs to be rebuilt from the ground up.

While the reservation works toward a long-term solution for its water issues, Warm Springs relies on neighbors to help when the pipes fail.

"We rely on donated water from outside sources, which has been something that's happening on a daily basis," Martinez said. "We rely not so much on the government but on our neighbors and religious groups and donations from outside sources to give out drinking water."

Gilbert Brown, who grew up on the north end of the reservation and now lives in Portland, helps haul water donations from a Portland coffee shop to Warm Springs.

"Last year, the pipes kept breaking, and [the reservation] kept going on boil notices," he said. "People had to come bring water, and I was asked to help. And here we are again."

New York Times
Saturday, June 26, 2021, page A19

Correction

An article on June 20 about the Centers for Disease Control and Prevention misidentified the act of Congress that funded electronic medical-record systems. It was the American Recovery and Reinvestment Act of 2009, not the Affordable Care Act of 2010.

From: Walensky, Rochelle (CDC/OD)
Sent: Tue, 29 Jun 2021 01:27:26 +0000
To: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Cc: Berger, Sherri (CDC/OCOO/OD);Schuchat, Anne MD (CDC/OD);Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI)
Subject: RE: Monday TODAY'S NEWS

Super, thank you much, Henry.
R

-----Original Message-----
From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Monday, June 28, 2021 9:26 PM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>
Subject: FW: Monday TODAY'S NEWS

-----Original Message-----
From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>
Sent: Monday, June 28, 2021 10:43 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>
Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD) <akc9@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>
Subject: RE: Monday TODAY'S NEWS

Henry -

The case had been reported to VAERS. CDC has spoken with ME, but we are following protocol for f/u re the case. Additionally, CDC remains in contact with MI and has offered to assist in the investigation.

Best,
David
-----Original Message-----
From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Monday, June 28, 2021 10:02 AM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>
Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD) <akc9@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>
Subject: FW: Monday TODAY'S NEWS

Any details on cdc engagement?

-----Original Message-----
From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Sent: Monday, June 28, 2021 10:00 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>

Subject: FW: Monday TODAY'S NEWS

Any details on this?

CDC reportedly probing Michigan teen's death after COVID-19 vaccination

By Shen Wu Tan - The Washington Times

Federal health officials are investigating the case of a Michigan teenager who died days after he received a COVID-19 vaccine, Fox News reported Friday.

The 13-year-old boy died three days after getting a second dose of a COVID-19 vaccine, the Saginaw County Health Department told the news agency in a statement. The department learned of the teenager's death on June 17.

"The investigation as to whether there is a correlation between his death and vaccination is now at the federal level with [the Centers for Disease Control and Prevention," the health department said. "Meanwhile, the health department continues to encourage families to speak with their physicians to weigh their own risks and benefits of vaccination."

It is unknown whether the teenage boy had previous health problems. The news report did not specify whether the teenager received the two-dose Pfizer-BioNTech COVID-19 vaccine or the Moderna vaccine. The death has been supposedly reported to the Vaccine Adverse Event Reporting System (VAERS), a national surveillance system.

Neither the CDC nor the Saginaw County Health Department immediately responded to requests for comment.

CDC officials say deaths following COVID-19 vaccinations have been rare. More than 318 million COVID-19 doses were administered in the U.S. from Dec. 14 through June 21, and about 5,400 deaths, or 0.0017%, among those vaccinated were reported to VAERS during that time.

"Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. A review of available clinical information, including death certificates, autopsy and medical records, has not established a causal link to COVID-19 vaccines," the CDC says on its website.

However, there could be a "plausible causal relationship" between the one-shot Johnson & Johnson COVID-19 vaccine and a rare, serious blood clotting condition, which has caused deaths.

Health care providers are required by the Food and Drug Administration to report any death after a COVID-19 vaccination to VAERS.

-----Original Message-----
From: Mike Cooper <mcooper@panix.com>
Sent: Monday, June 28, 2021 9:51 AM
To: cdc@panix.com

Subject: Monday TODAY'S NEWS

TODAY'S NEWS

MONDAY, JUNE 28, 2021

CDC Director Rochelle Walensky On Coronavirus Variants And Vaccinations, National Public Radio

Half of public health workers experiencing mental health strain: study; TheHill.com

CDC says roughly 4,100 people have been hospitalized or died with Covid breakthrough infections after vaccination, CNBC.com

U.S. FDA adds warning about rare heart inflammation to Pfizer, Moderna COVID vaccines; Reuters

Vaccine-associated myocarditis tends to resolve quickly, Reuters

CDC reportedly probing Michigan teen's death after COVID-19 vaccination, WashingtonTimes.om

Bipartisan senators ask CDC, TSA when they will update mask guidance for travelers; TheHill.com

U.S. Senate Republicans press CDC to end mask mandate on airplanes, transit; Reuters

Ted Cruz joins forces with other GOP lawmakers to call for an end to mask mandates for vaccinated travelers, ahead of Independence Day; BusinessInsider.com

Senate Republicans urge CDC to lift public transportation mask mandate, TheHill.com

Ted Cruz Urges Joe Biden to 'Follow the Science' and End Travel Mask Requirement, Newsweek.com

Georgia State Looks To Boost Vaccine Rate Among Refugees, AP Georgia

U.S. average daily COVID-19 vaccination drops by over 50 pct: CDC; Xinhua

U.S. reaches 323 million doses of COVID-19 vaccine administered -CDC, Reuters

CDC reports 4,115 breakthrough COVID-19 cases involving hospitalizations or deaths, FoxNews.com

Some fully vaccinated people may still get sick if exposed to variants, CDC warns; CNN.com

Booster may be needed for J&J shot as Delta variant spreads, some experts already taking them; Reuters

'Please get your second shot,' top health official urges as Delta variant remains a pressing threat; CNN.com

States Hesitant To Adopt Digital Covid Vaccine Verification, Associated Press

`A tough slog': White House struggles to increase vaccination rates as Delta variant surges; Politico.com

Wisconsin's Johnson To Tout Claims Of Vaccine Side Effects, AP Wisconsin

Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic, research finds; CNN.com

1st Post-Pandemic Cruise Ship From US Sails Away, Associated Press

How the first cruise of the Covid era got ready to safely set sail, CNN.com

Virus-Origin Review Likely to Be Unclear, Wall Street Journal

What We Know About the Origins of Covid-19, WSJ.com

The US is concealing its research on deadly viruses -- while criticizing China's secrecy over the Wuhan lab, BusinessInsider.com

Why US labs need to be investigated for COVID-19 origins, Global Times

Celebrity Cruises to Be First to Resume Sailing From U.S., New York Times

Harris Seeks Nuance On Migration Debate During Tour of Border, New York Times

Harris views immigration problems up close, Los Angeles Times

CDC director Robert Redfield 'prayed' Trump would understand how serious COVID-19 was after contracting it, a book excerpt says; BusinessInsider.com

How Trump's blunders fueled our coronavirus nightmare, Washington Post

Hospitals Strain Under Surge in Mental-Health Cases, Wall Street Journal

ACIP approves dengue vaccine for endemic areas, tweaks flu vaccine advice; CIDRAP News

CDC Gives Maine $7M To Prep For Future Public Health Crises, AP Maine

CDC: `Don't kiss or snuggle the birds;' Salmonella outbreak linked to more than 400 infections; SILive.com

Backyard poultry Salmonella outbreak grows to 474 cases, 1 death; CIDRAP News

Avanti Frozen Foods recalls several shrimp products linked to salmonella outbreak, CNN.com

Competing events make their marks on LGBTQ+ Pride Day in New York, Reuters

HIV SOS: Action Sought For Spike In Cases In West Virginia; AP West Virginia

ACLU In West Virginia Sues Over Needle Exchange Law, AP West Virginia

Johnson & Johnson to Pay $230 Million as Part of Exit From Opioid Industry, New York Times

Johnson & Johnson settles New York opioid suit in $230 million deal, CNN.com

J&J to pay $263 mln in New York opioid settlements, avoids trial; Reuters

For Native Americans, clean water is rare; Los Angeles Times

Correction, New York Times

National Public Radio
Friday, June 25, 2021

CDC Director Rochelle Walensky On Coronavirus Variants And Vaccinations

NPR's Audie Cornish checks in with Centers for Disease Control and Prevention Director Dr. Rochelle Walensky about vaccinations, variants and the current state of the pandemic.

AUDIE CORNISH, HOST:

Fifty thousand baseball fans showed up to see the Dodgers play the Phillies last week. The Foo Fighters drew a full-capacity crowd, all vaccinated, to New York's Madison Square Garden on Sunday. And tomorrow, the first major cruise ship will set sail from Fort Lauderdale. Even as the nation returns to life as it once was, thousands of people are still dying of COVID every week. And in unvaccinated pockets of the country, the delta variant of the virus is taking hold. So here to talk about the challenges that remain, Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention. Welcome back to ALL THINGS CONSIDERED.

ROCHELLE WALENSKY: Thanks so much, Audie. Great to be here.

CORNISH: I want to talk about that delta variant. It's more contagious - potentially more dangerous strain of the coronavirus. But more importantly, it makes up to 20% of cases nationwide at this point. And that's doubled in just a few weeks. So what's your concern as this is beginning to spread?

WALENSKY: Yeah, that's exactly right. So we have been doing genomic surveillance now for a while and have a really good window as to the variants that are circulating here in the United States. About a month ago, we were seeing the delta variant at about 2- to 3%. Two weeks ago, we were seeing it at about 9- to 10%. And this last...

CORNISH: And this is assuming that we're - the testing is good enough that we know the true infection rate. I mean, do you think that's the case?

WALENSKY: Oh, that's a really good point. We have scaled up our genomic sequencing in an extraordinary fashion just in the last six months. So I do believe that we're sequencing enough to have quite a good window as to what's going on here in this country. And more recently, our - we're seeing that the delta variant makes up about 20% of virus circulating and up to 30-, 40-, 50% in some regions of the United States.

As you noted, the things that we worry about with this variant specifically is not only how quickly it is scaling up - and what we've seen in the U.K. is, you know, it really has taken over as the predominant variant, which I expect to happen - but it really is more transmissible. And early data actually suggest it may actually lead to more severe disease as well.

CORNISH: So what's your concern when you look at, say, vaccination rates among people under the age of 25? How do you convince those groups in particular that they're still vulnerable?

WALENSKY: Well, you know, anybody is vulnerable to coronavirus. And so we really do need to make sure that we get vaccine to people who are unvaccinated. We do know that younger people have not had as long of an opportunity to be vaccinated as our older people who were eligible first. And what we really do need to do is figure out ways to talk to these young folks and ensure that they understand, not just about the severity of the disease, about the morbidity and mortality related to the disease, but about the implications of long COVID.

You know, what we have seen and the data have shown us is that the young folks are not getting hospitalized or die at the same rate of older people. But young people shouldn't die at the same rate of older people. And we do have - we have seen, for example, just in the last month that there have been over 300 deaths among people ages 20 to - 12 to 29. And that is - that shouldn't happen in that demographic, which is why we really want to get people vaccinated.

CORNISH: I want to jump in here because it's not just about the vaccinated people. Studies in England - the unvaccinated, I mean. Because there are studies in England that have shown one shot isn't enough to give full protection against the delta variant. And there's some - I think I'm reading 27 million people in the U.S. who are still only half vaccinated; either still waiting for their second shot or who maybe decided one shot was enough. What's your message to them?

WALENSKY: Right. So thank you for raising that. My message is to please get your second shot. So what we do know is you get some protection from the first shot. But really, that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this delta variant and other variants as well. And as you note, data from the U.K. show that one shot is really not working as well to stave off, especially, the delta variant and you really do need that second shot. So we are really encouraging people not only to get their first, but to get their second. And if you didn't, if you missed your second within the time window, get it whenever - get it now. But do get that second shot.

CORNISH: Is it clear how helpful that is? When you look at a country like Israel, where the variant accounts for 90% of new cases there - in cases where people had been fully vaccinated with the Pfizer vaccine. I mean, they reimposed indoor mask requirements. Looking at our map, we've got states that aren't doing that now. So what are your concerns?

WALENSKY: So I do think we have more to learn about this delta variant, but here's what I'll say. It is the case that if you're vaccinated, we believe you actually have quite good protection against the delta variant. But nothing is foolproof. What we do know is that if you have been vaccinated, you are far less likely to have severe disease, to have - to result in death and also to be able to transmit to others. So yes, perhaps we're seeing breakthrough infections at a higher rate than we would like to see, but we're also seeing that if you've been vaccinated, you have less severe disease, less transmission and less death.

CORNISH: President Biden has said the variant is unlikely to force the U.S. into another lockdown situation. Looking at a state like, say,

Missouri that has low vaccination numbers and climbing cases, are you guys going to be urging local leaders to put mask mandates back in place or social distancing requirements back in place?

WALENSKY: Right. So that's a really great question. We are encouraging all local areas to look at their vaccination rates, to look at the case rates and to make their policies that - with those both in mind. It may very well...

CORNISH: So if they've got no mask mandate or no social distancing and they're like, we've only got a few people in the hospital but a low vaccination rate, is that a recipe that you want?

WALENSKY: Well, that would be - if you have low cases, then the answer there is to make sure you scale up your vaccination rates. If you also have high cases, then we might encourage states to take the mitigation strategies that we know work to decrease the number of cases and increase the vaccination rate. For the most part, CDC has said since its initial mask guidance for fully vaccinated people that if you are not vaccinated, you should continue the standard mitigation strategies - distancing, handwashing and masking - that we know work to protect people.

CORNISH: In our final few seconds - even if you wanted to, do you think you could convince anyone to go back into lockdown? I mean, politically, it was tough.

WALENSKY: Yeah. I think my job is to make sure that the public is safe. And so we have many strategies, many tools in our toolbox now to be able to do that. Vaccine is certainly one of them. And I think we have continued work ahead of us to get into these communities and to let people - give people the information they need so that they know vaccine is the best protection for them.

CORNISH: That's Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention. Thank you for your time.

WALENSKY: Thanks so much.

(SOUNDBITE OF NATIONAL AIR AND SPACE MUSEUM, DIPLO, AND HRISHIKESH HIRWAY'S SONG, "MOTION MMXX -- I")

TheHill.com
Friday, June 25, 2021

Half of public health workers experiencing mental health strain: study

By Reid Wilson

More than half of public health workers reported experiencing symptoms of mental health conditions, according to a new study, a toll that disproportionately falls on those who spent most of their time treating patients suffering from COVID-19.

The study, to be published in the Centers for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report, found nearly a third of the 26,000 health care workers polled suffered from symptoms of depression in the last two weeks. Three in 10 reported suffering from anxiety, and more than a third say they have experienced symptoms of post-traumatic stress disorder (PTSD).

Eight percent, or about one in twelve, told researchers they experienced suicidal ideation.

All of the mental health conditions were more prevalent among public health workers under the age of 29, among those who worked more than 60 hours per week and among those who reported they were unable to take time off work.

The symptoms were particularly pronounced among those who spent most of their time in COVID-19 wards. Among public health workers who spent three-quarters of their time responding to the pandemic, nearly half reported symptoms of PTSD within the last two weeks alone and more than a third reported signs of depression and anxiety.

The CDC researchers said stress-inducing events like the coronavirus pandemic can undermine the public health workforce at exactly the time when they are most essential.

"Increases in adverse mental health symptoms among workers have been linked to increased absenteeism, high turnover, lower productivity, and lower morale, which could influence the effectiveness of public health organizations during emergencies," the researchers wrote.

The report found nearly three-quarters of all public health workers felt overwhelmed by work. One in 8 reported receiving job-related threats, in an echo of abuse hurled at health care workers early on in the pandemic. And almost a quarter said they had felt bullied, harassed or threatened because of their work.

Public health care workers are more likely to have experienced traumatic events or stressors during the pandemic than are members of the general population. More than a quarter reported losing a loved one, and more than 10 percent reported they had been diagnosed with COVID-19 themselves.

The CDC researchers surveyed 26,174 public health workers from state, tribal, local and territorial health departments over a three-week period in late March and early April of 2020, as the pandemic began.

CNBC.com
Friday, June 25, 2021

CDC says roughly 4,100 people have been hospitalized or died with Covid breakthrough infections after vaccination

Rich Mendez@richmendezcnbc

More than 4,100 people have been hospitalized or died with Covid-19 in the U.S. even though they've been fully vaccinated, according to new data from the Centers for Disease Control and Prevention.

So far, at least 750 fully vaccinated people have died after contracting Covid, but the CDC noted that 142 of those fatalities were asymptomatic or unrelated to Covid-19, according to data as of Monday that was released Friday.

The CDC received 3,907 reports of people who have been hospitalized with breakthrough Covid infections, despite being fully vaccinated. Of those, more than 1,000 of those patients were asymptomatic or their hospitalizations weren't related to Covid-19, the CDC said.

"To be expected," Dr. Paul Offit, a top advisor to the Food and Drug Administration on children's vaccines told CNBC. "The vaccines aren't 100% effective, even against severe disease. Very small percentage of the 600,000 deaths."

Breakthrough cases are Covid-19 infections that bypass vaccine protection. They are very rare and many are asymptomatic. The vaccines are highly effective but don't block every infection. Pfizer and Moderna's phase three clinical studies found that their two-dose regimens were 95% and 94% effective at blocking Covid-19, respectively, while Johnson & Johnson's one-shot vaccine was found to be 66% effective in its studies. All three, however, have been found to be extremely effective in preventing people from getting severely sick from Covid.

The CDC doesn't count every breakthrough case. It stopped counting all breakthrough cases May 1 and now only tallies those that lead to hospitalization or death, a move the agency was criticized for by health experts.

Most Americans have received at least one shot of the two currently authorized mRNA vaccines. The U.S. has administered 178.3 million shots and fully vaccinated 46% of its population.

"You are just as likely to be killed by a meteorite as die from Covid after a vaccine," Dr. Peter Chin-Hong, an infectious disease expert at the University of California San Francisco, told CNBC. "In the big scheme of things, the vaccines are tremendously powerful."

Efficacy rates decrease slightly for variants like alpha and delta, with studies indicating 88% efficacy against the delta strain after two doses of the Pfizer vaccine. It was unclear if any of the reported breakthrough cases were caused by variants.

In Israel and the United Kingdom, concerns about the delta variant are rising after growing reports of breakthrough infections.

Even with 80% of adults vaccinated, Chezy Levy, director-general of Israel's Health Ministry, said the delta variant is responsible for 70% of new infections in the country. Levy also said that one-third of those new infections were in vaccinated individuals.

In the U.K., Public Health England released a report that found 26 out of 73 deaths caused by the delta variant occurred in fully vaccinated people from June 8 to June 14. Most of the deaths occurred in unvaccinated individuals.

"Determination of whether hospitalizations and deaths are more represented in immunocompromised patients and the type of vaccine received will be important for future guidance," Chin-Hong said.

On June 7, the CDC received reports of 3,459 breakthrough cases that led to hospitalization or death. On June 18, that number was updated to 3,729, an increase of 270 cases. Today, the number stands at 4,115.

An overwhelming majority, 76%, of the hospitalizations and deaths from breakthrough cases occurred in people over the age of 65.

"We do not have the years and years of data we have for vaccines against other airborne pathogens -- and therefore it is really essential that the CDC provides up to date reporting on breakthrough cases," David Edwards, aerosol scientist and Harvard University professor, told CNBC.

The CDC says its numbers are "likely an undercount" of all Covid infections in vaccinated people because the data relies on passive and voluntary reporting.

-- CNBC's Berkeley Lovelace Jr. contributed to this report.

Reuters
Friday, June 25, 2021

U.S. FDA adds warning about rare heart inflammation to Pfizer, Moderna COVID vaccines

(Reuters) - The U.S. drug regulator on Friday added a warning to the literature that accompanies Pfizer Inc/BioNTech and Moderna vaccine shots to indicate the rare risk of heart inflammation after its use.

For each vaccine, the fact sheets have been revised to include a warning about myocarditis and pericarditis, FDA said.

The latest update follows an extensive review of information and the discussion by CDC's Advisory Committee on Immunization Practices meeting on Wednesday.

(Reporting by Maria Ponnezhath in Bengaluru; Editing by Chris Reese)

Reuters
Friday, June 25, 2021

Vaccine-associated myocarditis tends to resolve quickly

By Nancy Lapid

Cases of an inflammation of the heart muscle known as myocarditis have been reported after receiving COVID-19 shots, mostly in young men after the second dose of the mRNA vaccines. When myocarditis symptoms, such as chest pain and rapid or irregular heartbeats, do occur after vaccination, they usually resolve quickly, suggests a report of a small study published in the journal Circulation. Doctors tracked seven male patients, ages 19 to 39, who were hospitalized for myocarditis-like illness not long after receiving a COVID-19 vaccine manufactured by either Pfizer and BioNTech, Moderna - the two mRNA vaccines - or Johnson & Johnson. All recovered and left the hospital after two to four days of treatment. Study co-author Dr. Christopher deFilippi of the Inova Heart and Vascular Institute in Fairfax, Virginia, noted that in his health system, which represents about 2 million patients, myocarditis after COVID-19 vaccination has been a "rare event" and "fortunately so far associated with a benign outcome." The U.S. Centers for Disease Control and Prevention this week said reports of the heart condition occurred at a rate of 12.6 cases per million people who received either the Pfizer/BioNTech or Moderna vaccines, a higher rate than would be expected in the general population. However, deFilippi's team advised that given the dangers of COVID-19, even for younger adults, "the risk-benefit decision for vaccination remains highly favorable." (https://bit.ly/35NyLRv)

WashingtonTimes.om
Friday, June 25, 2021

CDC reportedly probing Michigan teen's death after COVID-19 vaccination

By Shen Wu Tan - The Washington Times

Federal health officials are investigating the case of a Michigan teenager who died days after he received a COVID-19 vaccine, Fox News reported Friday.

The 13-year-old boy died three days after getting a second dose of a COVID-19 vaccine, the Saginaw County Health Department told the news agency in a statement. The department learned of the teenager's death on June 17.

"The investigation as to whether there is a correlation between his death and vaccination is now at the federal level with [the Centers for Disease Control and Prevention," the health department said. "Meanwhile, the health department continues to encourage families to speak with their physicians to weigh their own risks and benefits of vaccination."

It is unknown whether the teenage boy had previous health problems. The news report did not specify whether the teenager received the two-dose Pfizer-BioNTech COVID-19 vaccine or the Moderna vaccine. The death has been supposedly reported to the Vaccine Adverse Event Reporting System (VAERS), a national surveillance system.

Neither the CDC nor the Saginaw County Health Department immediately responded to requests for comment.

CDC officials say deaths following COVID-19 vaccinations have been rare. More than 318 million COVID-19 doses were administered in the U.S. from Dec. 14 through June 21, and about 5,400 deaths, or 0.0017%, among those vaccinated were reported to VAERS during that time.

"Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. A review of available clinical information, including death certificates, autopsy and medical records, has not established a causal link to COVID-19 vaccines," the CDC says on its website.

However, there could be a "plausible causal relationship" between the one-shot Johnson & Johnson COVID-19 vaccine and a rare, serious blood clotting condition, which has caused deaths.

Health care providers are required by the Food and Drug Administration to report any death after a COVID-19 vaccination to VAERS.

TheHill.com
Sunday, June 27, 2021

Bipartisan senators ask CDC, TSA when they will update mask guidance for travelers

By Olafimihan Oshin

A bipartisan group of senators has asked the Centers for Disease Control and Prevention (CDC) and Transportation Security Administration (TSA) when they will update their mask guidance for travelers.

In a letter, Sens. Brian Schatz (D-Hawaii), Roger Wicker (R-Miss.), Amy Klobuchar (D-Minn.), Susan Collins (R-Maine), and Jerry Moran (R-Kan.) requested information about the agency's process for updating the mask guidelines for vaccinated people, adding that they want answers by July 12.

"As there has not yet been any change in the requirement for masks while traveling, we request an update on the CDC's and TSA's process for updating the mask requirement for fully vaccinated individuals and what the science is showing about the transmission of COVID-19 for fully vaccinated individuals while traveling," the senators said in their letter.

The letter asked five questions including whether removing mask mandates for fully vaccinated people would encourage others to get vaccinated and whether lifting mask mandates for fully vaccinated people would create administrative challenges.

The senators noted they understand social distancing can be difficult on public transportation conveyances and public transportation hubs.

"If the requirement for wearing masks while traveling can be safely lifted and would serve the public health interest, then we believe it would benefit the traveling public. We appreciate your prompt attention to this matter and hard work in responding to the COVID-19 pandemic," the letter said.

The letter comes days after Democratic lawmakers on Wednesday shot down a bill from Republican Sens. Rick Scott (Fla.) and Mike Lee (Utah) that would have revoked the Biden administration's mask requirement on public transportation.

The Hill has reached out to the CDC and the TSA for comment.

Reuters
Friday, June 25, 2021

U.S. Senate Republicans press CDC to end mask mandate on airplanes, transit

By David Shepardson

June 25 (Reuters) - A group of Senate Republicans urged the Centers for Disease Control and Prevention (CDC) on Friday to stop requiring fully vaccinated Americans to wear masks on public transportation, including airplanes, trains and buses but also in airports and train stations.

Roger Wicker, the most senior Republican on the Senate Commerce Committee, and Ted Cruz, top Republican on an aviation subcommittee, along with Susan Collins, Jerry Moran, Cynthia Lummis and Marsha Blackburn introduced a resolution urging the CDC to lift mask requirements in place since Feb. 1.

"Over 150 million people in the United States are fully vaccinated and mask mandates have been lifted across the country. But the CDC inexplicably still hasn't lifted the mask mandate for public transportation," Cruz said. "It's long past time for President Biden and the CDC to follow the science."

The lawmakers argued the change "would incentivize a greater number of individuals to receive the COVID-19 vaccine."

A CDC spokeswoman declined to comment.

In May, the CDC said fully vaccinated Americans could stop wearing masks in nearly all indoor spaces - with transportation one of the few exceptions.

The Transportation Security Administration on April 30 extended orders to enforce face mask requirements through Sept. 13.

Sara Nelson, international president of the Association of Flight Attendants-CWA, representing nearly 50,000 Flight Attendants at 17 airlines, said the union supported the mandate to help stop the spread of the virus and protect those who don't have access to the vaccine, such as children under 12.

Since January, the Federal Aviation Administration has received 3,100 reports of unruly behavior on airlines, including 2,350 reports of passengers refusing to comply with federal face mask requirements.

On June 10, the CDC said it would no longer require travelers to wear masks in outdoor transit hubs and in outdoor spaces on ferries, buses and trolleys but left indoor requirements unchanged.

(Reporting by David Shepardson Editing by Sonya Hepinstall)

BusinessInsider.com
Saturday, June 26, 2021

Ted Cruz joins forces with other GOP lawmakers to call for an end to mask mandates for vaccinated travelers, ahead of Independence Day

Kevin Shalvey

A group of Republican senators led by Ted Cruz on Friday announced a bill seeking an end to federal mask mandates for vaccinated travelers on planes, trains, and other public transport.

Mask requirements from the Centers for Disease Control & Prevention (CDC) and Transportation Security Administration (TSA) have outlasted their purpose, the lawmakers said.

The CDC in February recommended that travellers stayed home until they were fully vaccinated, but still required everyone to wear a mask while on public transport. The same was true for the TSA, which extended its requirement until September. Airlines have their own requirements, too.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," Sen. Ted Cruz said in a statement accompanying the bill.

In addition to Cruz, the GOP effort involved Susan Collins, Jerry Moran, Roger Wicker, Cynthia Lummis, and Marsha Blackburn. It came as states across the country continued loosening restrictions on daily life.

TSA mask mandates have led to altercations in airports and on flights, where cabin crews have had to deal with unruly passengers. Flight attendants have described "unprecedented" violence. The TSA in July will restart its self-defense training for flight crews.

A frequent flier last week sued seven airlines, saying vaccinated travelers should be able to fly without masks.

The resolution, introduced in the Senate on Thursday, said the CDC could incentivize more people to get vaccines by dropping the mask requirement.

The three-page text said that getting rid of the mask mandate "would be instrumental in helping the economic recovery of the United States by boosting travel and benefitting the travel and tourism industries without sacrificing public health."

In late May, the transportation secretary, Pete Buttigieg, said the mask requirement on public transit was a "matter of safety, but it's also a matter of respect" for flight crews.

The World Health Organization in a Friday press briefing said vaccines alone won't end the pandemic. The organization urged fully vaccinated people to continue wearing masks.

Collins in a statement said she'd spoken with flight attendants about the mandate. The senator said she'd heard about "horrendous and unthinkable violence" on recent flights.

If vaccinated people on the ground no longer need masks indoors, then fliers don't need them either, Collins said.

"It makes no sense that someone can go to a restaurant without wearing a mask, but they cannot fly on an airplane without one, even though it has a far better ventilation system," she said.

TheHill.com
Saturday, June 26, 2021

Senate Republicans urge CDC to lift public transportation mask mandate

By Celine Castronuovo

A group of GOP lawmakers led by Sen. Ted Cruz (R-Texas) on Friday introduced a resolution formally calling on the Centers for Disease Control and Prevention (CDC) to lift its mask mandate for fully vaccinated individuals on public transportation.

Cruz, along with Republican Sens. Susan Collins (Maine), Jerry Moran (Kan.), Roger Wicker (Miss.), Cynthia Lummis (Wyo.) and Marsha Blackburn (Tenn.), argued that the CDC's guidance that fully vaccinated individuals do not have to wear masks in most settings should also apply when traveling on commercial planes, buses, trains and other forms of public transit.

President Biden on his first full day in office signed an executive order directing federal agencies to "immediately take action" to require masks on public transportation.

While the federal mask mandate was initially set to expire May 11, the Transportation Security Administration (TSA) has since extended it to Sept. 13.

However, Cruz and his colleagues said in their resolution Friday that "science shows that individuals fully vaccinated against COVID-19 are protected against asymptomatic infection, and thus very unlikely to

spread the disease," adding that Americans "have sacrificed immensely" throughout the coronavirus pandemic.

In a press release announcing the resolution, Cruz said, "It's long past time for President Biden and the CDC to follow the science and end this mask mandate for fully vaccinated individuals.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," he added.

Collins in a statement included in the release said she had spoken with flight attendants who had expressed fears on enforcing the federal mask mandate amid multiple viral incidents showing passengers attacking or threatening workers over the safety restrictions.

"It makes no sense that someone can go to a restaurant without wearing a mask, but they cannot fly on an airplane without one even though it has a far better ventilation system," Collins argued.

The resolution comes just days after Democrats blocked a bill from Senate Republicans that would have revoked Biden's mask requirement on public transit.

GOP Sens. Rick Scott (Fla.) and Mike Lee (Utah), who had introduced the bill, cited the nation's vaccination rates in arguing against the need for a face mask requirement.

However, Sen. Patty Murray (D-Wash.), chair of the Senate Health, Education, Labor and Pensions Committee, said when blocking the bill, "This virus is still spreading, it is still mutating, it is still costing lives, and it is still leaving survivors with long-haul symptoms."

"We cannot pretend this pandemic is over," she added.

Newsweek.com
Saturday, June 26, 2021

Ted Cruz Urges Joe Biden to 'Follow the Science' and End Travel Mask Requirement

By Darragh Roche

Senator Ted Cruz (R-TX) has called on President Joe Biden to end the requirement for people who are fully vaccinated to wear face masks while traveling on trains, airplanes, buses and other vehicles.

Cruz is leading a group of Republican senators who are introducing a bill calling on the Centers for Disease Control and Prevention (CDC) to end the mask requirement for travelers.

The CDC issued updated guidance on COVID-19 mask-wearing in May, saying that fully vaccinated people could go without face coverings in most

indoor and outdoor settings but masks continue to be required on forms of transportation.

Cruz issued a statement on Friday to accompany the lawmakers' resolution.

"Over 150 million people in the United States are fully vaccinated and mask mandates have been lifted across the country," Cruz said.

"But the CDC inexplicably still hasn't lifted the mask mandate for public transportation. It's long past time for President Biden and the CDC to follow the science and end this mask mandate for fully vaccinated individuals.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," Cruz said.

Biden had previously set July 4 as the deadline for the administration's goal of having at least 70 percent of Americans with one shot of the COVID vaccine but recently admitted it will not now meet that goal. However, around 65 percent of adults have been at least partially vaccinated, according to CNBC.

The CDC issued a sweeping mask mandate for public transport following Biden's executive order on the pandemic on January 21 - the day after he took the oath of office. That order came into effect on February 1.

Though CDC advice has been updated since the order on public transport was issued, the mask-wearing requirements for buses, airplanes, trains and other forms of transport remain in place.

Marty Cetron, director for CDC's Division of Global Migration and Quarantine, explained the rationale behind the decision in the 11-page written order on January 29.

"Requiring masks on our transportation systems will protect Americans and provide confidence that we can once again travel safely even during this pandemic," Cetron said.

The CDC updated its advice on June 10 to say that fully vaccinated people no longer needed to wear masks while outdoors at transportation hubs such as bus stations but that unvaccinated people should continue to do so.

Cruz, who is the ranking member of the Senate Subcommittee on Aviation Safety, Operations, and Innovation, called legal requirements for mask-wearing on airplanes "performative theater" on June 16.

Newsweek has asked the White House, Senator Ted Cruz and the CDC for comment.

AP Georgia
Saturday, June 26, 2021

Georgia State Looks To Boost Vaccine Rate Among Refugees

CLARKSTON, Ga. (AP) -- Researchers at Georgia State University will use a $500,000 grant to try to increase COVID-19 vaccination rates among refugees and other groups in the Atlanta area city of Clarkston -- one of the largest refugee resettlement communities in the U.S., the university announced.

The money from the U.S. Centers for Disease Control and Prevention will help train and deploy six outreach workers to address residents' concerns about coronavirus vaccines and encourage them to get jabbed. The workers will represent major refugee groups living in Clarkston, including the Burmese, Congolese, Afghan and Somali communities, as well as the African American community, the university said in a news release.

The school plans to use workers who are known and trusted in their respective communities and send them out within a month, Michael Eriksen, a public health professor at Georgia State who is leading the effort, said during a phone interview Wednesday. Thousands of refugees live in the Clarkston area.

"We're really pushing this as quickly and as hard as we can," Eriksen said, citing the need for urgency because of the ongoing pandemic.

Vaccination rates in Georgia and elsewhere in the South have lagged behind the rest of the country. In some Clarkston neighborhoods, the percentage of people fully vaccinated as of June was below 30, according to researchers at Georgia State. That was lower than the state's vaccination rate.

Eriksen said many refugees receive additional conspiracy theories and false information about vaccines from people in their home countries.

They may also be struggling to overcome traumatic events that brought them to the U.S. and face language and cultural barriers -- all of which can hamper vaccine uptake.

The outreach workers will also help local clinics and the DeKalb County Board of Health schedule vaccine appointments, arrange transportation and follow up with residents to make sure they get a second dose. The goal is to increase vaccine rates in Clarkston by 50 percent by spring 2022.

The one-year grant was awarded to the Prevention Research Center located on the Clarkston campus of Perimeter College -- a two-year school in the Georgia State system.

Xinhua (China)
Saturday, June 26, 2021

U.S. average daily COVID-19 vaccination drops by over 50 pct: CDC

WASHINGTON, June 26 (Xinhua) -- The latest 7-day average number of administered vaccine doses per day decreased by 55.3 percent from the previous week, according to a weekly report of the U.S. Centers for Disease Control and Prevention (CDC).

As of June 24, the 7-day average number of administered vaccine doses reported to the CDC per day was 0.37 million, according to the report released on Friday.

About 45.8 percent of the U.S. population was fully vaccinated against COVID-19, and 53.9 percent of the population received at least one shot as of Saturday, CDC data showed.

Roughly 152.2 million people were fully vaccinated. But some states, such as Alabama, Arkansas, Louisiana, Mississippi, Tennessee and Wyoming, had low vaccination rates.

A new CDC study showed adults aged 18 to 24, as well as non-Hispanic Black adults and those with less education, no insurance, and lower household incomes, had the lowest reported vaccination coverage and intent to get vaccinated.

The White House confirmed earlier this week that the country would not hit U.S. President Joe Biden's goal of getting 70 percent of American adults to receive at least one COVID-19 vaccine shot by July 4, the Independence Day.

Reuters
Sunday, June 27, 2021

U.S. reaches 323 million doses of COVID-19 vaccine administered -CDC

(Reuters) - The United States has administered 323,327,328 doses of COVID-19 vaccines in the country as of Sunday morning, and distributed 381,282,720 doses, the U.S. Centers for Disease Control and Prevention (CDC) said.

Those figures are up from the 322,123,103 vaccine doses the CDC said had gone into arms by June 26 out of 381,276,030 doses delivered.

The agency said 179,261,269 people had received at least one shot, while 153,028,665 in the United States are fully vaccinated as of Sunday.

The CDC tally includes two-dose vaccines from Moderna Inc and Pfizer/BioNTech, as well as Johnson & Johnson's one-shot vaccine as of 6 a.m. EDT (1000 GMT) on Sunday.

(Reporting by Maria Ponnezhath in Bengaluru; Editing by Matthew Lewis)

FoxNews.com
Monday, June 28, 2021

CDC reports 4,115 breakthrough COVID-19 cases involving hospitalizations or deaths

Cases reflect small percentage of 150 million people who are fully vaccinated

By Alexandria Hein | Fox News

The Centers for Disease Control and Prevention (CDC) has received reports of 4,115 patients with COVID-19 vaccine breakthrough cases who were hospitalized or died. Of those cases, 26% of hospitalizations were reported as asymptomatic or not related to COVID-19, and 19% of the 750 fatalities were reported as asymptomatic or not related to COVID-19.

The data, which includes information through June 21, is amid a backdrop of 150 million people who are fully vaccinated in the U.S. Nearly half of the breakthrough cases, or 49%, involve females, and 3,124, or 76%, occurred in patients ages 65 years and older.

Officials have long predicted vaccine breakthrough cases would be reported, as "no vaccines are 100% effective at preventing illness in vaccinated people." The agency has also warned there would be a "small percentage" of vaccinated people who get sick, require hospitalization or even die from COVID-19.

"The number of COVID-19 vaccine breakthrough infections reported to CDC likely are an undercount of all SARS-CoV-2 infections among fully vaccinated persons," the agency noted. "National surveillance relies on passive and voluntary reporting, and data might not be complete or representative. These surveillance data are a snapshot and help identify patterns and look for signals among vaccine breakthrough cases."

The agency noted that "no unexpected patterns" have been identified in the reported breakthrough infections. It also states that vaccines remain effective and everyone ages 12 and older who have not received it should get one as soon as possible.

CNN.com
Saturday, June 26, 2021

Some fully vaccinated people may still get sick if exposed to variants, CDC warns

By Madeline Holcombe and Jacqueline Howard, CNN

(CNN)The US Centers for Disease Control and Prevention told CNN Friday that the agency is tracking the Delta coronavirus variant, among others -- and warned that there is a small chance a fully vaccinated person could still get infected if they're exposed.

"Current data suggest that COVID-19 vaccines authorized for use in the United States offer protection against most variants currently spreading in the United States. However, some variants might cause

illness in some people even after they are fully vaccinated," CDC spokesperson Jade Fulce told CNN in an email on Friday.

While Covid-19 vaccines are effective, Fulce said no vaccine is "100% effective at preventing illness."

And with millions of people getting vaccinated against the virus, some who are fully vaccinated "will still get sick if they are exposed," Fulce said.

"However, people with breakthrough infections may get less severely ill or have a shorter illness than they would have if they had not been vaccinated."

That's why experts are especially worried about people who have not yet gotten their Covid-19 shots.

More than 53% of the US population has received at least one Covid-19 vaccine dose and more than 45% is fully vaccinated, CDC data shows.

'Please get your second shot'

As officials urge more people to get their shots, the US surgeon general warns a big obstacle stands in their way: Misinformation.

"There is so much misinformation out there about the vaccine, coming through so many channels -- a lot of it being spread on social media," Dr. Vivek Murthy told CNN's Erin Burnett. "It's inducing a lot of fear among people."

"Two-thirds of those who are unvaccinated in polls say that they either believe the myths about Covid-19 or think that they might be true," he added.

Experts, including Dr. Anthony Fauci, have estimated that 70 to 85% of people in the US will need to become immune to the virus through vaccination or infection in order to control community spread. But after initial surges, vaccination rates have now slowed across the country.

And more than 1 in 10 people who have received one dose of the Pfizer/BioNTech or Moderna vaccine have missed their second dose, according to data shared with CNN by the CDC.

That statistic is especially concerning to experts because studies have shown that the vaccines are much more effective against the Delta variant after the two-dose series is completed.

"Please get your second shot," CDC Director Dr. Rochelle Walensky said in a Friday NPR interview. "What we do know is you get some protection from the first shot, but really that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this Delta variant and other variants as well.

"If you missed your second within the time window, get it whenever, get it now, but do get that second shot," Walensky added.

Officials worried about unvaccinated Americans

The Delta variant is believed to be more transmissible and cause more severe disease than other strains. Murthy said he is worried for those who are unvaccinated as the variant spreads.

In Los Angeles County, the impact is already clear. Nearly all of the Covid-19 cases, hospitalizations, and deaths in Los Angeles County are occurring among people who are unvaccinated, county health officials said Thursday.

Out of nearly 437,000 positive coronavirus cases reported in L.A. County since December 2020, 99.6% of those were among individuals who were unvaccinated, health officials said in a press release.

"The virus is still with us," Los Angeles County Public Health Director Barbara Ferrer said at a press conference. "Even now, we need to be careful to mask and maintain distance from people outside of our households, especially if they're not yet vaccinated."

Missouri hospitals stretched thin

Missouri is the state with the largest proportion of the Delta variant of Covid-19 infections, according to the CDC. And hospitals in the state are feeling the stress of managing Covid-19 patients on top of their regular intake, one hospital leader told CNN's Ana Cabrera on Thursday.

"Both hospitals here in town are stretched," said Erik Frederick, chief administrative officer at Mercy Hospital Springfield in Springfield, Missouri.

"We saw a very rapid escalation in our in-patient census starting June 1, we went from 26 to 90 in about three weeks. To go back to last year when our peak started, it took us six to seven weeks to escalate that quickly. Today to hit 97, it really took us almost two months to hit that level which we've done in under a month."

Frederick said a return of typical hospital patients is exacerbating the issue.

"The difference between last year and this we have traditional business back we didn't have last year during the initial surge. The demand for beds is higher for both Covid and non-Covid patients. It's definitely a stretch."

Frederick said there is also a high amount of pressure on available labor.

"The staff are right back into the mix of it, and I don't think they were fully recovered from last year," he said.

Smell and taste come back, studies show

In a bit of good news, researchers reported Thursday that those who did

not regain their sense of taste and smell when they cleared their Covid-19 infections should get them back after a year.

Studies confirm that many, if not most, Covid-19 patients say their sense of smell is affected -- a condition called anosmia or hyposmia.

Because smell and taste are closely linked, many people feel their ability to taste food normally is also affected when their sense of smell is disrupted.

An ongoing experiment of about 100 people who lost their sense of smell in early 2020 showed it can take months for it to come back, but it does. Some patients didn't realize or appreciate it, however, the international team of researchers reported in the Journal of the American Medical Association's JAMA Network Open.

"At eight months, objective olfactory assessment confirmed full recovery in 49 of 51 patients (96.1%)," they wrote. Two continued to have an abnormal sense of smell a year later -- one who couldn't smell much and another who had an abnormal smell sense.

"Our findings suggest that an additional 10% gain in recovery can be expected at 12 months, compared with studies with 6 months of follow-up that found only 85.9% of patients with recovery," they wrote.

CNN's Lauren Mascarenhas, Deidre McPhillips, Alexandra Meeks, Maggie Fox and Virginia Langmaid contributed to this report.

Reuters
Sunday, June 27, 2021

Booster may be needed for J&J shot as Delta variant spreads, some experts already taking them

By Michael Erman

NEW YORK (Reuters) -Infectious disease experts are weighing the need for booster shots of the Pfizer/BioNTech or Moderna mRNA-based vaccines for Americans who received Johnson & Johnson's one-dose vaccine due to the increasing prevalence of the more contagious Delta coronavirus variant.

A few say they have already done so themselves, even without published data on whether combining two different vaccines is safe and effective or backing from U.S. health regulators. Canada and some European countries are already allowing people to get two different COVID-19 shots.

The debate centers on concerns over how protective the J&J shot is against the Delta variant first detected in India and now circulating widely in many countries. Delta, which has also been associated with more severe disease, could quickly become the dominant version of the virus in the United States, Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky has warned.

There is no substantial data showing how protective the J&J vaccine is against the new variant. However, UK studies show that two doses of either the Pfizer/BioNTech or AstraZeneca vaccines are significantly more protective against the variant than one.

Andy Slavitt, former senior pandemic advisor to U.S. President Joe Biden, raised the idea this week on his podcast. At least half a dozen prominent infectious disease experts said U.S. regulators need to address the issue in short order.

"There's no doubt that the people who receive the J&J vaccine are less protected against disease," than those who get two doses of the other shots, said Stanford professor Dr. Michael Lin. "From the principle of taking easy steps to prevent really bad outcomes, this is really a no brainer."

The CDC is not recommending boosters, and advisors to the agency said at a public meeting this week there is not yet significant evidence of declining protection from the vaccines.

Jason Gallagher, an infectious diseases expert at Temple University's School of Pharmacy, recently received a Pfizer dose at the Philadelphia vaccine clinic where he has been administering shots. He got the J&J vaccine in a clinical trial in November.

Gallagher said he was concerned about the UK data https://www.gov.uk/government/news/vaccines-highly-effective-against-b-1-617-2-variant-after-2-doses showing lower efficacy against the Delta variant for people who received one vaccine dose.

"While the situation has gotten so much better in the U.S., the Delta variant that's spreading ... and really quickly taking over in the U.S. looks a little more concerning in terms of the breakthrough infections with the single-dose vaccines," he said. "So I took the plunge."

Cases, hospitalizations and deaths have plummeted in the United States with 56% of the adult population fully vaccinated.

J&J said it is testing whether the immune response from its vaccine is capable of neutralizing the Delta variant in a laboratory setting, but no data is available yet.

Both mRNA vaccines showed efficacy rates around 95% in large U.S. trials, while J&J's vaccine was 66% effective in preventing moderate-to-severe COVID-19 globally when more contagious variants were circulating.

Dr. Angela Rasmussen, a researcher at the University of Saskatchewan's Vaccine and Infectious Disease Organization, said on Twitter she had gotten a dose of Pfizer's vaccine this week after receiving J&J's in April.

Rasmussen, who declined to be interviewed, encouraged Americans who received the J&J vaccine to talk to their doctors about a possible second shot.

"If you live in a community with overall low vaccination, I'd suggest you strongly consider doing so," she tweeted.

Vaccine expert Dr. Peter Hotez from Baylor College of Medicine in a tweet said adding a second J&J dose or one of the mRNA vaccines might provide broader protection, "but we need data and CDC-FDA guidance."

The U.S. National Institute of Allergy and Infectious Diseases (NIAID) is running a trial to determine the need for boosting all currently authorized shots with another dose of Moderna's vaccine. NIAID scientist Dr. John Beigel told Reuters the agency hopes to have that data by September to help inform regulators' decisions on boosters.

As long as case counts remain low in the United States, J&J recipients should wait for more data, he said.

If Delta variant-driven infections and hospitalizations increase significantly, he said, "then decisions might need to be made with an absence of data. But right now, I do think it's appropriate that they wait."

(Reporting by Michael Erman; Editing by Caroline Humer and Bill Berkrot)

CNN.com
Saturday, June 26, 2021

'Please get your second shot,' top health official urges as Delta variant remains a pressing threat

By Aya Elamroussi, CNN

(CNN)America is in a far better place now than it was six months ago in its fight against the coronavirus pandemic, with overall cases and deaths down, according to the latest data.

It shows that vaccines are effective, experts say, although they have some protection limitations when faced with more aggressive virus variants.

The Delta variant, which can spread more easily and cause even more severe disease than other strains, has been a major concern for health experts who are worried about those who remain unvaccinated.

That variant, first identified in India, has been found in 49 states and Washington, D.C., according to GISAID, an independent data sharing initiative, and the Hawaii Department of Health. South Dakota did not report cases of the variant as of Wednesday, a state health department spokesperson told CNN.

To be sure, the US Centers for Disease Control and Prevention has said there's a low chance people who are fully vaccinated may get infected with virus variants.

And any illness could be shorter or milder if one is fully vaccinated--but the keyword is "fully" because a second shot is essential for optimal protection against variants.

"Please get your second shot," CDC Director Dr. Rochelle Walensky said Friday in an interview with the National Public Radio.

"What we do know is you get some protection from the first shot, but really that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this Delta variant and other variants as well."

More than one in 10 people in the US who received one dose of the Pfizer/BioNTech or Moderna vaccine have missed their second dose, according to CDC data.

"If you missed your second within the time window, get it whenever, get it now, but do get that second shot," Walensky added.

In Los Angeles County, 99.8% of the 12,234 people who died from Covid-19 since December 2020 were unvaccinated, local health data shows.

"The virus is still with us," Los Angeles County Public Health Director Barbara Ferrer said at a news conference Thursday. "Even now, we need to be careful to mask and maintain distance from people outside of our households, especially if they're not yet vaccinated."

President Joe Biden took note of the variant's dangerousness in remarks Thursday, warning that the variant is "now the most common variant in America."

"And unvaccinated people are incredibly vulnerable," he said, underscoring that the Delta variant is "more easily transmittable," and "potentially deadlier and especially dangerous to young people."

In the US overall, the Delta variant has accounted for about 21% of cases in the two weeks ending June 19, according to CDC data.

More than 151.6 million Americans are fully vaccinated, according to CDC data on Friday, which is nearly 45.7% of the total US population.

Nearly 65.8% of adults in America have had at least one dose of a vaccine as of Friday, according to the CDC. Biden's goal of 70% of adults with at least one dose by July 4 is all but likely to fall short, as officials are currently targeting mid-July.

Distribution of some antibody treatments are paused due to variants

It's not only the Delta variant that is complicating matters for health care providers.

The increase of cases due to the Gamma or P.1 variant first identified in Brazil, and the Beta or B.1.351 variant first identified in South Africa, are being cited as the reason for a pause in nationwide

distribution of certain monoclonal antibody treatments from Eli Lilly, according to an announcement on Friday from the US Health and Human Services Department (HHS).

The monoclonal antibody treatment of etesevimab, as well as a combination treatment of etesevimab and bamlanivimab, don't work as well with the variants, according to the HHS statement.

In May, federal regulators had paused the distribution of these treatments to eight states where there were a high number of variant cases. Eli Lilly's single monoclonal antibody treatment bamlanivimab was put on pause in March. In April, the company had asked the FDA to revoke its emergency use authorization of the single antibody treatment, so it could focus on its combination treatment.

The Beta and Gamma variants now make up at least 11% of the cases in the US, and case numbers are increasing, according to CDC data.

Rare heart risk warning is added to 2 vaccine fact sheets

Meanwhile, the US Food and Drug Administration added a warning about the risk of the heart inflamations known as myocarditis and pericarditis to fact sheets for Moderna and Pfizer-BioNTech Covid-19 vaccines Friday.

The warning notes that reports of adverse events following vaccination suggest increased risks of both types of inflammation, particularly after the second dose.

Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of tissue surrounding the heart.

Vaccine advisers to the CDC met Wednesday and said there is a likely association between the mRNA Covid-19 vaccines and rare cases of heart inflammation in adolescents and young adults.

However, the risk is rare: Following about 300 million administered doses of Pfizer and Moderna vaccines through June 11, the CDC has received roughly 1,200 preliminary reports of myocarditis and pericarditis.

Advisers urged that the benefits of vaccination outweigh the risks, and almost all the cases resolved with little treatment and patients recovered quickly.

The FDA is advising those who receive one of the two vaccines to seek immediate medical attention if they experience "chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after vaccination."

Both the FDA and CDC are monitoring reports of these adverse events and will follow up to assess longer-term outcomes, the FDA noted.

CNN's Lauren Mascarenhas, Jen Christensen, Jacqueline Howard, Deidre McPhillips, Jamie Gumbrecht and Travis Caldwell contributed to this report.

Associated Press
Saturday, June 26, 2021

States Hesitant To Adopt Digital Covid Vaccine Verification

By DAVID A. LIEB
Associated Press

Customers wanting to wine, dine and unwind to live music at the City Winery's flagship restaurant in New York must show proof of a COVID-19 vaccination to get in. But that's not required at most other dining establishments in the city. And it's not necessary at other City Winery sites around the U.S.

If City Winery tried doing such a thing at its places in Atlanta and Nashville, "we would have no business, because so many people are basically against it," said CEO Michael Dorf.

Across the U.S., many hard-hit businesses eager to return to normal have been reluctant to demand proof of vaccination from customers. And the public and the politicians in many places have made it clear they don't care for the idea.

In fact, far more states have banned proof-of-vaccination policies than have created smartphone-based programs for people to digitally display their vaccination status.

The Centers for Disease Control and Prevention still recommends masks when dining or gathering indoors for those who aren't fully vaccinated. But few states require it, and most businesses rely on voluntary compliance -- even in places with low vaccination rates where COVID-19 cases are climbing.

Digital vaccine verification programs could make it easier to enforce safeguards and tamp down new outbreaks.

"But that only works when you have mass adoption, and mass adoption requires trust and actual buy-in with what the state health department is doing, which is not necessarily present in all states," said Alan Butler, executive director of the Electronic Privacy Information Center, a Washington-based nonprofit organization.

Hawaii is the only state enforcing some version of a vaccine passport. It requires travelers to upload a photo or PDF of their Hawaii vaccination document or pass a pre-arrival COVID-19 test to avoid having to quarantine for 10 days.

Earlier this month, California became just the third state -- behind New York and Louisiana -- to offer residents a way to voluntarily display digital proof of their COVID-19 shots. None of those states requires the use of their digital verification systems to access either public or private-sector places.

By contrast, at least 18 states led by Republican governors or legislatures prohibit the creation of so-called vaccine passports or ban public entities from requiring proof of vaccination. Several of those -- including Alabama, Florida, Iowa, Montana, North Dakota and Texas -- also bar most businesses from denying service to those who aren't vaccinated.

"Texas is open 100%, and we want to make sure that you have the freedom to go where you want without limits," Gov. Greg Abbott said in signing a law against vaccine passports.

The prohibition doesn't apply to the demands employers make on their employees. Earlier this month, a federal judge in Texas threw out a lawsuit from 117 Houston hospital employees who challenged a workplace requirement that they get vaccinated. More than 150 were later fired or resigned for not getting their shots.

In Louisiana, under a Republican-passed bill facing a potential veto from Democratic Gov. John Bel Edwards, public facilities would not be allowed to bar unvaccinated people until the COVID-19 vaccines have received full approval from the Food and Drug Administration. The vaccines for now are being dispensed under emergency FDA authorization.

In May, Louisiana launched a program allowing residents using the state's digital driver's license, LA Wallet, to add a record of their COVID-19 vaccination.

But its reach is still limited. About 105,000 people have activated the COVID-19 verification function. That's about 14% of those with a digital license and less than 4% of Louisiana's 3.1 million people with valid driver's licenses.

Democratic state Rep. Ted James, who wrote the bill creating the digital driver's license, said he has used the feature just once -- to show an Uber driver in Nevada that he didn't need to wear a mask. But James said he has never been asked to show it in Louisiana and doubts he ever will.

"Earlier in the year, I felt that at some point we would be limited in travel, going to certain places, unless we had the vaccine," James said. Now, "I don't foresee us ever having some type of requirement."

As a step in reopening, New York in March launched its Excelsior Pass, the first state system to provide digital proof of COVID-19 vaccination or a recent negative test. As of early June, more than 2 million people had gotten the digital pass -- about one-fifth of those who have been vaccinated.

At the City Winery, most customers bypass the Excelsior Pass and instead show their paper CDC vaccination cards to gain entry, according to Dorf, who said patrons at the 1,000-person capacity venue "appreciate going into a bubble of safety, knowing that everyone around them is vaccinated."

Though larger ticketed events, like concerts at Madison Square Garden, require proof of vaccination, most businesses don't ask.

"Think of a bar," said Andrew Rigie, executive director of the New York City Hospitality Alliance. "You have four friends that go in -- maybe two of them have it, the other two don't. You're going to turn the other two away when small businesses are struggling so much?"

Though most states have shied away from creating digital vaccination verification systems, the technology may soon become widespread nonetheless.

Vaccine providers such as Walmart and major health care systems already have agreed to make digital COVID-19 vaccination records available to customers. Apple also plans to incorporate the vaccination verification function into a software update coming this fall.

Within months, hundreds of millions of people across the U.S. will be able to access digital copies of their COVID-19 vaccination records, said Brian Anderson, chief digital health physician at the nonprofit MITRE Corp., part of a coalition of health and technology organizations that developed such technology.

People will receive QR codes that can be stored on smartphones or printed on paper to be scanned by anyone seeking vaccine verification. Those who scan the codes won't retain any of the information -- a protection intended to address privacy concerns.

The California Chamber of Commerce said it welcomes the state's new vaccine verification system as a way for employers to check on their employees. California regulations require most employees who aren't fully vaccinated to wear masks when dealing with others indoors.

Digital vaccine verification "allows an employer who really wants to make sure the workplace is vaccinated to require that without having the impossible problem of `John says he's vaccinated but he lost his vaccine card. What do we do?' This solves that issue," said Rob Moutrie, a policy advocate at the California Chamber of Commerce.

Politico.com
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`A tough slog': White House struggles to increase vaccination rates as Delta variant surges

By ERIN BANCO and DAVID LIM

Top Biden administration health officials trying to slow the spread of the Covid-19 Delta variant have largely given up on the possibility of reinstating mask and social-distancing rules in favor of a grassroots vaccine education campaign.

The Centers for Disease Control and Prevention, the Department of Health and Human Services and the White House Covid-19 Task Force have discussed whether to press mayors and governors in the Midwest and South, where the highly transmissible Delta variant is spreading

quickly, to once again require mask mandates, according to three senior Biden health officials. But the administration ultimately concluded that many people who are not vaccinated are also those who have resisted wearing masks.

Instead, the federal government will try to convince hesitant Americans to get vaccinated by working with state officials and trusted community members to communicate the benefits of the shots, the three senior officials said. The president's team is not confident that the new campaign will change hearts and minds, the two officials said, but it is falling back on old messaging in part because top administration officials are unsure what other tactics will work.

Only about 46 percent of the U.S. population is vaccinated, and the number of doses administered has fallen by almost 300,000 per day since June 7, according to the Centers for Disease Control and Prevention.

The plateauing vaccination rate underscores the extent to which the White House is struggling to find new and better ways to convince Americans to get Covid-19 shots -- while much of the rest of the world struggles to secure a steady supply of vaccines. And it raises questions about how the federal government will manage increasing Covid-19 cases associated with the Delta variant in the months ahead, with businesses and schools returning to normal operations.

"This is the door-to-door campaign, this is the church-to-church, this is going into the community and meeting people where they are. We're not going to convince everybody," said Scott Becker, CEO of the Association of Public Health Laboratories. "The Delta variant and its explosive growth -- I wish there was a better way to articulate the damage that it is doing and will do in those communities, but it is going to be a tough slog."

New Covid-19 infections have increased by more than 50 percent over the last two weeks in under-vaccinated states such as Missouri and Oklahoma. Many of the cases are tied to the Delta variant, which the CDC says now accounts for one-fifth of new infections nationwide.

"Based on the data that we have right now, the Delta variant is more transmissible than Alpha," the strain that has predominated in the U.S. this spring, said Summer Galloway, a senior adviser at the agency.

Preliminary data from the U.K. suggests that unvaccinated people infected with the Delta variant have an increased risk of hospitalization, she added. The CDC is studying whether the variant leads to more severe infections in undervaccinated communities. But there is good news: recent data shows the Pfizer vaccine is nearly 90 percent effective against Delta, making vaccination one of the most effective ways to stop the variant's march across the U.S.

"We really just want to encourage everyone ... to get vaccinated. What we don't want to have happen is we have a significant proportion of the population that's unvaccinated and you see an increase in the number of cases and the number of hospitalizations, the number of deaths," Galloway said. "It could lead to another surge."

In the meantime, the CDC is still encouraging people who are unvaccinated to wear masks and avoid crowded indoor gatherings, an agency spokesperson said.

The number of U.S. adults who say they will definitely not take a Covid-19 vaccine has remained steady at 13 percent, according to a Kaiser Family Foundation survey released last month. Twelve percent say they are waiting to decide if they will get vaccinated, while 7 percent say they will only opt for immunization if it is required for work or other activities.

The Biden administration in March rolled out a $1 billion advertising campaign, relying on radio and television spots to educate Americans on the benefits of vaccination and on where and when they could receive the shot. The administration partnered with 275 groups, including the Christian Broadcasting Network and Nascar, to reach areas where hesitancy or outright opposition to the vaccines is high.

The federal government has also joined up with the Ad Council -- a nonprofit organization that often partners with the federal government on public service announcements -- and the Covid Collaborative, a group of organizations working together to combat the virus, on ads promoting Covid-19 vaccines. The CDC Vaccine Task Force is also offering "vaccine confidence consultations" to interested jurisdictions. The consultations include briefings between CDC officials and local leaders about how states can build trust in their communities around vaccination.

The three senior Biden health officials said the administration is pushing more of the responsibility of convincing the unvaccinated to get the jab to local officials, who can tap trusted community leaders to spread the word. The hope is that those local leaders will be more effective messengers than national ad campaigns or top federal officials.

Over the last two weeks, officials from the CDC, HHS and the White House Covid-19 Task Force have formulated a plan to work with local officials, including mayors, to knock on doors in areas with low vaccination rates to talk with people about signing up for the shot. Officials like President Joe Biden's chief medical adviser, Anthony Fauci, and CDC Director Rochelle Walensky also are increasing their appearances on national TV programs and with local press in the South where the Delta variant is spreading.

Fauci, for instance, has visited vaccine sites in New York and Florida this month with First Lady Jill Biden. He spent the Juneteenth holiday going door-to-door with Washington, D.C., Mayor Muriel Bowser, urging city residents to get vaccinated.

But the Biden team is still unsure how many people could be swayed by these more local appeals. The White House is now planning for what top officials see as inevitable Covid-19 surges in several states with low vaccination rates later this summer and into the fall.

Many states have already tried on their own to encourage people to get Covid-19 shots -- often through lotteries and other financial

incentives. But that strategy has largely failed, and Delta Covid-19 cases continue to rise.

The CDC is now considering whether to update guidelines for schools and for domestic and international travel. Federal and state health officials are debating how and whether to recommend proof of vaccination for everything from restaurants to movie theaters to office buildings. The fear, Fauci recently told POLITICO, is that recommending proof of vaccination could cause an uproar among unvaccinated people. While federal health officials have pledged so-called vaccine passports will not be implemented at the national level, some states and private businesses have explored using vaccine passes to support safe reopening.

European Union officials have recently put pressure on U.S. diplomats overseas to open up travel to the U.S. with proof of vaccination, according to a U.S. official with direct knowledge of the matter. Germany recently issued an order that allows all U.S. residents to fly into the country if they can prove vaccination or a negative Covid-19 test.

For now, Biden administration officials say the increasing number of Delta cases is cause for worry but not overwhelming dread. The Pfizer vaccine in wide use in the U.S. works well against the variant; Moderna's vaccine uses similar technology, so the hope is that it will be similarly effective in warding off Delta. The CDC is currently in the midst of conducting studies to pin down just how well the current vaccines protect against Delta and what impact it has on the unvaccinated population, particularly children.

"We have to stay vigilant. We see this strain is affecting how much protection people get from the first dose dramatically," said Phil Febbo, chief medical officer of DNA sequencing company Illumina, which is working with the CDC to study the spread of Covid-19 variants in the U.S. "I don't think we're that far away from a different variant that goes beyond the Delta and decreases significantly the efficacy of both doses."

AP Wisconsin
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Wisconsin's Johnson To Tout Claims Of Vaccine Side Effects

By SCOTT BAUER
Associated Press

MADISON, Wis. (AP) -- Republican U.S. Sen. Ron Johnson, a vocal critic of COVID-19 vaccine mandates, announced plans Friday to hold a news conference bringing together people who claim to have had adverse reactions to the vaccine, including the wife of a former Green Bay Packer player.

Johnson, who has also advocated for alternative and unproven treatments for COVID-19, said the Monday event in Milwaukee will allow people from

across the country to tell their stories and concerns he said have been "repeatedly ignored" by the medical community.

Johnson, who has no medical training or expertise, hasn't been vaccinated, saying he doesn't think he has to because he had the virus last year and formed natural antibodies. He has said he's "just asking questions" and isn't against vaccines, but doctors and other critics have blasted him for spreading misinformation.

Dr. Jeff Huebner, a family doctor in Madison, said Johnson was "promoting dangerous and unfounded claims about COVID-19 vaccines" that contradict medical data and evidence.

"As a member of the Wisconsin medical community I'm gravely concerned about the impact his event and remarks will have on our ability to return to normal and protect Wisconsinites from COVID-19.," Huebner said in a statement.

Nearly all COVID-19 deaths in the U.S. now are in people who weren't vaccinated, with "breakthrough" infections in fully vaccinated people accounting for fewer than 1,200 of the more than 853,000 COVID-19 hospitalizations in May, based on an Associated Press analysis.

YouTube this month removed an interview Johnson did with the Milwaukee Press Club during which he touted the benefits of alternative treatments for COVID-19 and suspended Johnson for a week, saying his comments violated the company's "medical misinformation policies."

Johnson, during the June 3 event, criticized the administrations of President Joe Biden and former President Donald Trump for "not only ignoring but working against robust research (on) the use of cheap, generic drugs to be repurposed for early treatment of COVID."

Johnson said Monday's event at the federal courthouse in Milwaukee will include former Green Bay Packers offensive lineman Ken Ruettgers, a member of the Packers Hall of Fame, and his wife Sheryl. Johnson said Sheryl Ruettgers will detail "severe neurological reactions that still inhibit her ability to live a normal life, including muscle pain, numbness, weakness and paresthesia" that she experienced after getting the COVID-19 vaccine this month.

Other speakers with similar stories are from Ohio, Missouri, Utah, Michigan and Tennessee.

The medical community has been consistent in stressing that the risk of side effects is exceedingly low and the benefits of getting vaccinated for the virus far outweigh the risks. Earlier this week, top U.S. government health officials, medical organizations, laboratory and hospital associations and others issued a statement touting the overriding benefit of the vaccines.

Still, certain elected officials in some states continue to push back against the vaccination recommendations.

On the same day the government and medical experts issued their statement on the vaccines' benefits, Republican attorneys general in

Louisiana, Alabama and Montana wrote to a Centers for Disease Control and Prevention COVID-19 task force leader requesting a pause in recommending that children and healthy young adults get vaccinated against the disease.

The letter accused the CDC of providing "dismissive, misleading, and deadly advice" regarding incidents of heart inflammation among young people who get the vaccines.

U.S. health officials paused the Johnson & Johnson's single-dose shot for 11 days earlier this year, after 15 vaccine recipients developed a highly unusual kind of blood clot out of nearly 8 million people given the J&J shot. Experts said Wednesday that there also seems to be a link between the Pfizer and Moderna shots and some cases of heart inflammation.

Johnson's seat is up for election in 2022 and he has not yet said whether he will seek a third term.

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Associated Press writer Kevin McGill in New Orleans contributed to this report.

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Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic, research finds

By Lauren Mascarenhas, CNN

(CNN)Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic at one Louisiana hospital, according to research presented Friday. The researchers say the cases increased in severity, too.

Dr. Daniel Hsia, an associate professor at Pennington Biomedical Research Center in Baton Rouge, Louisiana, and colleagues looked at the hospitalization rate for new onset type 2 diabetes among children at Our Lady of the Lake Children's Hospital.

From March to December 2019, the rate was .27% -- 8 cases out of 2,964 hospitalizations. During the same period in 2020, the rate jumped to .62% --17 cases out of 2,729 hospitalizations.

"These are very small numbers," Hsia told CNN. "We're a single hospital, but we think that we may be a microcosm of what's happening across the country."

Type 2 diabetes is by far the most common type of diabetes, and it's associated with obesity, poor diet and a lack of exercise.

Among the 25 cases of type 2 diabetes over both years, 23 were in Black

children, the team noted. Black, Latinx, Asian, Native American, Alaska Native and Pacific Islander children may be at increased risk for type 2 diabetes, according to the US Centers for Disease Control and Prevention. Hsia said these existing health disparities may have worsened over the course of the pandemic.

"Risk factors for type two diabetes may worsen even more during a time like this, where they have to stay home, and they don't have access to healthy foods and physical activity, and there are sleep disturbances," Hsia said.

Children who were admitted for type 2 diabetes in 2020 had more severe symptoms than children admitted in 2019, the team said. They had higher blood sugar levels and signs of more severe dehydration -- caused when the body tries to get rid of excess glucose through urination.

Dr. Lily Chao, interim medical diabetes director at Children's Hospital Los Angeles, said she's seen the same trend in her hospital, particularly in cases of ketoacidosis, a severe complication of diabetes that occurs when the body does not have enough insulin.

"Historically, in people with type 2 diabetes, the rates vary from 5 to 10% in our hospital," said Chao. "In this past year, our rates went up to 20% of new type 2 diabetes cases presenting in that severe state." Chao noted that her hospital serves a primarily Latinx population.

"There are reports of new-onset diabetes that occur after someone's been infected with the SARS-CoV-2 virus," said Chao. "We know the Covid pandemic disproportionally affected people of color. What we don't know is how many of these cases are related to prior exposure to the virus."

A new lifestyle

Andrew Aparicio, a 17-year-old patient of Chao's, said it was about a year ago when he started experiencing stomach cramps and fatigue. At first, he thought it could be coronavirus.

"I wasn't eating. I would be sleeping most of the day and not doing anything," Aparicio said.

His father took him to the hospital, where he stayed for a week and was diagnosed with type 2 diabetes. Aparicio said the news came as a shock.

"I left the hospital pretty traumatized," Aparicio said. "What happened to me really scared me."

Aparicio said he weighed around 257 pounds at the time, "Being stuck at home all day, I would just eat. Covid kind of messed me up."

He started taking medication, scheduling workouts and eating healthier.

"Andrew's case is really inspirational," said Chao. "It is extremely difficult for many of our young people to really accomplish what he has in terms of motivation to stay as physically active as he has and to exercise that discipline."

A year later and about 120 pounds lighter, Aparicio is ready to take on his senior year of high school. He no longer needs the same level of medication to manage his diabetes and says that in a few months, he may be able to stop taking some medication completely -- a sign that he is doing much better.

"Overall, I'm both mentally and physically happy with the change I've been able to accomplish," he said. "I have a whole new lifestyle."

A growing problem

Children and teens almost never got type 2 diabetes until recently, according to the CDC, which now says the condition is a growing problem among pediatric patients.

"Getting diabetes at this age is very different than getting diabetes as an adult," said Chao. "The complications occur sooner. It is a much more progressive condition."

Hsia says additional research is needed to understand the factors driving the increase in cases, but the lifestyle changes associated with the pandemic -- including less physical activity and more screen time -- could drive weight gain in children.

"The little weight changes and small amounts of weight gain can certainly tip the scale and cause someone to develop type 2 diabetes," Hsia said.

Doctors say symptoms to look out for include increased fatigue, thirst, urination, and sudden, unexplained weight loss.

The CDC says having a family member with type 2 diabetes, being born to a mother with diabetes while pregnant, and having conditions related to insulin resistance can place children at increased risk. The agency advises that children who are overweight and have a combination of risk factors check with their doctor about getting their blood sugar tested.

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1st Post-Pandemic Cruise Ship From US Sails Away

By ADRIANA GOMEZ LICON and MARTA LAVANDIER
The Associated Press

FORT LAUDERDALE, Fla. (AP) -- The first cruise ship to leave a U.S. port since the coronavirus pandemic brought the industry to a 15-month standstill sailed away on Saturday with nearly all vaccinated passengers on board.

Celebrity Edge departed Fort Lauderdale, Florida, at 6 p.m. with the number of passengers limited to about 40% capacity, and with nearly all 1,100 passengers vaccinated against COVID-19. Celebrity Cruises, one of Royal Caribbean Cruise's brands, says 99% of the passengers are

vaccinated, well over the 95% requirement imposed by the Centers for Disease Control and Prevention.

A giant greeting was projected on a wall of one of the port buildings: "Someday is here. Welcome back."

Passengers arrived with matching T-shirts that read phrases such as "straight outta vaccination" and "vaccinated and ready to cruise."

"Words can't describe how excited we are to be a part of this historic sailing today," said Elizabeth Rosner, 28, who moved from Michigan to Orlando, Florida, in December 2019 with her fiance just to be close to the cruise industry's hub.

To comply with both the CDC's requirement and a new Florida law banning businesses from requiring customers to show proof of vaccination, Celebrity Cruises asked guests if they would like to share their vaccination status. Those who did not show or say they are vaccinated face additional restrictions.

Saturday's sailing kicks off the cruise lines' return to business with Carnival vessels already scheduled to depart from other ports next month.

"This is an emotional day for me. When I stepped on board the ship, I was proud. It's a beautiful ship," said Royal Caribbean Cruises' CEO Richard Fain, after expressing condolences to the victims of the Surfside building collapse, less than 15 miles (about 24 kilometers) south of the port.

Celebrity Cruises had unveiled the $1 billion boat in December 2018 -- betting on luxury cruising, offering a giant spa and multifloor suites. The seven-night cruise will sail for three days in the Western Caribbean waters before making stops in Costa Maya, Cozumel and Nassau.

The ship is led by Capt. Kate McCue, the first American woman to captain a cruise ship, who has more than 1 million followers on TikTok.

"You can truly feel the palpable sense of excitement and energy amongst the group as we prepare for our welcoming of our first guests," McCue said. "I've never honestly seen a group so excited to get back to work."

Industry officials are hoping all goes smooth to move past a chapter last year of deadly outbreaks on cruise ships that prompted ships to be rejected at ports and passengers to be forced into quarantine. Some passengers died of COVID-19 at sea while others fell so ill they had to be carried out of the vessels on stretchers.

The CDC extended no-sail orders repeatedly last year as the pandemic raged, and came up with strict requirements for the industry that have already been contested in court by the state of Florida. Florida Gov. Ron DeSantis says the industry generates billions for the state's economy.

On Saturday, officials at Port Everglades in Fort Lauderdale said only

that port lost more than $30 million in revenue in fiscal year 2020 from the cruise shutdown.

During that hiatus, Carnival, Norwegian and Royal Caribbean, the three largest cruise companies, have had to raise more than $40 billion in financing just to stay afloat. Collectively they lost $20 billion last year and another $4.5 billion in the first quarter of 2021, according to Securities and Exchange Commission filings.

The pandemic forced Kurt and Carol Budde to cancel their beach celebration wedding aboard the world's largest ship, Symphony of the Seas, in March 2020. COVID-19 halted cruising six days before they were scheduled to tie the knot in St. Maarten. Kurt Budde's part-time gig as a travel agent also dried up.

"It's a honeymoon make-up cruise," said Kurt Budde, sporting matching shirts with the phrase "On Cruise Control."

"We are living our best lives post COVID today," he said.

CNN.com
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How the first cruise of the Covid era got ready to safely set sail

By Andrea Kane and Nadia Kounang, CNN

(CNN)It's anchors aweigh and full steam ahead for the Celebrity Edge. On Saturday, the cruise ship, owned by the Royal Caribbean Group, will become the first to sail from a U.S. port since the US Centers for Disease Control and Prevention brought the industry to a halt more than 15 months ago with a no-sail order that was ultimately extended a number of times. It is scheduled to sail from Fort Lauderdale on a seven-night trip that will take it around the Caribbean, with ports of call in Mexico and the Bahamas.

CNN Chief Medical Correspondent Dr. Sanjay Gupta got an exclusive early look at the procedures and safety features in place to make cruising in the Covid era possible. The question is, will they be enough to keep passengers and crew coronavirus-free?

Smooth sailing or troubled waters?

For die-hard cruise fans, this event, after several false starts, has been a long time coming. For the more skeptical, the event is tempting fate to once again reveal that cruise ships are floating petri dishes for one infectious disease or another. It will be a long while before the world forgets the high-profile saga of the Diamond Princess, which saw more than 700 coronavirus infections on board, and others like it -- a situation made worse and more dramatic by nationwide lockdowns and travel bans that left some ships literally racing toward any welcoming port.

For cruising to be possible in the Covid era, leaders in the industry

convened the Healthy Sail Panel -- which included experts in the public health, infectious diseases, biosecurity, maritime and hospitality industries -- to come up with recommendations to make the experience healthier and safer for guests and crew. These wide-ranging recommendations, developed before vaccines became available, dovetail with the Covid-19 Member Policy of the industry's largest trade group, Cruise Lines International Association, and with the requirements and guidelines for cruise ships set forth by the CDC, which has been -- up to now -- deciding the circumstances under which ships can sail from the United States.

Dr. Calvin Johnson, the chief medical officer for Celebrity, told CNN neither he nor the crew are apprehensive. "I think everyone really believes in -- because they were part of it -- the protocols that we've developed, the processes we put in place," he said.

"This has been over a year of consistent, methodical, science-based, operational examinations to look at the business, how it operates, and how we can do it safely. Putting in place protocols to protect our crew, and then looking at what it will look like when our guests come back to protect them -- and so it's been a process that brought us to this place," he said.

The industry battens down the hatches

So, what's the plan to make sailing safer? This summer at least, there will be fewer people on board; the Edge is sailing at 40% of its capacity. Because the coronavirus is spread through airborne particles, fewer people, less crowding and good ventilation can make a big difference.

"For this start-up period, we're sailing with a reduced capacity to give us all a chance to get used to the protocols and to really allow for natural social distancing," said Susan Lomax, head of global public relations at Celebrity Cruises. She said the cruise line does not plan to exceed 50% capacity on any of its trips this summer. Because of the reduced capacity, cabin occupancy will be spaced out and people will be put into cabins with windows that face outward. Crew members will get their own cabins.

Lomax said filtration experts from the University of Nebraska were asked to evaluate the ventilation/HVAC system and pronounced it "better than what hospitals have."

Linsey Marr, an environmental engineer and professor at Virginia Tech, agrees the Edge's ventilation system is more than adequate. "The combination of high air change rates and high-quality filters ... will greatly reduce the amount of virus that can build up in the air. Thus, it is unlikely that people will be exposed to elevated levels of virus in cabins and public indoor spaces," she told CNN. "If this is the case, then the biggest risk comes from being in close proximity, within the exhaled respiratory plume of an infected individual."

Yuguo Li, from the department of mechanical engineering at The University of Hong Kong, sides with Marr.

"Taking all evidence so far, I highly believe that SARS-CoV-2 is predominantly transmitted by the short-range inhalation route in inadequately ventilated spaces. We have studied about 20 outbreaks of SARS-CoV-2, and performed ventilation measurement for 10 of them, all supporting this hypothesis," Li wrote in an email. His study on the Diamond Princess was published online in April in the journal Building and Environment and his editorial appeared in the journal Indoor Air in mid-May.

"For the Diamond Princess outbreak, we showed that their cabin ventilation might be sufficient, and suspect that infections occurred in the public areas. There are two major factors in these public areas: First, in gyms and dancing floors, people perform high [energy] activities with more droplet release and higher inhalation flow, hence infection risks are high ... Second, if occupancy is not controlled in these public spaces, the ventilation per person can be even lower. In some spaces such as restaurants, people cannot wear masks," he explained.

On the Edge, other procedural changes include staggered arrival and departure times to prevent large crowds, and a muster drill -- the mandatory safety exercise done at the start of every trip -- done virtually instead of in person, again to avoid large crowds. And, food lovers need not fear: the all-you-can-eat buffets will still be a staple of the dining experience, but instead of self-serve, crew members will lend a hand.

In the unfortunate event of an outbreak, the Edge has the capacity to manage 33 patients, and there are four ICU beds. The entire medical area is on a separate ventilation system.

Contact tracing plans that make use of the ship's CCTV have been drawn up, there are protocols for isolation and quarantining, and disinfection procedures following positive cases.

Importantly, Royal Caribbean has agreements with a number of countries to act as disembarkation ports, should there be a need to get people off the ship.

"There's no longer any 'Oh my gosh, we're sailing for days and no one will take us,' " said Lomax. "There's no reason to wait till the end of the cruise; we have the ability to go to those disembarkation ports if and as needed."

Vaccines are game changers

But everyone, from those in the cruise industry to health experts, says the real game changers are vaccines, which offer up to 95% protection against symptomatic Covid-19. Even if there are breakthrough infections, vaccines reduce the amount of virus in the body, making people less infectious to others.

"It's really the vaccines that have enabled us to return to cruising with a low enough level of risk of transmission," said Marr.

On the Edge, 100% of the crew and at least 95% of passengers are

vaccinated, which considerably lowers the risk of people getting infected and sparking an outbreak.

However effective vaccines are, it's unclear whether, when and where they can be mandated on future cruises. The CDC currently advises unvaccinated people against going on a cruise -- but that's just guidance. Additionally, Florida is one of several states that has banned businesses from requiring customers to provide proof of vaccination, although upcoming cruises leaving from ports in Washington state and Alaska are expected to have vaccination requirements.

And to top it off, a federal district judge in Tampa recently concluded the CDC's restrictions on the cruise industry are likely unconstitutional and the agency is overstepping its legal authority.

So, starting July 18, the agency will no longer be able to enforce its sailing rules, including requirements that either 95% of passengers be vaccinated or that the ship successfully conduct a simulated voyage.

The judge gave the CDC until July 2 to propose more modest guidelines.

In navigating these murky, fluctuating rules, Lomax said that the Edge capped at 5% the number of cabins for people who choose not to disclose their vaccination status. They are counted as unvaccinated. People presumed to be unvaccinated will have to wear masks in public areas and will also have to undergo additional Covid-19 testing -- both to board and midway through the cruise -- at their own expense. Everybody has to be tested before disembarking in the United States.

"With 95% of passengers vaccinated, that's far more than we have in any country. And we know that the higher vaccination rates have really brought down cases. So I think it's probably reasonable for healthy vaccinated people to go on a cruise," said Marr. "The risk of an outbreak on a cruise ship, together with the measures that they're taking requiring unvaccinated people to wear masks, the overall risk of an outbreak should be quite low. And I'd be surprised if we saw something like the Diamond Princess again."

But, despite all the precautions, the experience is still not guaranteed to be 100% coronavirus-free, if the Celebrity Millennium is any example. That ship, carrying the first North American paying passengers, set sail in early June out of St. Maarten, and made several ports of call. The crew were all fully vaccinated as were more than 95% of passengers. Nonetheless, two passengers tested positive for coronavirus at the end of the trip.

"In term of vaccination, the protection is not 100%. Sufficient vaccination protects us from developing a chain of infection, i.e. sustained infection in a large population but ... that means sporadic outbreaks can still occur particularly with the new variants of concern," Li noted.

Johnson, Celebrity's CMO, said the incident was unfortunate but it shows the system is working. "It certainly got my attention," he said.

"But we also know that, if we look [at] the world around us, in every

venue infections are happening every day. And so we fully anticipate that... as thorough as our efforts are and as much as we do prevent, on the front end, virus from coming on board the ship, that it can happen," he said. "It's why we have protocols, we have a process; we've trained our folks to know what to do when we do identify this. We work very quickly to identify and isolate that, and prevent and stop the spread."

But perhaps the most reassuring statement for would-be cruise goers comes from Marr, who said that she would not stop her healthy, vaccinated, 70-year-old cruise-loving mother from taking one.

CNN Health's Keri Enriquez and Michael Nedelman contributed to this story

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Virus-Origin Review Likely to Be Unclear

Biden administration warns that the hunt for clues is a challenge for U.S. spy agencies

By Michael R. Gordon and Warren P. Strobel

Biden administration officials are cautioning that a 90-day review into the origins of the Covid-19 virus may not produce a definitive explanation as intelligence agencies take on the challenge of unraveling the global pandemic.

Spy agencies conducting the review have yet to find conclusive evidence that would settle the debate over whether the virus came from human contact with an infected animal or was leaked from a Chinese government virology lab, a person familiar with the efforts said.

President Biden is due to receive a 45-day update in mid-July, and administration officials said that even partial progress might narrow differences among scientists, politicians and intelligence experts and turn up clues for further investigation.

Mr. Biden "is mindful of the fact that after 90 days we may not have an absolutely definitive answer, but he wanted a focused, intense, time-bound effort," a senior administration official said.

Experts say that knowing the origins of Covid-19 could be important in preparing for future pandemics. The virus has killed more than 600,000 Americans and nearly four million people world-wide, and disrupted the global economy.

The review is being overseen by Director of National Intelligence Avril Haines, a lawyer and former deputy director of the Central Intelligence Agency. It requires the vast intelligence community to train its resources on an area it has long treated as far less of a priority than spying on the Russian military, terrorist dangers or China's weapons

buildup: the detection and analysis of global pandemics.

Ms. Haines told lawmakers this spring she had hired additional personnel to work on pandemic threats.

Absent a breakthrough, the review faces many obstacles, chief among them China's refusal to provide further access to data and scientists from the Wuhan Institute of Virology, a biosecurity lab that has studied coronaviruses. China has said the search should turn to other countries and cited the conclusion of a World Health Organization-led team of experts early this year that a lab leak was "extremely unlikely."

A daily intelligence briefing Mr. Biden received in the Oval Office in February showed the difficulties the intelligence community has had in identifying the source of the virus. Intelligence officials told Mr. Biden during that session they had numerous questions about the origin of the virus but didn't have "high confidence" in any particular explanation, more than a year after the virus was first detected in the Chinese city of Wuhan.

Mr. Biden instructed national security adviser Jake Sullivan to follow up, which he did in a meeting with intelligence officials in early March. The White House ordered a written assessment from intelligence officials. Delivered to Mr. Biden in May, the assessment showed one intelligence agency leaning toward the hypothesis that the virus leaked out of a lab and two intelligence agencies leaning toward the view that it arose naturally -- all with low or moderate confidence.

That inconclusive assessment and China's statement to the WHO that it considered the Covid-19 origins investigation in its country to be complete, led to Mr. Biden's order to mount what a senior administration official called an "all hands on deck effort" over a 90-day period.

Within Ms. Haines's office, officials said, the review is being coordinated by the National Counterproliferation Center, which oversees intelligence efforts to combat nuclear, chemical and biological proliferation.

The National Security Agency, the officials said, will look for clues in its vast stores of intercepted foreign electronic communications, most of which aren't analyzed in real time. The effort is being aided by experts from government labs, the Centers for Disease Control and Prevention, the National Institutes of Health and other parts of the Department of Health and Human Services. Experts outside the government are being consulted, as are allied intelligence agencies.

One outcome, Mr. Biden said in May, could be a list of specific questions that the U.S. would put to China as well as recommendations on what additional inquiries might be needed.

Given the possibility that the intelligence review might be inconclusive, there are already calls by leading lawmakers, some experts outside government and a grass-roots group of people affected by Covid-19 for an independent national commission.

"There has not yet been a properly organized, independent, scientific evaluation of all of the available evidence," said Philip Zelikow, the former executive director of the commission on the 9/11 terror attacks. Mr. Zelikow is heading a planning group, backed by prominent foundations, for a possible commission to investigate how Covid-19 emerged and how to prepare for future pandemics.

The Trump administration didn't organize an intensive governmentwide review into Covid-19's origins, though intelligence agencies and the Lawrence Livermore National Laboratory probed the matter, former Trump administration officials said.

WSJ.com
Saturday, June 26, 2021

What We Know About the Origins of Covid-19

Key findings from The Wall Street Journal's investigation into how the global pandemic began

By Drew Hinshaw, Jeremy Page and Betsy McKay

It is among the world's most consequential mysteries: Where did the coronavirus that killed millions of people and shattered the global economy come from?

The Wall Street Journal has covered the global quest for answers, tracking the World Health Organization, doctors and scientists in China and around the world, the U.S. intelligence community and the vast network of disease specialists, all struggling to piece together a puzzling set of disparate clues. Here are some of the key findings:

1. A WHO-led inquiry into the origins of the virus was stymied from the start.

A Journal investigation found China resisted international pressure for an investigation it saw as an attempt to assign blame, delayed the probe for months, secured veto rights over participants and insisted its scope encompass other countries as well. The WHO-led team that traveled to China in early 2021 to investigate the origins of the virus struggled to get a clear picture of what research China was conducting beforehand, faced constraints during its monthlong visit and had little power to conduct thorough, impartial research without the blessing of China's government. In their final report, the investigators said insufficient evidence meant they couldn't yet resolve when, where and how the virus began spreading.

2. China withheld data on potential early cases and delayed sharing information on animals sold at a market where the first cluster was found.

Chinese authorities refused to provide WHO investigators with raw data on confirmed and potential early Covid-19 cases that could help

determine how and when the coronavirus first began to spread in China. Chinese researchers also directed a U.S. government archive to delete gene sequences of early Covid-19 cases , removing an important clue.

For months before the WHO investigators arrived, Beijing declined to disclose information about samples authorities took in the first weeks of the pandemic from animals sold at the Wuhan market linked to many early cases . During their visit, the investigators found no proof of live mammals being sold at that market and quoted market authorities saying there was no illegal wildlife traded there. A study later suggested the Wuhan market was the site of widespread trading in illegal caged wildlife , providing evidence that the virus could have spread naturally from market animals to humans.

3. The question of whether a lab accident was the cause of the pandemic remains unanswered.

Since the early days of the pandemic, questions have surrounded the Wuhan Institute of Virology and whether an accident at one of its labs could have caused the pandemic . The WHO-led team declared that a lab accident was an extremely unlikely cause of the pandemic. But afterward, WHO Director-General Tedros Adhanom Ghebreyesus called for further investigation into the lab-leak hypothesis.

A group of leading scientists also published an open letter saying the lab hypothesis was plausible enough to merit serious consideration. Other scientists sought more information about the WIV's role in investigating a mysterious respiratory illness that afflicted six people clearing bat guano from a mine in southwest China in 2012. Three of them died, and samples the WIV took from bats in the mine were later found to contain the closest known virus on earth to the one that causes Covid-19.

Unanswered questions about the miners' illness, the viruses found at the site and the research done with them elevated into the mainstream an idea once dismissed as a conspiracy theory: that SARS-CoV-2, the virus that causes Covid-19, might have leaked from a lab in Wuhan. China denies that the virus came from the Wuhan Institute of Virology or any other Chinese laboratory.

4. International pressure for a fuller inquiry into the origins of the virus grows.

The WHO-led investigators have pushed for a second phase of research into the origins of the virus, warning that time was running out to examine blood samples and other important clues in China . Meanwhile, the Journal disclosed a U.S. intelligence report asserting that three WIV researchers became sufficiently ill in November 2019 to seek hospital care. In late May, President Biden ordered that U.S. intelligence agencies report to him within 90 days on how the virus emerged , with a focus on two scenarios--whether the coronavirus came from human contact with an infected animal or from a laboratory accident.

Meanwhile, China said further investigations should now turn to other countries, suggesting that the virus might have originated outside its

borders and spread via frozen food.

5. Other efforts to trace the path of the pandemic continue.

As part of an international effort to pinpoint the origin of the Covid-19 pandemic and prevent future disease outbreaks, scientists around the world and organizations such as the American Red Cross and the U.S. Centers for Disease Control and Prevention are looking for new clues in frozen blood , searching for SARS-CoV-2 antibodies or signs of infection.

Other independent scientists are also trying to piece together a picture of how the virus could have been evolving before it exploded in late 2019. Many scientists believe that the most likely explanation is that the virus evolved and jumped from an animal to humans naturally, given evidence that two other coronaviruses spilled over to humans that way in the past two decades and signs of ample opportunity for that to occur.

At least four recent studies have identified coronaviruses closely related to the pandemic strain in bats and pangolins in Southeast Asia and Japan, a sign that these pathogens are more widespread than previously known and that there was ample opportunity for the virus to evolve.

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The US is concealing its research on deadly viruses -- while criticizing China's secrecy over the Wuhan lab

Mattathias Schwartz

In January 2020, an obscure government panel met at the Hyatt Regency in Bethesda, Maryland, to discuss a branch of virology known as "gain of function." The goal of such research is to take infectious diseases -- including the viruses that can cause pandemics -- and alter them in ways that make them deadlier or more transmissible, in the hope of getting a jump on outbreaks. It was two days after the United States had its first confirmed case of COVID-19, but the empty seats in the Hyatt conference room were due to lack of interest, not social distancing.

The gathering "couldn't be more timely," said David Christian Hassell, a career official at the Department of Health and Human Services, as he began loading slides for his presentation. "We're seeing this virus reassort and mutate as it spreads. It's just pointing out the need for doing this kind of work."

In fact, many critics would soon be pointing to the COVID pandemic as the ultimate proof that gain-of-function research needs to be shut down. At the time, the virus was still widely viewed as a problem confined to China, where it originated. Later, as the US went into lockdown, President Trump would try to rebrand the pandemic as the

"China virus." The city of Wuhan was home to a laboratory conducting "experimental investigations" into what it called the "origin, diversity, capacity to cause illness, and risk of spillover" from bat coronaviruses. If an altered virus escaped from the lab, then gain-of-function research might have accidentally caused the very sort of pandemic it's intended to prevent.

Trump's national-security adviser accused the Chinese government of engaging in a "cover-up" of what happened in Wuhan. But as the meeting in Bethesda demonstrated, the Chinese have nothing on the US when it comes to keeping secrets about dangerous viral research.

Discussion at the meeting focused on the government committee that recommends which studies get funded -- and which are too dangerous to perform. Its formal name is the P3CO Review Group. The group is cloaked in an opacity even more impenetrable than the one surrounding the military's drone-strike program or FISA's wiretapping court. Until that morning at the Hyatt, when Hassell identified himself as chair of P3CO, no one beyond a handful of officials knew who served on the panel. Only federal employees are permitted to take part in its proceedings, which are kept confidential; neither academia nor industry is represented. Even as Trump accused the Chinese of a cover-up, Americans had no way of knowing what their own government was doing to protect them from some of the riskiest science since the development of the atomic bomb.

"This lack of transparency is unacceptable," two scientists from Harvard and Johns Hopkins argued in The Washington Post. "Making decisions to approve potentially dangerous research in secret betrays the government's responsibility to inform and involve the public when approving endeavors, whether scientific or otherwise, that could put health and lives at risk."

Officials insist that the near-total secrecy surrounding P3CO is necessary "to preserve confidentiality and to allow for candid critique and discussion of individual proposals." A spokesperson for Health and Human Services told Insider that the review group meets "as needed," and that its membership varies depending on the proposal under review.

At the Hyatt meeting, which was prompted by scientists sounding the alarm over the apocalyptic risks of gain-of-function studies, Hassell said he was open to broadening P3CO's authority and defended the integrity of its process. "This isn't some rubber-stamp group," Hassell said. "Right now, you don't see evidence of that. But it is a very tough group."

At the moment, unfortunately, we have little choice but to take Hassell's word for it. What we do know is that the group weighed in on -- and approved -- at least one gain-of-function study conducted on American soil. The research, which took place at the University of Wisconsin-Madison in 2019, sought to make the deadly H5N1 bird flu transmissible between mammals. Another study, conducted at the University of North Carolina at Chapel Hill in 2015, created a new "chimeric" hybrid that combined elements from bat and mouse coronaviruses.

We may never know for certain how the coronavirus made the jump from

animals to humans. But even the slightest possibility of a lab leak should be worrisome enough to warrant a hard look at whether the benefits of gain-of-function research outweigh the risks, and who gets to make the call about which experiments move forward. Billions of people, after all, would suffer if a risky experiment inadvertently starts the next pandemic. "It is unethical to put the general public at risk," David Relman, a microbiologist at Stanford, said in a Nature roundtable, "and then minimize inclusion of the public in discussions about the appropriateness and oversight of such research."

Uncalculated risks

There's no question that tinkering with infectious diseases in the lab has saved lives. It was passing the yellow-fever virus through chicken cells, for example, that enabled researchers to create a vaccine for humans. And herpes viruses have been altered in the lab to create a treatment for cancer. Today, according to one of the funders of the Wuhan bat studies, hybrid viruses developed in the lab were used as reagents to test possible vaccines.

Michael Imperiale, a professor of microbiology and immunology at the University of Michigan, says that gain-of-function studies have made important contributions to biomedical research. The studies on H5N1 bird flu, he told me, provided vital insights into protein changes that could allow for human-to-human transmission. "The better we get at making these kinds of correlations," he said, "the further ahead we'll be in the game of anticipating dangerous pathogens."

There aren't many scientists who conduct gain-of-function research. "It's a very small part of virology," Richard Ebright, a critic of gain-of-function research who teaches molecular biology at Rutgers University, told me. "Less than 1%." And it would be wrong to suggest that biomedical research as a whole is unregulated. The federal government has a number of regulations that cover the conduct of scientific research, including special rules for 67 "select agents and toxins." Among them is SARS-CoV-2, the virus that causes COVID-19.

But what biomedicine lacks is anything approaching a consensus about risk. The potential dangers of gain-of-function research were apparent long before the events in Wuhan drew attention to them. One comprehensive survey found that over a period of 75 years, there were 1,267 documented cases of "laboratory-acquired infections," or LAIs, caused by exposure to the kind of pathogens used in gain-of-function experiments, which resulted in 22 deaths. Infections by the deadliest agents in high-security labs appear to be far less frequent -- there were only 11 self-reported LAIs over a period of seven years.

There is sharp disagreement among scientists about the risk that a deadly gain-of-function pathogen could escape from a lab. Marc Lipsitch, a professor of epidemiology at Harvard, has estimated that it would take only one year of experimenting on a flu virus to put the risk of infecting a single person at 1 in 1,000. But Ron Fouchier, who induced mutations in H5N1 avian flu to make it transmissible between ferrets, calculated that under the safety measures in his own lab, it would take a million years of research to infect a single person -- and 33 billion years before an infected lab worker spread the disease to

others. "This probability," he wrote, "could be assigned the term 'negligible,' given that the age of our planet is only 5 billion years."

Whatever the overall risks, there have already been some close calls. In 2014, fears of a lab-spawned pandemic, along with the Ebola outbreak in West Africa, spurred the Obama administration to impose a two-year moratorium on government funding for gain-of-function studies. Unsecured vials of smallpox from the 1950s turned up in a storage room at the Centers for Disease Control. In another incident, the CDC mistakenly sent samples of the virulent H5N1 flu to a lab in Athens, Georgia. And in a third mishap, as many as 75 CDC employees were accidentally exposed to anthrax when they handled samples they thought were inactive.

While none of the incidents involved gain-of-function studies, they underscore the risks inherent to cutting-edge biomedical research and the difficulty of solving for human error. At the time the moratorium was imposed, 19 studies identified as possible gain-of-function research were underway in 11 states. Health and Human Services set about devising a framework for evaluating the risks, which led to the establishment of the P3CO review group.

But even after the moratorium was lifted in 2017, the lab accidents kept coming. In 2019, the CDC briefly shut down the Pentagon's biodefense lab at Fort Detrick after numerous containment failures. And in April 2020, as the nation went into lockdown, a scientist at the University of North Carolina in Chapel Hill was forced to self-quarantine for two weeks after being bitten by a mouse that had been infected with a strain of the virus that causes COVID-19. Research at UNC -- some of which was carried out with the assistance of Shi Zhengli, who led the experiments on bat coronaviruses at the Wuhan Institute of Virology -- resulted in four incidents of potential human exposure to SARS coronaviruses. UNC confirmed to ProPublica that the viruses had been created in a lab.

Ralph Baric, who helped lead the UNC research, has denied that it involved gain of function. Zhengli, meanwhile, told The New York Times that the Wuhan lab "never conducted or cooperated in conducting GOF experiments that enhance the virulence of viruses." (She did not comment on whether the lab was trying to enhance the transmissibility of viruses, which is another key criterion for gain of function.) Dr. Anthony Fauci and the National Institute of Health, which provided funding for the Wuhan experiments, also insisted that the work did not involve any gain-of-function research. The study was "subjected to rigorous peer review and was judged to be very high priority, given how SARS-CoV had already emerged in this bat population," an NIH spokesperson told Insider.

Experts I spoke with were skeptical of the NIH's claim that the Wuhan study didn't involve gain of function, noting that the term is subject to competing definitions. But when it comes to oversight, the NIH's definition -- which is extremely narrow -- is the one that counts. The agency told The Washington Post that the Wuhan study was determined to be "outside the scope" of oversight by the P3CO committee.

It's a telling admission: What turned out to be one of the most controversial and perhaps consequential experiments in history was deemed not to require government oversight. As a result, the grant proposal was never even passed along to the P3CO review group. And there's no way to know the reasoning behind the decision, or the identities of the officials who made it.

Made in the USA

After much obstruction and foot dragging, most scientists now agree that there is a need to investigate what happened in Wuhan. At the end of May, President Biden ordered the intelligence community to conduct a 90-day review of what they know about COVID-19's origin.

It's possible, of course, that the lab-leak scenario will turn out to be wrong. If, as many scientists believe, the virus had a natural origin, then the Wuhan lab -- now vilified by everyone from Mike Pompeo to Jon Stewart -- was actually conducting critical, prescient research into a soon-to-emerge disease. The lab would be held up as a shining example of the need for gain-of-function research, which proponents view as the last line of defense in humanity's arms race against nature. Unless we know what could be headed our way, they argue, we won't have enough time to stop it.

But the relentless focus on China-based research, and what may have gone wrong there, misses a deeper and more disturbing truth. The vast majority of virology -- including the Wuhan study and other gain-of-function research conducted outside the US -- is supported by American funding. The training, ethical guidelines, and standards for bioscience adhered to by top researchers worldwide are dominated by US institutions. If it becomes demonstrably true that a cutting-edge laboratory caused a pandemic, either now or in the future, America would deserve the blame, regardless of which country happens to be hosting those experiments. And much like the international regulatory regime around nuclear weapons, any effort to create an independent authority capable of overseeing dangerous biomedical experiments would need to be spearheaded by the US.

At the moment, though, we have no way of knowing the number or nature of studies working to change viruses in ways that could lead to the deaths of millions. Even more striking, the public has no way to know who is responsible for reviewing those studies, or how they are making their decisions about funding. Regardless of how COVID-19 emerged, we are being kept in the dark about scientific work that seeks, as its primary objective, to make the most frightening diseases more frightening.

"Everyone on earth has now experienced a pandemic in their lifetimes," Ebright told me. "Nobody wants to see another. If there's even a possibility that this category of work caused this pandemic, or could result in the next pandemic, then it needs to be regulated."

Global Times (China)

Monday, June 28, 2021

Why US labs need to be investigated for COVID-19 origins

Suspect No.1: Why Fort Detrick lab should be investigated for global COVID-19 origins tracing

By Fan Lingzhi, Huang Lanlan and Zhang Hui

The lab-leak theory, that COVID-19 was leaked from a laboratory, has once again caused a clamor since the beginning of this year, months after the argument was thrown into the trash can of conspiracy theories by an overwhelming number of scientists.

Observers found that things only get more complicated when the origins of the coronavirus - an already difficult scientific issue - is entangled in political manipulation tricks. Combing through more than 8,000 pieces of news reports related to the lab-leak theory, the Global Times found that as many as 60 percent of the coverage was from the US alone.

It is worth noting that many media outlets in the US-led Western world, which hyped the lab-leak theory, are only willing to focus on the Chinese labs though they have been thoroughly investigated by the World Health Organization (WHO), while turning a blind eye to the more suspicious American biological research institutions, such as the infamous US Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, Maryland.

The USAMRIID was temporarily shut down in 2019 after a Centers for Disease Control and Prevention (CDC) inspection. Although this mysterious lab reported the reason for the closure as "ongoing infrastructure issues with wastewater decontamination," the explanation was not persuasive enough. The Global Times found that the lab's failure to control toxins seemed to have alarmed the Countering Weapons of Mass Destruction related institutions in the US.

Resurgence of lab-leak theory

A joint study into the origins of COVID-19 by Chinese experts and the WHO in March dismissed the "lab-leak" conspiracy theory. More evidence pointed to the fact that the virus had probably jumped from bats to humans via another intermediary animal, and it was "extremely unlikely" that it leaked from a lab, the study report said.

Nonetheless, the lab-leak theory has not disappeared; instead, especially from the beginning of May, it has been largely promoted by some US politicians and media outlets as a "plausible science." In an article published on Bulletin of the Atomic Scientists on May 5, without any evidence, science writer Nicholas Wade claimed that "proponents of lab escape can explain all the available facts about SARS2 considerably more easily than can those who favor natural emergence."

Days later, The Wall Street Journal reported on May 23 that three researchers at Wuhan Institute of Virology (WIV) "became sick enough in November 2019 that they sought hospital care," and they had "symptoms

consistent with both Covid-19 and common seasonal illness." The WSJ report quoted a "previously undisclosed US intelligence report."

On May 26, President Biden stated that he had ordered the US intelligence community to "redouble" its efforts to investigate the origins of COVID-19. The US national security adviser Jake Sullivan even claimed on June 20 that China will face "isolation in the international community" if it doesn't cooperate with a further probe into the origin of the COVID-19 pandemic, Bloomberg reported that day.

Pressure from politicians and the media seems to have affected some authoritative medical scientists in the US, including Director of the US National Institute of Allergy and Infectious Diseases (NIAID), Anthony Fauci. On May 11, after Rand Paul, a Republican to the Senate, accused Fauci of helping the Wuhan lab "create" the virus, Fauci strongly denied the accusation but said he is "fully in favor of any further investigation of what went on in China."

This sudden change in attitude of some US experts is due to the political pressure they have received, a Chinese virologist told the Global Times. "Western media like to ask the experts misguiding questions, like, 'is (lab leak) absolutely impossible?'" said the virologist who requested anonymity.

It's very difficult for experts to answer a question like that, as the possibility, although very little, still exists, the virologist said. "All they can say is, 'it's possible,'" he told the Global Times. Actually, most experts usually add "but it's highly unlikely" after "it's possible," but the media only presents the part which confirms their own bias, he said.

Big data shows the US is pushing the narrative of the COVID-19 lab-leak theory. Among the 8,594 pieces of news report related to "lab leak" that database GDELT collected since 2020, 5,079 were from the US, accounting for 59 percent. Following the US was the UK (611 pieces) and Australia (597 pieces). Almost all the coverage targeted the WIV lab.

While the US is solely focused on Chinese labs, the US seldom pays attention to the fault in its own domestic labs, some of which have even triggered virus-related accidents before. According to an August 2020 article by ProPublica, an independent newsroom that produces investigative journalism, the University of North Carolina at Chapel Hill reported 28 lab incidents involving genetically engineered organisms to safety officials at the National Institutes of Health between January 2015 and June 2020. "Six of the incidents involved various types of lab-created coronaviruses," ProPublica said in the article. "Many were engineered to allow the study of the virus in mice."

Weirdly, very few US mainstream media outlets have raised the question whether there is the possibility that COVID-19 was leaked from US labs, said the Chinese virologist. "They dare not ask that," he said.

In an article published on the independent political blog site Moon of Alabama on May 27, the author pointed out that some Westerners' hyping of the Wuhan lab leak conspiracy is similar to the trick the US played

in pushing the Iraq War in 2002 - the US claimed "Saddam Hussein will soon have nuclear weapon," which was "obvious nonsense," the author said.

"The 'lab leak' theory is similar to the WMD claim - evidence-free speculation long promoted by a neoconservative leaning administration that was extremely hostile to the 'guilty' country in question," said the author.

The lab-leak theory, therefore, "isn't just about an implausible, evidence free tale of a SARS-CoV-2 lab escape," the author noted. "It is a campaign launched to depict China as an enemy of humankind."

Intl concerns on US bio-labs

The US has many bio-labs in 25 countries and regions across the Middle East, Africa, Southeast Asia and the former Soviet Union states, with 16 in Ukraine alone. Some of these labs have seen large-scale outbreaks of measles and other dangerous infectious diseases, according to media reports.

The international community has frequently expressed concern over US' biological militarization activities in other countries.

In October 2020, Deputy Chairman of the Security Council of Russia, Dmitry Medvedev, said that the US research activities in bio-labs in members of the Commonwealth of the Independent States have caused grave concern. The US not only builds bio-labs in these countries, but also tries to do so in other places across the world. However, its research lacks transparency and runs counter to the rules of the international community and international organizations.

Anatoly Tsyganok, a corresponding member of the Russian Academy of Military Sciences and associate professor of Faculty of World Politics at Lomonosov Moscow State University, told the Global Times that biological and bacteriological weapons tests on US territory are prohibited by the US Congress. He said that the US military has been and is still carrying out tests of biological and bacteriological weapons in Georgia.

This is done under the guise of providing sick people with various therapeutic vaccines conducted by the US military and American private contractors at the Richard Lugar Center for Public Health Research, Tsyganok said. Related tests have been exposed by various media outlets.

In December 2015, 30 patients at the research center who were being treated for hepatitis C died. Twenty-four of them died on the same day, and their cause of death was listed as "unknown," according to Tsyganok and Russia news outlet.

Residents of neighborhoods around these labs often complain about health problems.

Bulgarian journalist Dilyana Gaytandzhieva published a story about the Lugar center in early 2018. In her interviews for the report, most residents who lived nearby the labs complained of headaches, nausea and

high blood pressure. They also said there was black smoke coming from the lab.

USA Today reported that since 2003, hundreds of incidents involving accidental contact with deadly pathogens occurred in US bio-labs at home and abroad. This may cause the direct contacts to be infected, who can then spread the virus to communities and start an epidemic.

A member of the Russian Academy of Sciences, Armais Kamalov said in an interview with TASS in early June that development of genetically-engineered viruses as biological weapons should be subject to the same worldwide ban as the testing of nuclear weapons. He mentioned US labs in Georgia and Armenia as reference.

"There are a lot of labs, which are bankrolled today by the United States Department of Defense. It's no secret that they are in Georgia, Armenia and other republics. It's surprising that access to such labs is off-limits, and we don't understand what they are doing there," he said.

What had happened in July 2019?

The terrible safety records of American biological labs around the world shows a possibility of a virus escaping from an American lab. Many point to the shutdown of Fort Detrick lab in July 2019.

In July 2019, six months before the US reported its first COVID-19 case, Army laboratory at Fort Detrick that studies deadly infectious material like Ebola and smallpox was shut down after the US Centers for Disease Control and Prevention issued a cease-and-desist order. CDC officials refused to release further information after citing "national security reasons."

The USAMRIID in Fort Detrick said in August 2019 that the shutdown was because the center did not have "sufficient systems in place to decontaminate wastewater" from its highest-security labs, the New York Times reported.

What exactly happened at Fort Detrick in the summer of 2019? Some US media previously turned to CDC to get answers, but many key contents in the report had been redacted.

In early June, a Virginia-based Twitter user got the CDC documents on the inspection of the Fort Detrick under The Freedom of Information Act (FOIA). Global Times found that most of the documents were emails between CDC officials at various departments and USAMRIID from 2018 to 2019. Although some of the emails were covered by an ABC-affiliated television station in Washington, the report did not catch much attention.

The emails revealed several violations at the Fort Detrick lab during

CDC's inspections in 2019. Four of which were labeled serious violations.

One of these serious violations, the CDC said, was one inspector who

entered a room multiple times without the required respiratory protection while other people in that room were performing procedures with a non-human primate on a necropsy table.

This deviation from entity procedures resulted in a respiratory occupational exposure to select agent aerosols, the CDC said.

In another serious violation, the CDC said the USAMRIID had "systematically failed to ensure implementation of biosafety and containment procedures commensurate with the risks associated with working with select agents and toxins."

Other violations included lack of proper waste management where waste wasn't transported in a durable leak proof container, which creates the potential for spills or leaks.

The CDC documents show that it sent a letter of concern to USAMRIID, which resulted in a temporary shutdown of the Fort Detrick lab in 2019.

In an email on July 12, 2019, the CDC said the USAMRIID reported two breaches of containment on July 1 and July 11, 2019, and this demonstrated a "failure of USAMRIID to implement and maintain containment procedures sufficient to contain select agents or toxin generated by BSL-3 and BSL-4 laboratory operations."

"Effective immediately, USAMRIID must cease all work involving select agents and toxins in registered laboratory areas until the root cause investigation has been conducted for each incident and the results have been submitted to FSAP for review," the CDC said.

The FSAP (Federal Select Agent Program) is jointly comprised of the Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Division of Agricultural Select Agents and Toxins. The program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to cause a severe threat to the public, animal or plant health or to animal or plant products. Common examples of select agents and toxins include the organisms that cause anthrax, smallpox, and the bubonic plague.

Three days later, the Fort Detrick replied the email by saying that it had submitted messages in response to the immediate action, but the messages were deliberately blotted out.

The message was submitted by a director for Strategic Studies (Countering Weapons of Mass Destruction) at the USAMRIID whose name was also blotted out.

The Fort Detrick's public statement released in August 2019 said the shutdown was due to problems in decontaminating wastewater. But it's not clear whether the statement was consistent with CDC's inspection results.

The management of such high-level labs in general must be very strict with regular inspections. Various systems should be able to ensure that no potential risks can occur, and equipment failure and wastewater

leakage certainly should not occur, a Chinese scientist from the WHO-China virus origins tracing team who requested anonymity told the Global Times.

The wastewater problems revealed major loopholes in the management at the Fort Detrick lab, and one has to wonder what else was leaked with the mismanaged wastewater.

"Some highly pathogenic pathogens in the laboratory were likely released. And the US military never told the public about what they were doing," the scientist said.

It is highly likely that researchers at Fort Detrick may have been infected accidentally but showed no obvious symptoms. In this way they could have brought the virus to the outside world, the scientist said.

"Under the circumstances of no obvious symptoms, 9 of the 10 individuals may not have known that they were infected and it's possible that more than 90 percent of the transmission routes had been lost when the virus was finally detected. This is also why the tracing of virus origins is difficult to conduct," he said, noting only serological survey on a large scale could find some of the early infections.

Why not open Fort Detrick lab

Several virologists and analysts interviewed by the Global Times urged the Fort Detrick lab to open its doors for an international investigation, since international experts have already visited the Wuhan Institute of Virology.

Many Western politicians and media outlets pinned the blame of the pandemic on Wuhan, saying that Wuhan was where the virus was first detected and where the virus came from despite mounting evidence that it's not the case.

In a recent example in June, a research study run by the National Institutes of Health's All of Us Research Program found evidence of COVID-19 infections in the US as early as December 2019, weeks before the first documented infection in the country.

Wuhan recorded the earliest COVID-19 symptoms from a patient on December 8, 2019.

When asked to give more details on the study, a media person with the All of Us Research Program told the Global Times that the program "has nothing further to add" from the information it had already released.

As for why the virus was first detected in Wuhan, the anonymous scientist said that the virus was difficult to be detected at an early stage, especially in autumn and winter with more cold cases. And it would not attract attention until a large number of people were infected. That's what happened in densely populated Wuhan, the scientist said.

China's public health system is very sensitive especially after the

SARS outbreak in 2003, but this is not always the case abroad, especially when the population density is low and the virus does not spread so fast, the expert said.

"The novel coronavirus was first discovered by three Chinese companies at the same time. It is very simple to detect these things, and China has lots of such third-party companies with strong medical detection ability," he said.

Without going back to earlier serum samples elsewhere now, it is going to be difficult to find the source of the virus. The retrospective studies that have been done in China have not found any evidence. It's important for the world to work together now to sort through the evidence and do early serological investigations where necessary, he said.

Zeng Guang, former chief epidemiologist of the Chinese Center for Disease Control and Prevention, told the Global Times that laboratory leak is easy to identify, as infections are bound to show signs, whether it is an operational problem or an infection of a lab staff.

The WHO experts assessed the lab-leak hypothesis when they visited Wuhan and found no evidence, and the speculation on its possibility in a Wuhan lab should have ended by now. In the meantime, we should put a question mark on other hypotheses, such as other labs around the world, Zeng said.

Zeng said the US is afraid of WHO's inspection in the same way it was done in China, Zeng said.

The US, the only country obstructing the establishment of a Biological Weapons Convention (BWC) verification mechanism, has systematic problems, Zeng said, adding that the US is afraid that the investigation into its labs would lead to more of its dirt being dug out.

Xia Wenxin contributed to this story

New York Times
Saturday, June 26, 2021, page B6

Celebrity Cruises to Be First to Resume Sailing From U.S.

By Ceylan Yeginsu

The Celebrity Edge will depart from Fort Lauderdale, Fla., on Saturday with 95 percent of its passengers all crew members vaccinated.

The Celebrity Edge is poised to set sail out of Fort Lauderdale, Fla., on Saturday, becoming the first major cruise ship to restart operations from a United States port since the pandemic all but hobbled the industry over a year ago.

The ship will sail at 35 percent capacity, with at least 95 percent of

passengers and all crew members fully vaccinated, its owner, Celebrity Cruises, said in a statement. Vaccines are not mandated for the cruise because of a new Florida state law banning businesses from requiring proof of immunization, but unvaccinated guests will face more stringent coronavirus protocols.

All guests over the age of 16 who do not show proof of vaccination will be required to wear masks on board and take a series of antigen tests during the cruise at an additional cost. (Testing for vaccinated guests will be free of charge.)

"We're definitely finding that cruisers prefer to be vaccinated and to share this information with us," said Susan Lomax, associate vice president for global public relations at Celebrity Cruises.

The sailing is a major milestone for the $150 billion global cruise industry, which has been decimated by the pandemic and spent months in a battle with the Centers for Disease Control and Prevention over its requirements for the safe resumption of cruising.

Earlier this month, Celebrity Cruises tested its Covid protocols during a seven-day sailing in the Caribbean, the line's first international cruise with American passengers. All adult passengers and crew members were fully vaccinated, and they were not required to wear masks or socially distance during the sailing.

Halfway through the cruise and following two shore excursions on the islands of Barbados and Aruba, a vaccinated couple tested positive for the virus and were immediately put into isolation. Other passengers who had come into contact with them were required to quarantine and get tested.

Before the ship reached its final destination, all passengers on board were tested, and no further positive cases were identified. Celebrity said the handling of the incident demonstrated that the company's virus protocols worked in preventing the spread of the virus.

Other major lines, including Carnival Cruise Line and Royal Caribbean, are preparing to restart U.S. operations in July. As of July 18, cruise ships departing from and arriving in Florida will not be required to follow C.D.C. guidance, after a judge ruled last week that the order was based on "stale data" and failed to take into account the prevalence of effective vaccines.

New York Times
Saturday, June 26, 2021, page A18

Harris Seeks Nuance On Migration Debate During Tour of Border

Advocates pushed the vice president to end Title 42, a Trump-era rule that allows the government to expel migrants for public health reasons.

By Katie Rogers

WASHINGTON -- Vice President Kamala Harris on Friday made her first visit to the southern border since she took office, hitting back at Republican criticism and meeting with advocates who pushed her on why the Biden administration had not yet ended restrictive Trump-era policies on migration.

"We can take all of these perspectives into account and have meaningful good public policy if we just stop the rhetoric," Ms. Harris told reporters after a four-hour visit to El Paso. "You can't just react to a problem without solving it at its roots. Let's just agree to that."

During her trip, she confronted an issue that has bedeviled the administration for months and is now tied to her own political future after President Biden put her in charge of addressing the root causes of migration. But for all of the questions she took from reporters, immigration advocates and even a group of detained migrant children -- whom she met behind closed doors -- the vice president had few answers.

In one private meeting, she heard from immigration advocates who said they did not understand why the Biden administration had yet to deliver on promises to roll back Trump-era policies like Title 42. Several pressed Ms. Harris to end that rule, which allows the government to expel migrants, including asylum seekers, for public health reasons.

"We were very forceful about that," Fernando Garcia, the executive director of the Border Network for Human Rights, who attended the meeting, said in an interview. "She asked how we think it could happen. She was looking for some answers."

The Biden administration is working to phase out Title 42, but on Friday, Alejandro N. Mayorkas, the secretary of homeland security who accompanied Ms. Harris to El Paso, told reporters that the Centers for Disease Control and Prevention would ultimately decide.

"It's a public health decision," Mr. Mayorkas said. "It's based on the well-being of the American public."

The agency, however, has directed questions about the policy to the White House.

In some ways, the trip was notable for what Ms. Harris did not do: visit a tent complex at nearby Fort Bliss, where migrant children are being held. (As she traveled to Texas, the Biden administration announced that Xavier Becerra, the secretary of health and human services, would head there next week.)

"She'll check off the box of going down to the border," Representative Henry Cuellar, a Texas Democrat who wrote a letter to the vice president last week urging her to visit the border, said in an interview. Mr. Cuellar said his letter went unanswered.

Ms. Harris stopped at Customs and Border Protection's processing center, where she received a briefing from officials and asked questions about the technology used to process people who crossed the border illegally.

She also said she had met with young girls detained at the Paso del Norte port of entry, a meeting that had not been announced and was kept private. Ms. Harris said the girls reminded her that the issue should not be reduced to partisan politics.

"They were asking me questions: 'How do you become the first woman vice president?'" Ms. Harris said. "It also reminds me of the fact that this issue cannot be reduced to a political issue. We're talking about children, we're talking about families, we are talking about suffering."

Human rights and immigration advocates have assailed the Biden administration for not doing enough in its first six months to reopen the border to asylum seekers, reunite unaccompanied children with families and provide the appropriate facilities to hold detained migrants. In a report released last week, the human rights group Amnesty International said that the Biden administration had failed to fulfill some of its early pledges.

"Rebuilding an immigration system takes time, but nearly half a year in, the administration still needs to deliver promised change," the report read. "No matter the situation or who heads the administration, the government cannot get out of its human rights obligations."

Still, some Democrats praised Ms. Harris, saying her trip showed a dedication to finding solutions, including a push for bipartisan immigration overhaul, an effort that has eluded modern presidents.

"Her attendance today in El Paso is an indication of her caring and commitment to meaningful immigration reform," said Senator Richard J. Durbin, the chairman of the Judiciary Committee, who stood next to her on the tarmac in El Paso. "And I want to join her in saying that Congress needs to do its part."

The visit came together quickly after Ms. Harris was criticized on her trip to Mexico City and Guatemala, where Lester Holt of NBC grilled her about why she had not been to the border. She responded by calling the visit a "grand gesture" and pointed out that she had not been to Europe yet, either -- answers that confounded her critics and members of the administration.

Though her office denied politics played a part, the El Paso stop does carry some significance. The city is a major port of entry and has complicated ties to former President Donald J. Trump, who will travel to the border with Gov. Greg Abbott of Texas days after Ms. Harris.

As president, Mr. Trump called El Paso "one of our nation's most dangerous cities," castigating it as overrun by immigrants and crime. It typically ranks among the safest cities in the United States. In 2019, after 22 people were killed at a Walmart and the white suspect warned of a "Hispanic invasion," Mr. Trump was greeted with protests when he met with the victims' families.

On Wednesday, a group of House Republicans said they would join Mr. Abbott and Mr. Trump on their trip, a move intended to add more

pressure on the Biden administration, which has struggled to chip away at Mr. Trump's "zero tolerance" immigration policies while warning migrants not to make the journey to the United States.

The number of unaccompanied minors crossing the border has hit a record high under the Biden administration, and officials have struggled to quickly move them out of cramped facilities and into the care of family members. A surge in the apprehensions of single adults -- some 121,000 last month -- has offset a small decline in the number of unaccompanied minors and families traveling north, according to Customs and Border Protection data.

As she prepared to leave El Paso, Ms. Harris was asked about criticism that she had stopped by El Paso instead of the lower Rio Grande Valley, which is considered the center of the current surge in migration. The vice president, who spent her visit pleading for partisan politics to be omitted from the conversation about immigration, pointed to Mr. Trump to make her case.

"It is here in El Paso that the previous administration's child separation policy was implemented," she said. "We've seen the disastrous effects of that right here in this region."

Zolan Kanno-Youngs and Eileen Sullivan contributed reporting.

Los Angeles Times
Saturday, June 26, 2021, page A5

Harris views immigration problems up close

Criticism continues after she meets with border agents, migrant children in El Paso.

By Noah Bierman and Molly Hennessy-Fiske

Kamala Harris made her first trip as vice president to the U.S.-Mexico border Friday, meeting with border agents and migrant children as she toured a processing center in El Paso and became more closely tied to one of the Biden administration's diciest political problems.

Her visit comes after months of Republicans' criticism that she and President Biden hadn't seen firsthand the effects of an immigration system overwhelmed by an increase in migrant families and unaccompanied children seeking entry into the United States.

Even as Harris traveled around the El Paso area, critics on both sides of the immigration debate lambasted her for avoiding some more problematic spots along the border, where children and families are experiencing long delays and often dangerous conditions as they wait to have their fates determined.

The migrant children she met "are filled with optimism," Harris said as she left Texas for a weekend at her Brentwood home. "But they are without their family -- young children. They're being processed through

the system."

"This issue cannot be reduced to a political issue," she added. "We're talking about children. We're talking about families. We're talking about suffering. And our approach has to be thoughtful and effective."

Harris was accompanied by Homeland Security Secretary Alejandro N. Mayorkas, who has been to the border previously. Health and Human Services Secretary Xavier Becerra plans to visit a nearby facility Monday -- a federal tent city for hundreds of children at the Army's Ft. Bliss, where there have been outbreaks of COVID-19 and lice, reports of sexual abuse and other unsafe conditions.

During her visit, which lasted about four hours, Harris blamed the Trump administration for leaving her and Biden with "a tough situation," which she asserted was improving.

"We're not exactly where we want to be yet, but we've seen extreme progress," she said, noting that wait times for unaccompanied children in El Paso had been reduced.

Despite months of taunts from Republicans that she was avoiding the border, Harris told reporters that "it was always the plan to come here" as part of her work on immigration diplomacy with Central America. She had been to the U.S.-Mexico frontier numerous times as a senator and as California's attorney general.

"We have to deal with causes and we have to deal with the effects," she said. Her recent trip to Mexico and Guatemala, she added, was about probing the causes of residents' decisions to migrate north, while her border visit is intended to allow her to see "the effects of what we have seen happening in Central America."

Harris said the border stop reinforced her belief that deterring people from leaving their home countries will require long-term, consistent investment in Central American countries to reduce poverty there.

In addition to touring the processing center, Harris met privately with five migrant girls ages 9 to 16. Aides said the girls drew pictures and told the vice president what they wanted to be when they grew up. Harris also went to a nearby inland entry port where asylum seekers arriving from Mexico, including unaccompanied children, are initially screened.

The Biden administration is facing tough policy decisions as it tries to balance efforts to deter migrants and to develop a more humane system of processing those who have made the journey.

Mayorkas told reporters traveling on Air Force Two that his office is still reviewing how quickly to rescind a Trump-era policy, initiated amid the pandemic, that allows agents to turn away migrants by citing a public health law known as Title 42.

Mayorkas said the decision on whether to end the policy would be based on the assessment of the Centers for Disease Control and Prevention, based on public health data and the threat of spreading COVID-19.

Harris' role in immigration policy dates to March, when Biden asked her to examine ways to reduce migration through Mexico from Honduras, Guatemala and El Salvador by attacking its root causes, including corruption, poverty and gang violence -- problems that have been exacerbated by devastating hurricanes and the pandemic.

The vice president visited the capitals of Guatemala and Mexico earlier this month to confer with their leaders, encourage investment and discourage corruption in the region. But those diplomatic activities were overshadowed by questions raised back in the United States about why she wasn't visiting the border.

On Friday, Sen. Ted Cruz (R-Texas) tweeted of Harris' trip: "93 days too late," adding: "It only took more than half a million illegal immigrants entering the U.S., more than 400,000 pounds of drugs seized, dozens of U.S. Senators and House members traveling to the southern border for Border Czar Kamala Harris to finally visit the southern border."

White House officials said Harris did not go to Texas in response to the partisan pressure, which includes former President Trump's recent announcement that he would visit a border site with GOP members of Congress next week.

Republicans say the Biden administration is looking at the wrong causes for the increase in migrants. They say the reason they're coming is because Biden has relaxed some of Trump's hard-line policies.

Republicans have decried Biden's early order to halt border wall construction while his administration reviews the legality of how Trump funded his signature project.

More than 200 miles of barrier were in some stage of construction in Texas, which is the least-fenced border state, when Trump left office, according to U.S. Customs and Border Patrol.

Texas Gov. Greg Abbott, a Republican who plans to host Trump next week, has vowed that his state will continue to build the wall, though it's not clear he has the authority to see that it's done.

Liberal groups and immigrant advocates have their own issues with the administration, complaining that officials have been too slow to roll back Trump's policies, including the use of Title 42, and to fix conditions for children at Ft. Bliss.

"There is a long way to go," said Shaw Drake of the ACLU of Texas in El Paso, a staff attorney and policy counsel for border and immigrants' rights.

From the administration's vantage, El Paso was an appealing destination for Harris. The largest city on the long Texas border, it's a military outpost but also a Democratic college town and a bastion of liberal activism for immigrant rights. It is also home to Democratic Rep. Veronica Escobar, who was traveling with the vice president.

El Paso also was the first place where the Trump administration began separating children and parents who crossed the border -- one of the former president's most reviled policies.

Rep. Henry Cuellar, a Texas Democrat who had urged Harris to visit the border, said El Paso is "politically safer to go to than the Rio Grande Valley, where you can see unaccompanied kids, family units, and where you get most of the single adults that are coming in."

Migrant numbers fell sharply in 2020 amid the pandemic, when the U.S., like many countries, restricted entry. This year the numbers began to increase.

Some progressive activists in the Rio Grande Valley also expressed disappointment that Harris and Mayorkas were visiting El Paso, where far fewer asylum-seeking families have been forced by U.S. policies to wait across the border in Mexico.

Karla Vargas, an attorney with the Texas Civil Rights Project, based in the Rio Grande Valley east of El Paso, said: "We would have hoped they would have tried to also visit this area to see how difficult it is for the families waiting here. We welcome them trying to address this. We hope it is not just showmanship."

Times staff writer Molly O'Toole contributed to this report.

BusinessInsider.com
Sunday, June 27, 2021

CDC director Robert Redfield 'prayed' Trump would understand how serious COVID-19 was after contracting it, a book excerpt says

Yelena Dzhanova

Robert Redfield, the director of the Centers for Disease Control and Prevention, prayed that former President Donald Trump would take the coronavirus more seriously after being diagnosed with it, according to a new book by two reporters from the Washington Post.

An excerpt of the book, "Nightmare Scenario: Inside the Trump Administration's Response to the Pandemic That Changed History," illustrates the White House's chaotic response to Trump's October 2020 COVID-19 diagnosis and hospitalization at the Walter Reed Medical Center. The book, written by Yasmeen Abultaeb and Damian Paletta, is due for release on June 29.

Over the weekend that Trump announced that he and then first lady Melania had the virus, Redfield prayed for a recovery, the excerpt says. Redfield also prayed that it would be a wake-up call for the president, who for months at this point had flouted or mocked COVID-19 safety restrictions like mask-wearing.

He also held giant rallies with thousands of mask-less people in attendance to drum up support for his 2020 re-election bid.

Redfield "prayed that Trump would tell Americans they should listen to public health advisers before it was too late," the excerpt says.

Just days after his hospitalization, Trump walked the White House South Lawn. Watching the event unfold on television, Redfield prayed again, this time that the former president would "show some humility" and "remind people that anyone could be susceptible to the coronavirus -- even the president, the first lady and their son. That he would tell them how they could protect themselves and their loved ones."

But Trump didn't do that. Instead, he took off his mask and gave the cameras a thumbs up, the excerpt says.

In a video taken just over the weekend while at Walter Reed, Trump appeared to be visibly paler than usual. He released a video from the hospital, saying he felt "much better now." In the video message, Trump appeared to have no trouble speaking and breathing.

During the moment he addressed the cameras on the South Lawn, he was likely still contagious.

"He made a military salute as the helicopter departed the South Lawn, and then strode into the White House, passing staffers on his way and failing to protect them from the virus particles emitted from his nose and mouth," the excerpt says.

That's when Redfield began to understand the hospitalization changed neither Trump nor his response to the coronavirus, according to the excerpt.

Washington Post
Sunday, June 27, 2021, page B1

How Trump's blunders fueled our coronavirus nightmare

Nightmare Scenario
Inside the Trump Administration's Response to the Pandemic That Changed History
By Yasmeen Abutaleb and Damian Paletta
Harper. 478 pp. $30

By William Hanage

Early in the pandemic, an outbreak of the novel coronavirus on the Diamond Princess cruise ship had spread out of control. The passengers included many Americans, prompting urgent questions about whether they should be repatriated and where they should be quarantined. Among the most eye-popping and jaw-dropping revelations in a new book by Washington Post reporters Yasmeen Abutaleb and Damian Paletta, "Nightmare Scenario," is the claim that President Donald Trump suggested sending them to Guantanamo Bay.

It shouldn't need saying, but a military compound used to house

terrorism suspects is not a suitable place for the quarantine, isolation and treatment of mostly elderly citizens, already known to be a group vulnerable to severe infection. The alleged reason for the suggestion was the president's obsession with keeping the numbers of cases in the United States low. While energies were consumed with the Diamond Princess and other cruise ships, the virus quietly entered the country and started to spread, even as the Centers for Disease Control and Prevention struggled to develop a test capable of establishing that fact.

This episode illustrates two of the common factors that tie together the many missteps documented in the book. One is the wasting of time and energy on narrow issues such as cruise ships, or the discredited treatment hydroxychloroquine, rather than accepting that the situation was bad and going to get much worse without the hard work of pandemic management. The other is the conviction that the negative press coverage was the problem, not the virus itself.

Over and over again, whenever public health and public relations came into conflict, public health lost out. Trump's complaints directed at "the Doctors" kept coming back to the same charge - negativity - including a remarkable, petulant presidential Oval Office outburst roughly halfway through the book. "I am sick and tired of how negative you all are. . . . I spend half of my day responding to what Tony Fauci has to say, and I'm the president of the United States!" Later in the same exchange, Trump told coronavirus response coordinator Deborah Birx: "Every time you talk, I get depressed. You have to stop that." As if the pandemic could be defeated by the power of positive thinking, and Birx should just cheer up and promote policies that she knew would lead to more illness and death than the alternatives.

In general, the book is not strong or detailed on the scientific nuts and bolts. This is not a place to come if you want to understand the nitty-gritty of why the CDC's test development went so very awry. But Abutaleb and Paletta are on the money when it comes to the challenges in formulating policy advice on the basis of science that was not fully settled. As they write, "The task force members . . . had to make the best decisions they could and update their guidelines as the scientific understanding grew."

The point is illustrated well by the politicization of masks. Amid early concerns about an exponential wave of infections flooding into the health-care system, experts including Fauci, director of the National Institute of Allergy and Infectious Diseases, argued against mask use, concerned that hoarding by the public would leave health-care workers deprived of vital personal protective equipment (PPE). This advice would later change as evidence accumulated showing that mask-wearing by a large fraction of the population is an effective intervention. This shift was interpreted as a political flip-flop, rather than science in progress, and adopted as ammunition by those adamantly opposed to masks. Mask use became irrevocably politicized, and attempts to convince doubters foundered amid an epidemic of cherry-picked evidence.

Shortages of PPE were in fact a serious concern early in the pandemic, because of an incoherent approach that set states and even individual

health-care networks against one another. In just one example of many, the book alleges that the work of a "Shadow Task Force" run by Jared Kushner diverted "30 percent of 'key supplies' from the Strategic National Stockpile to operate forty-four drive through testing sites for five to ten days."

That the response was chaotic and dysfunctional will not be news, but according to this account there were opportunities to take a different course. Some officials emerge with credit, although it must be noted that, as with all tales of palace intrigue, the story is inevitably shaped by the sources. As time went on more efforts were put into finding ingenious reasons to deny the seriousness of the pandemic rather than to respond to it, with the nadir being the appointment of Scott Atlas as special coronavirus adviser to the president, to give the advice Trump wanted to hear.

This casting of reality as whatever you want to believe led to a sort of choose-your-own-pandemic, in which decisions were pushed ever downward to governors, mayors or individuals. Some of these were well resourced, others not, but all less well than they would have been with adequate federal support. Members of the coronavirus task force resorted to broadcasting their own advice as widely as possible, either in meetings with local officials or through the media, so those who were willing to hear and act on it could benefit. The divided, inconsistent messaging set up the disastrous fall and winter, when deaths peaked at well over 4,000 each day.

We will be examining the mistakes and missteps of 2020 for decades, probably centuries. This book will be one of the places future historians will start, if far from where they will finish. The epilogue expresses hopes that in the next pandemic, "the nation rallies together." Unfortunately the partisan divisions in the United States are deep, illustrated by reluctant vaccine uptake in Republican strongholds. This book will not change that, although it reminds us of the dangers of relying on policy-based evidence rather than evidence-based policy. You cannot intimidate an earthquake or bully a hurricane to do your bidding, and a virus cannot be fired.

Pandemics have a way of making history. From the Black Death to the 1918-19 flu to HIV, infectious-disease outbreaks convulse societies in a way matched only by how readily humans forget them once they are over. Abutaleb and Paletta describe in sobering detail how the Trump White House chose to forget about the current pandemic while it was still going on.

William Hanage is an associate professor of epidemiology at the Center for Communicable Disease Dynamics at the Harvard T.H. Chan School of Public Health.

Wall Street Journal
Monday, June 28, 2021, page A7

Hospitals Strain Under Surge in Mental-Health Cases

By Robbie Whelan

PITTSBURGH -- Before the coronavirus pandemic took hold, psychiatrist Garrett Sparks usually treated about a dozen patients on his overnight shift in the emergency department at Western Psychiatric Hospital, this city's biggest mental-health hospital. On a recent Thursday evening, he saw 21 cases.

As the night began, an agitated man sitting on a couch in a space reserved for acute cases loudly demanded turkey sandwiches. Parents of a 7-year-old who had been kicked out of school for emotional outbursts came in, saying their child's behavior was spiraling and he was becoming more aggressive. A few hours later, police brought in a 17-year-old boy who had tried to commit suicide by jumping from a bridge.

"It seems like everyone has been holding their breath for a year, and now, it's just a total explosion of everything, both in terms of high volume but also the severity of cases," Dr. Sparks said. "You see a lot more people who were, pre-pandemic, kind of overwhelmed and stressed, and now they have full-on anxiety disorders or depression."

In the coronavirus pandemic, a wave of mental-health crises has grown into a tsunami. As the country appears to be emerging from the worst of the Covid-19 crisis, emergency departments say theyare overwhelmed by patients who deferred or couldn't access outpatient treatment, or whose symptoms intensified or went undiagnosed during the lockdowns.

Doctors say it could be years before we see the full impact of the pandemic on mental health, but a host of studies indicate how strained the system has become. Emergency visits for patients seeking help for overdoses and suicide attempts rose 36% and 26%, respectively, between mid-March and mid-October of last year, the U.S. Government Accountability Office said in March. U.S. Centers for Disease Control and Prevention surveys have found that 38% of respondents reported symptoms of anxiety or depression between April of last year and February, up from about 11% in 2019.

Children have been hit particularly hard. School closures have allowed serious mental-health issues to go unnoticed, because teachers and school psychologists are a primary source of referrals, doctors say. Even before the pandemic, the country faced a shortage of mental-health professionals to serve juveniles; the American Academy of Pediatrics last year estimated the need for child psychiatrists at 47 per 100,000 people, roughly four times the number in practice.

Emergency-room visits for mental-health crises among 12- to 17-year-olds increased 31% between 2019 and 2020, the CDCreported in June. Among the same group, emergency-room visits for suspected suicide attempts rose 22% last summer compared with the previous year, and 39% this past winter compared with the previous winter.

At the University of Pittsburgh Medical Center, which includes Western Psychiatric, pediatric-outpatient volume surged 30% in the first four months of 2021 compared with the year earlier.

"We have more kids waiting for care than we ever have before," said Abigail Schlesinger, the hospital's chief of child and adolescent psychiatry. "We're in the mental-health emergency phase of this pandemic."

Mental-health crisis cases are ending up in emergency rooms in higher numbers in part because outpatient facilities, including private psychiatrists' offices, therapy practices and crisis centers, are saturated with patients whose mental-health problems have worsened during the pandemic, doctors and hospital administrators say.

"For us, it's definitely a lot of people who either had pre-existing conditions or have neglected to address their new onset of emotional imbalance," said Damir Huremovic, a psychiatrist at North Shore University Hospital on Long Island. "Many developed anxiety or insomnia, and they tried to see a provider but no one was taking new patients, and then things sort of just snowballed."

For patients dealing with depression, anxiety or eating disorders, physicians recommend getting out of the house, seeing people and establishing a normal routine, said Jeanne Noble, an emergency physician at the University of California, San Francisco.

"That's the exact opposite of what's happened with the school closures and lockdowns," Dr. Noble said.

The pandemic has taken its toll on mental-health providers, too. In his downtime, Dr. Sparks trains for marathons, listens to audiobooks, and sees a therapist to treat his own longstanding depression.

"You can only take so much when you're sleep-deprived, exhausted, and juggling other people's problems like balls on fire for so many nights in a row," he said.

CIDRAP News
Friday, June 25, 2021

ACIP approves dengue vaccine for endemic areas, tweaks flu vaccine advice

The vaccine advisory group to the Centers for Disease Control and Prevention (CDC) yesterday unanimously voted to recommend Sanofi's dengue vaccine (Dengvaxia) for children ages 9 to 16 years who live in areas such as Puerto Rico where the disease is endemic.

The vaccine is given in three doses and requires a test to confirm that a child has had a previous dengue infection. Vaccination in someone who has never been exposed to dengue before can lead to a more severe future infection through a phenomenon called antibody-dependent enhancement.

An Advisory Committee on Immunization Practices (ACIP) working group has been studying the issue and drafted the recommendation, which the whole group discussed and voted on yesterday, according to Stat. The experts acknowledged that the rollout of the vaccine would be

challenging, owin to lab testing before vaccination. Also, members discussed challenges regarding provider access to tests to assess previous exposure to dengue and to ensure that kids receive all three doses. However, the group was swayed by the benefits and manageable risks.

The Food and Drug Administration (FDA) approved Dengvaxia in May 2019 for children ages 9 to 16 who have had at least one lab-confirmed dengue infection.

In separate discussions, ACIP fine-tuned its flu vaccine recommendations, according to American Academy of Pediatrics (AAP) News. The committee green-lighted co-administration with COVID-19 vaccines and added guidance about flu vaccine timing for certain groups--such as for children ideally by the end of October. Also, ACIP said nonpregnant adults should avoid immunization in July and August because of concerns over waning immunity, and women in their third trimester should be vaccinated as soon as the vaccine is available to protect their babies.

On another topic, the group said children receiving pre-exposure rabies vaccination can receive two rather than three doses, similar to a change recommended earlier this year for adults.

AP Maine
Sunday, June 27, 2021

CDC Gives Maine $7M To Prep For Future Public Health Crises

PORTLAND, Maine (AP) -- The federal government has given Maine a $7 million boost to help prepare for another public health crisis.

Republican Sen. Susan Collins and independent Sen. Angus King said the Maine Department of Health and Human Services has received the money from the U.S. Centers for Disease Control and Prevention. About $1.8 million of the money is for preventing and controlling emerging diseases and the rest is for preparing and responding to public health emergencies.

The senators said the state "must not lose sight of other public health initiatives that protect the health and safety of the community" while it continues responding to the coronavirus pandemic.

SILive.com
Monday, June 28, 2021

CDC: `Don't kiss or snuggle the birds;' Salmonella outbreak linked to more than 400 infections

By Joseph Ostapiuk | jostapiuk@siadvance.com

STATEN ISLAND, N.Y. -- The Centers for Disease Control and Prevention

(CDC) said a salmonella outbreak linked to backyard poultry has now sickened nearly 500 people in the U.S.

The outbreak has caused 474 illnesses in 46 states, and more than 100 hospitalizations, the CDC announced late last week. One death has been reported in Indiana. Data from the agency shows that 15 people in New York have been sickened by salmonella germs.

Since May 20, the CDC said an additional 311 illnesses have been reported, and the agency said it is likely that the actual number of sick people is much higher, since many people recover without medical care and are not tested for salmonella.

About one-third of sick people are young children under the age of five, the CDC said.

Currently, backyard poultry is considered the "likely source" of the outbreak. Even if backyard poultry look clean, salmonella germs can spread in areas where the animals live and roam -- easily spreading from their environment to humans through physical contact.

To avoid infection, the CDC recommends washing your hands for 20 seconds after touching poultry or poultry supplies, and to also avoid letting children under the age of five touch the birds.

"Don't kiss or snuggle the birds, as this can spread germs to your mouth and make you sick," the CDC said.

Salmonella can cause a multi-day illness that includes diarrhea, fever and stomach cramps. Children under five and adults over the age of 65 are more susceptible to severe salmonella illness.

CIDRAP News
Friday, June 25, 2021

Backyard poultry Salmonella outbreak grows to 474 cases, 1 death

A US Salmonella outbreak linked to backyard poultry has grown by 311 cases, to 474 illnesses, and the CDC has reported the first outbreak death, according to a CDC update yesterday.

Three more states are affected (46 total) and a new serotype has been added (Salmonella Mbandaka) since the CDC's first notice of the outbreak on May 20, and 41% of isolates have shown some degree of antibiotic resistance, the agency noted. Of 334 people with information available, 103 (31%) have been hospitalized, up from 34 on May 20. An Indiana patient has died.

Illness-onset dates range from Dec 15, 2020, to Jun 4, 2021, and 58% of case-patients are female. Patient ages range from less than 1 to 97 years, with a median age of 31, and 139 patients (30%) are children younger than 5 years.

Of 271 people interviewed, 209 (77%) reported contact with backyard

poultry before getting sick.

"Epidemiologic and laboratory data show that contact with backyard poultry is making people sick," the CDC says. "The true number of sick people in an outbreak is likely much higher than the number reported, and the outbreak may not be limited to the states with known illnesses."

The agency recommends no close contact, such as snuggling, with backyard poultry, and to buy the animals from hatcheries that take steps to reduce Salmonella. Those who raise backyard birds should always wash their hands with soap and water immediately after touching poultry, their eggs, or their surroundings.

Newsweek.com
Sunday, June 27, 2021

Whole Foods, Safeway and Other Stores Recall Shrimp for Salmonella Contamination

By Scott McDonald

Several lots of frozen cooked shrimp have been recalled nationwide at major grocers, including Whole Foods, Safeway, Meijer and Hannaford. The U.S. Food and Drug Administration (FDA) stated the recalled shrimp has been found to contain Salmonella contamination.

The eight recalled brands include Chicken of the Sea and the supermarket house brands.

The Centers for Disease Control and Prevention (CDC) stated that six people have been infected with the contamination so far--four in Nevada and two more in Arizona. There were two hospitalizations and zero deaths. The last onset illness was April 25.

All recalled shrimp were distributed by Avanti Frozen Foods of India, and the affected lots were distributed between December 2020 and February 2021.

Salmonella was first found in an import sample during January, the FDA stated. Though that particular sample was destroyed in March, illnesses began sprouting up in April from the contaminated lots sold three months earlier.

"As of (Friday, June 25), there are six clinical isolates from ill people that are genetic matches to the salmonella collected from the import sample. Five of the six ill people were interviewed to determine the foods they ate before becoming sick, and all five ill people report eating shrimp," the FDA stated.

The shrimp that caused the reported sicknesses have already passed their expiration dates and have been pulled from the shelves. Here are the affected products still on the shelves and their lot numbers:

* Censea, tail off -- 2-pound pouch; Codes 140313D, 140314D, 140315D, 140316D; expiration dates 5/7/2022 -- 5/10/2022.
* Chicken of the Sea, tail on -- 16-ounce tray; Codes 91AS/02UN/216 and 91AS/03UN/217; expiration dates 5/1/2022 and 5/2/2022.
* Honest Catch, tail on -- 1-pound pouch; Code 3150-GFF; expiration date 11/9/2022.
* CWNO, tail on -- 7-pound pouch; Codes 91AS/06UN/220D, 91AS/07UN/221C, 91AS/23HN/206B, 91AS/24HN/207; expiration dates 1/23/2022; 1/24/2022; 2/6/2022; and 2/7/2022.
* Hannaford, tail on -- 1-pound pouch; Codes. AVF 30920 EF and AVF 31020 EF; expiration dates 10/25/2022 and 10/26/2022.
* Waterfront Bistro (Safeway house brand), tail on -- 16-ounce tray; Codes 20305 and 20306; expiration dates 10/30/2022 and 10/31/2022.
* Open Acres, tail on -- 1-pound pouch; Code 02572 0307 11 and 02572 0308 11; expiration dates 11/2/2022 and 11/3/2022.
* 365 (Whole Foods store brand), tail on -- 2-pound pouch; Codes 91AS/29HN/212B and 91AS/30HN/213; expiration dates 4/29/2022 and 4/30/2022.
* Meijer, tail on -- 1-pound pouch; Codes 29720 49982, 29820 49982, 30220 50736, 30320 50736, 30520 49486, 30620 49486, 30920 50737, 31020 50737; expiration dates 10/22/2022, 10/23/2022, 10/27/2022, 10/28/2022, 10/30/2022, 10/31/2022, 11/3/2022, 11/4/2022.

Healthy people who come in contact with Salmonella could experience nausea, vomiting, diarrhea or bloody diarrhea, abdominal cramping and fever. More serious problems could include arterial infections, endocarditis, arthritis, muscle pain, eye irritation, and urinary tract symptoms.

Should any person have these symptoms after handling the product, they should contact their health care provider.

The CDC says that roughly 1.3 million people get sick on an annual basis from Salmonella contamination.. There are about 26,500 hospitalizations and 420 deaths annually.

CNN.com
Saturday, June 26, 2021

Avanti Frozen Foods recalls several shrimp products linked to salmonella outbreak

By Rachel Trent, CNN

(CNN)If you eat frozen cooked shrimp at home, you may want to check your freezer.

A salmonella outbreak has been linked to certain frozen cooked shrimp products distributed nationwide, according to the US Centers for Disease Control and Prevention.

Salmonella was found in a sample of Avanti Frozen Foods' shrimp collected as part of the FDA's Imported Seafood Compliance Program, the CDC said.

In a statement on the FDA website, Avanti said that out of "an abundance of caution" it recalled some of its frozen cooked shrimp products sold under the brand names 365, Censea, Chicken of the Sea, CWNO, Hannaford, Honest Catch, Meijer, Open Acres and Waterfront Bistro.

Six people got sick from this outbreak and two of those were hospitalized, according to the CDC. The agency says the illnesses happened in Nevada and Arizona, but the outbreak may have affected other states.

The products in question were distributed from late December to late February.

Only products bearing certain codes are affected by the recall. Anyone who has purchased one of those can return them to where they bought them for a refund.

Salmonella can cause fever, diarrhea, nausea, vomiting and abdominal pain, the FDA said. The organism can cause serious and sometimes deadly infections in young children, frail or elderly people, and others with weakened immune systems.

The CDC said symptoms usually start six hours to six days after swallowing the bacteria and most people recover without treatment after four to seven days.

Reuters
Sunday, June 27, 2021

UPDATE 1-Competing events make their marks on LGBTQ+ Pride Day in New York

By Peter Szekely

(Recasts to reflect that events have begun, adds details and comments)

NEW YORK, June 27 (Reuters) - For the second consecutive year, the lingering pandemic consigned New York's annual Pride march to the virtual world on Sunday, even as its alter-ego, the Queer Liberation March, took its edgier message through the streets of Manhattan.

The NYC Pride march, the city's marquee LGBTQ+ event now in its 51st year, became a made-for-TV production as a cautionary measure to prevent coronavirus infections, which have dropped sharply as the number of people vaccinated has grown.

Only a small number of guests were invited to the group's three-block areas where floats and musical acts paraded for the cameras, but organizer Sue Doster said "something in the millions" of viewers were expected to tune in.

Guests included Brandon Wolf, a survivor of the June 2016 mass shooting at the Pulse, a gay nightclub in Orlando, Florida, who has since become

an advocate for LGBTQ rights legislation.

"Six days after the shooting, we had a funeral service for my best friend and I made a promise to him that day that I would never stop fighting for a world that he would be proud of," he told ABC, which aired the event.

"We've made incredible progress in equality across the country, but trans people are under attack," he added.

HIV/AIDS expert Dr Demetre Daskalakis, one of the event's grand marshals, urged all LGBTQ+ community members to get tested frequently for the virus.

"At the end of the day, HIV is just a virus, and we have the ability to prevent it and to treat it," said Daskalakis, who is director of the Division of HIV/AIDS Prevention at the Centers for Disease Control and Prevention.

MARCHING FOR 'LIBERATION AND JUSTICE'

Meanwhile, thousands of people organized by the Reclaim Pride Coalition, whose parade began as a protest to the Pride march two years ago, marched more than 30 blocks down New York's Seventh Avenue with rainbow flags and signs that included "Liberation and Justice."

Coalition cofounder Jay W. Walker said the group was hoping to draw up to 70,000 marchers.

Under sunny skies with muggy conditions that felt like 90 degrees Fahrenheit (32 degrees Celsius), a racially mixed crowd of men and women chanted "No Justice, No Peace," and other slogans, some critical of the New York Police Department.

After linking last year's message to the Black Lives Matter movement, Walker said this year's theme is returning to the coalition's standard: "None of us are free until all of us are free."

Although the group had urged marchers to wear masks, few did. Last year's march produced no discernable spike in new coronavirus cases, he said.

Both events commemorate the June 28, 1969, uprising at the Stonewall Inn, a gay bar in Manhattan's Greenwich Village, when patrons fought back during a police raid. The defiant stand gave birth to the modern LGBTQ rights movement.

The two groups have differed over their policies on police participation in their events, which the Reclaim Pride Coalition opposes. But Heritage of Pride last month also decided to bar uniformed police officers from its future parades. Doster said many of its Black, brown and trans members feel threatened by their presence. (Reporting by Peter Szekely in New York Editing by Grant McCool and Matthew Lewis)

AP West Virginia
Saturday, June 26, 2021

HIV SOS: Action Sought For Spike In Cases In West Virginia

By JOHN RABY
Associated Press

CHARLESTON, W.Va. (AP) -- Dozens of volunteers formed the letters "HIV SOS" at a health event Saturday as activists seek a public health emergency declaration in a city with one of the nation's highest spikes of such cases.

Kanawha County, which includes Charleston and has 178,000 residents, had two intravenous drug-related HIV cases in 2018. The number grew to 15 in 2019 and 39 last year, according to state data. There have been 14 such cases so far in 2021.

After volunteers wearing red T-shirts formed the plea for help along the Kanawha River near downtown Charleston, Joe Solomon, co-founder of the nonprofit group Solutions Oriented Addiction Response, called on the City Council and Mayor Amy Shuler Goodwin to act on the HIV crisis and overdoses from prescription pain pills.

"In Charleston and Kanawha County, there's a family butchered by the overdose crisis every other day," Solomon said. "All we're asking is for (them) to take one day to declare a public health emergency. We need to treat this like the emergency that it is."

Earlier this year, Dr. Demetre Daskalakis, the CDC's chief of HIV prevention at the Centers for Disease Control and Prevention, called Kanawha County's outbreak "the most concerning in the United States." He warned it could take years to address the surge and that the case count possibly "represents the tip of the iceberg."

Earlier this week the CDC presented preliminary findings of an investigatio n that showed emergency departments and inpatient medical personnel in Kanawha County rarely conducted HIV testing on intravenous drug users.

Republican Gov. Jim Justice in April signed a bill to introduce more stringent requirements to needle exchange programs like those offered by Solomon's group. The move came over the objections of critics who said it would restrict access to clean needles amid the spike in HIV cases.

The bill requires licenses for syringe collection and distribution programs. Operators would have to offer an array of health outreach services, including overdose prevention education and substance abuse treatment program referrals. Participants also must show an identification card to get a syringe. Advocates view the regulations as onerous.

The American Civil Liberties Union on Friday filed a lawsuit challenging the new law.

AP West Virginia
Friday, June 25, 2021

ACLU In West Virginia Sues Over Needle Exchange Law

CHARLESTON, W.Va. (AP) -- The American Civil Liberties Union of West Virginia on Friday filed a lawsuit opposing a law that would instate stringent requirements on needle exchange programs in the state.

Republican Gov. Jim Justice signed the bill in April over the objections of critics who said it will restrict access to clean needles amid a spike in HIV cases.

The bill requires licenses for syringe collection and distribution programs. Operators would have to offer an array of health outreach services, including overdose prevention education and substance abuse treatment program referrals. Participants also must show an identification card to get a syringe. Advocates see the regulations as onerous.

Supporters said the legislation would help those addicted to opioids get connected to health care services fighting substance abuse. Some Republicans lawmakers had said the changes were necessary because some needle exchange programs were "operating so irresponsibly" that they were causing syringe litter.

The ACLU-WV went to court to prevent it from taking effect on July 9.

The group called it "one of the most restrictive state laws governing syringe exchange services in the nation" and that it would likely lead to more HIV cases and the spread of other bloodborne illnesses.

The restrictions "will cost lives and deprive West Virginians of numerous constitutional rights, including due process and equal protection among others," ACLU-WV legal director Loree Stark said in a statement. "The bill should be declared unconstitutional and stopped."

The governor's office did not return an email seeking comment.

The law would take effect amid one of the nation's highest spikes in HIV cases related to intravenous drug use. The surge, clustered primarily around the capital of Charleston and the city of Huntington, is being attributed at least in part to the cancellation in 2018 of a needle exchange program.

It led to an investigation by the Centers for Disease Control and Prevention that this week found emergency departments and inpatient medical personnel rarely conducted HIV testing on intravenous drug users in Kanawha County.

Previously, city leaders and first responders complained that the program in Kanawha County led to an increase in needles being left in public places and abandoned buildings, and it was shut down.

The CDC describes syringe programs as "safe, effective, and cost-saving."

New York Times
Sunday, June 27, 2021, page A25

Johnson & Johnson to Pay $230 Million as Part of Exit From Opioid Industry

The settlement agreement came just days before opening arguments in a sweeping trial of several defendants, including the company.

By Sarah Maslin Nir

Johnson & Johnson will pay New York State more than $230 million in a settlement that also ensures the company will permanently stay out of the opioid business in the United States, the state attorney general's office announced on Saturday.

The settlement comes at a time when the opioid industry is facing over 3,000 lawsuits across the nation for its contribution to an epidemic of prescription and street opioid abuse that has killed more than 800,000 Americans in the last 20 years, according to the Centers for Disease Control and Prevention.

And it came just days before opening arguments in a sweeping New York trial in which the company was to be among the defendants. That trial will be the first of its kind to go before a jury, and the first to target the entire opioid supply chain, from the drugmakers who manufactured the pills to the distributors that supplied them to a pharmacy chain that filled prescriptions for them.

"The opioid epidemic has wreaked havoc on countless communities across New York State and the rest of the nation, leaving millions still addicted to dangerous and deadly opioids," Attorney General Letitia James said in a statement. "Johnson & Johnson helped fuel this fire, but today they're committing to leaving the opioid business -- not only in New York, but across the entire country."

In a statement, Johnson & Johnson said that the settlement was not an admission of liability or wrongdoing and that "the company's actions relating to the marketing and promotion of important prescription pain medications were appropriate and responsible."

It has not sold opioids in the United States since last year, when it ceased production of its last opioid product; and it stopped supplying opioid ingredients to other manufacturers in 2016.

Johnson & Johnson is the parent company of Janssen Pharmaceutical Companies, one of the defendants in the New York trial that will be removed from the case because of the settlement. The company will also pay an additional $33 million as reimbursement for New York's attorney fees and costs. The payments for the total will be made over nine years.

The money is not intended to compensate people harmed by the opioid crisis, but rather for what is known as abatement, mitigating harm and preventing future crises with things like education and addiction treatment programs.

The funds will be distributed to the counties subject to an allocation agreement with the state that is currently being finalized, according to Jayne Conroy, lawyer with Simmons Hanly Conroy, who is representing Suffolk County in the case.

The sprawling opioid case about to begin in New York was filed by the attorney general and by Nassau and Suffolk Counties on Long Island, and is being argued jointly. It includes claims that the companies, like Janssen, misled the public by initially denying the drugs were highly addictive, and aggressively marketed them as such, ignoring warnings of abuse as they chased profits.

The drugs that Janssen developed included a fentanyl patch and a tablet that was crush-resistant, marketed under names like Duragesic and Nucynta, which, according to Johnson & Johnson, accounted for less than one percent of total opioid prescriptions in the United States. It stopped marketing its opioids in 2016 in the United States and later discontinued the fentanyl patch. In 2020, it ceased production of the pill in the United States as well.

For years, Johnson & Johnson had supplied 60 percent of the ingredients that make opioids to companies that used them to make drugs like Oxycodone, contracting with poppy growers in Tasmania. In 2016, they sold the business that supplied the materials.

Johnson & Johnson has struggled under waves of bad publicity. It suffered a defeat in an opioid trial in 2019 when an Oklahoma judge ordered it to pay the state $465 million for its role in the public nuisance created by opioid addiction. It has been ordered to pay millions in courts that have found products like its talcum powder and hip implants to be harmful. Most recently, its coronavirus vaccine has been plagued by a troubled rollout.

The one-shot vaccine was initially seen as a vital tool in combating Covid-19, the disease caused by the coronavirus. But a host of concerns with production and the drug itself has seen the company's product account for just about 12 million of the more than 320 million doses administered in the United States so far, according to C.D.C. data.

In April, federal health officials paused use of the Johnson & Johnson vaccine after cases of a rare blood-clotting disorder emerged as a side effect. In June, a mix-up in a Baltimore factory resulted in the government ordering the disposal of 60 million potentially contaminated vaccine doses.

The exit of Johnson & Johnson from the New York case means that two of the country's biggest drugmakers will now be absent from the trial when opening arguments begin on Tuesday. Purdue Pharma, the maker of OxyContin, owned by members of the billionaire Sackler family and the company most publicly linked to the opioid epidemic, is also no longer standing trial.

Though initially named in the case, as were some individual Sacklers, Purdue filed for bankruptcy nearly two years ago as it faced thousands of opioid-related lawsuits. The bankruptcy process has paused cases against the drugmaker and the Sacklers.

In addition, in the weeks before opening arguments were to be made before a six-person jury and a New York Supreme Court justice, Jerry Garguilo, three of the four pharmacy chains -- Walmart Inc., Rite Aid Corp. and CVS -- were severed from the case; one of them, CVS, confirmed it had reached a settlement agreement with the counties, the terms of which are not yet final and public. Walmart and Rite Aid did not respond to emails requesting comment.

Walgreens remains one of the defendants that will face a jury next week.

Ms. Conroy, who is representing Suffolk County, cautioned that Saturday's announcement did not mark the end of the case. "While this settlement is good news, there still remains a crucially important trial starting next week," she said in a statement.

"We remain focused on ensuring the other defendants who played a major role in creating the opioid crisis are held accountable for their actions," she said.

Jan Hoffman contributed reporting.

CNN.com
Saturday, June 26, 2021

Johnson & Johnson settles New York opioid suit in $230 million deal

By Danielle Wiener-Bronner, CNN Business

New York (CNN Business)Johnson & Johnson has agreed to a $230 million settlement with New York state, resolving complaints from the state's attorney general over the pharmaceutical company's role in the opioid epidemic.

"Johnson & Johnson helped fuel this fire," New York Attorney General Letitia James said in a statement Saturday. "While no amount of money will ever compensate for the thousands who lost their lives or became addicted to opioids across our state ... these funds will be used to prevent any future devastation."

The settlement money will go toward opioid education, prevention and treatment, James added. Johnson & Johnson is set to pay out the funds over the course of nine years. The company may also be responsible for another $30 million if New York passes a law that creates an opioid settlement fund.

In a statement, Johnson & Johnson (JNJ) said that "the settlement is not an admission of liability or wrongdoing," adding that it "remains

committed to providing certainty for involved parties and critical assistance for communities in need."

The settlement also prevents Johnson & Johnson from manufacturing or selling opioids in the state, or promoting opioids or opioid-related products. The company had already decided to discontinue the production and sale of pain medication in the United States last year, a spokesperson said.

About 247,000 people died from overdoses involving prescription opioids in the United States from 1999 to 2019, according to the Centers for Disease Control and Prevention. The crisis has had a financial toll, as well -- a notice of claim filed last summer in bankruptcy court by nearly every US state and many territories said that opioid manufacturers have cost the American economy $2.15 trillion.

A New York lawsuit against the makers and distributors of opioids is going to trial next week. Johnson & Johnson was set to be a defendant but will no longer be a part of the trial due to the settlement agreement.

News of the settlement comes as lawsuits against major pharmaceutical companies over their role in the opioid epidemic play out in court. In May, a landmark trial involving three major prescription opioid distributors began in federal court in West Virginia. California's trial against opioid manufacturers began in April.

-- CNN's Lauren del Valle contributed to this report.

Reuters
Saturday, June 26, 2021

UPDATE 1-J&J to pay $263 mln in New York opioid settlements, avoids trial

By Jonathan Stempel

(Adds details of settlements, upcoming trial, New York attorney general comment, background)

NEW YORK, June 26 (Reuters) - Johnson & Johnson said on Saturday it will pay $263 million to resolve claims it fueled an opioid epidemic in New York state and two of its largest counties.

The settlements remove the drugmaker from a jury trial scheduled to begin on Tuesday on Long Island, where several big opioid makers and distributors are also defendants.

Johnson & Johnson did not admit liability or wrongdoing in settling with New York state, and with Nassau and Suffolk counties. The $229.9 million state settlement also calls for J&J to stop selling the painkillers nationwide.

"The opioid epidemic has wreaked havoc" across the nation, New York Attorney General Letitia James said in a statement. "Johnson & Johnson

helped fuel this fire."

She said her focus remains "getting funds into communities devastated by opioids as quickly as possible."

J&J said the settlements were consistent with its prior agreement to pay $5 billion to settle opioid claims by states, cities, counties and tribal governments nationwide.

The healthcare company and the largest U.S. drug distributors - AmerisourceBergen Corp, Cardinal Health Inc and McKesson Corp - have proposed paying a combined $26 billion to end thousands of opioid lawsuits.

J&J has also been appealing an Oklahoma judge's 2019 ruling that the New Brunswick, New Jersey-based company pay that state $465 million for its deceptive marketing of opioids.

Tuesday's opioids trial is one of several scheduled for this year, with others underway in California and West Virginia.

Drugmakers AbbVie Inc and Teva Pharmaceutical Industries Ltd and several distributors are among the defendants. Pharmacy chain Walgreens Boots Alliance Inc is also a defendant, though it was sued only by the counties.

Walmart Inc, Rite Aid Corp and CVS Health Corp were severed from the trial during jury selection. CVS has settled with Nassau and Suffolk counties. Settlement terms have not been disclosed.

The U.S. Centers for Disease Control and Prevention has said nearly 500,000 people died from opioid overdoses from 1999 to 2019. (Reporting by Jonathan Stempel in New York; Additional reporting by Nate Raymond in Boston; Editing by Bill Berkrot)

Los Angeles Times
Monday, June 28, 2021, page A2

For Native Americans, clean water is rare

Crumbling pipes and faulty sanitation systems leave many on reservations struggling for access

By Celina Tebor

When the clean water system failed last week at the Warm Springs Reservation in Oregon, thousands of residents relied on members of nearby communities to come to their aid with bottled water.

It was not the first time clean water had been difficult to find at Warm Springs, two hours southeast of Portland, or at many other Native American reservations across the United States.

The nonprofit U.S. Water Alliance says 58 out of every 1,000 Native

American households lack access to indoor plumbing.

Many Native American communities don't have access to clean water because of faulty, outdated or nonexistent pipes or sanitation systems that result in residents being forced to use bottled water or to boil water to kill viruses, bacteria and parasites.

Sen. Ron Wyden (D-Ore.) in February introduced a bill aimed at funding facilities for drinking water and sanitation in tribal communities. The bill calls for the Environmental Protection Agency to connect, expand or repair public water systems on reservations, at a cost of about $150 million by 2026.

" 'Boil water' notices and crumbling pipes are not acceptable," Wyden said during Interior Secretary Deb Haaland's nomination hearing. "Congress must do more to bring urgently needed resources to build sustainable tribal water infrastructure that has been neglected for far too long."

About 130,150 out of 409,535 homes of Native Americans surveyed by the government organization Indian Health Service needed sanitation facility improvements involving water, sewer or solid waste systems at the end of fiscal year 2018. The cost to improve those systems is estimated at $2.67 billion, according to the IHS.

In the 1960s, the federal government funded sanitation programs for tribes after the general American public began to become aware of poor living conditions on reservations.

The Sanitation Facilities Construction Act, passed in 1959, led to a sharp decrease in gastrointestinal and infectious respiratory disease in both Native American infants and white infants who lived near reservations, according to a Journal of Public Economics study.

According to the U.S. Water Alliance, Native American households are 19 times more likely than white households to lack indoor plumbing. Black and Latino households are twice as likely as white households to lack indoor plumbing.

Federal funding for reservations is not meeting needs, said Randall Akee, a UCLA professor of public policy and American Indian studies and chair of the university's America Indian Studies Interdepartmental Program.

"It's just woefully underfunded at the federal level, and tribes for a long, long time have not had the resources to fully develop these resources themselves," Akee said. "And frankly, it's a responsibility of the federal government -- a trust responsibility of treaties and hundreds of years of commitments. There has been a failure to fully live up to those commitments."

A problem for tribes across the U.S.

The Hopi tribe in Arizona has up to three times the amount of arsenic in its water that the EPA says is safe to drink. Many Native households in rural Alaska use a 5-gallon bucket as a toilet because they don't

have running water. And the Navajo Nation, the biggest reservation in the U.S., faces a diabetes crisis because soda is more accessible and cheaper than clean drinking water.

Bidtah Becker is a member of the Navajo Nation, which spans northeastern Arizona, southeastern Utah and northwestern New Mexico. She helped lead a report on access to clean water for tribes in the Colorado River Basin and has studied its effects on her own community and other tribes. She estimates that 30% to 40% of homes on the Navajo Nation lack piped water.

The federal Centers for Disease Control and Prevention and the Alaska Native Tribal Health Consortium have found links between low water service and respiratory infections. Studies from the CDC, the consortium and the IHS have also found links between a lack of access to clean water and skin and gastric infections.

"The other thing that people often don't think of with access to clean water is that it affects the economics of your community," Becker said. "If you don't have pipes to go to homes, you don't have pipes to go to laundromats or gas stations or stores. Clean water is integral to creating a healthy economy."

The cost of new infrastructure

Almost one-quarter of Native Americans lived below the poverty level in 2019, and fixing or building water infrastructure isn't cheap, nor is it easy or quick.

The IHS determined that there were 130,153 homes needing sanitation improvements in Native American communities at the end of fiscal year 2018 and identified 1,837 communitywide projects to assist those homes. The agency aims to bring sanitation systems to a level that complies with laws for water supplies and pollution control while requiring only routine maintenance.

About 28% of these projects are considered "infeasible" by the government, because they're too expensive. The IHS estimates the cost of all feasible projects across the country at $985 million.

According to the IHS report, the cost to bring sanitation to this level in Alaska was higher than the cost in every other community combined, at nearly $1.4 billion (for feasible and infeasible projects). Alaska is home to two-thirds of the nation's federally recognized tribes, with 229. Almost 16% of the state's population is American Indian or Alaska Native.

Jackie Qatalina Schaeffer is the community development manager for the tribal health Consortium's Division of Environmental Health and Engineering. Her role at the nonprofit is to work with rural Alaskan tribes, helping them access water and sanitation services.

Communities that don't have those services typically have access to a central watering point consisting of a hose connected to a building that provides showers, utility sinks andsometimes commercial washers and dryers, Qatalina Schaeffer said.

Residents can collect clean drinking water at the watering point, she said. They then haul the water by ATV, snowmobile or hand to their homes. They use either an outhouse or a "honey bucket," a 5-gallon bucket with a lid, as a toilet.

The average rural Alaskan living without piped water uses 3 gallons of water a day for bathing, drinking and cooking, compared with 156 for the average American.

Alaska's rural villages present particular challenges when it comes to providing water and sanitation systems.

"In Alaska, rural is not just 'away from a city,' " Qatalina Schaeffer said. "Rural is disconnected by any road systems. The only access to these communities is via small aircraft."

The average rural Alaskan village has a population of 400 to 500. It costs $40 million to $60 million to implement a communitywide water and sanitation system. While the infrastructure is often funded by the government, the burden of operation and maintenance falls on the community -- a burden most cannot afford.

Community support when pipes fail

Dan Martinez, emergency manager at Warm Springs, said the reservation's entire water system needs to be overhauled, at a cost of about $40 million. And while the federal and state governments provide emergency funds to the reservation, those often cover only the cost of quick fixes to a water system that he said needs to be rebuilt from the ground up.

While the reservation works toward a long-term solution for its water issues, Warm Springs relies on neighbors to help when the pipes fail.

"We rely on donated water from outside sources, which has been something that's happening on a daily basis," Martinez said. "We rely not so much on the government but on our neighbors and religious groups and donations from outside sources to give out drinking water."

Gilbert Brown, who grew up on the north end of the reservation and now lives in Portland, helps haul water donations from a Portland coffee shop to Warm Springs.

"Last year, the pipes kept breaking, and [the reservation] kept going on boil notices," he said. "People had to come bring water, and I was asked to help. And here we are again."

New York Times
Saturday, June 26, 2021, page A19

Correction

An article on June 20 about the Centers for Disease Control and

Prevention misidentified the act of Congress that funded electronic medical-record systems. It was the American Recovery and Reinvestment Act of 2009, not the Affordable Care Act of 2010.

From: Walensky, Rochelle (CDC/OD)
Sent: Tue, 29 Jun 2021 01:47:32 +0000
To: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Cc: Berger, Sherri (CDC/OCOO/OD);Schuchat, Anne MD (CDC/OD);Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI)
Subject: RE: Monday TODAY'S NEWS

Grateful...
R

-----Original Message-----
From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Monday, June 28, 2021 9:46 PM
To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>
Subject: FW: Monday TODAY'S NEWS

More info

-----Original Message-----
From: Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>
Sent: Monday, June 28, 2021 9:29 PM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD) <akc9@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>
Subject: RE: Monday TODAY'S NEWS

For awareness, further details. This case was reported through VAERS, and the investigation is proceeding.

From safety team:
CDC is not actively involved in this investigation (i.e., IDPB examining specimens). We have made contact with the state health department and the pathologist who did the autopsy and are in touch to maintain situational awareness. The initial report is in VAERS and we will receive the final autopsy report when it is complete. I can't speak to how the reporter got his/her information and came to his/her conclusions, but this is being investigated at the state level, as are all deaths. The autopsy was completed when we contacted the state health department and no request for CDC assistance has been made.

- The patient was a male aged 13 years with no notable medical history.
- He was found unresponsive 2 days after vaccination. Aside from a fever, he was in his usual state of health prior to his demise.
- An autopsy has been performed; the results and final report are pending.
- CDC and the state health department are in communication about this case, which remains under investigation.
- The pathologist indicated that there appeared to be bilateral ventricular enlargement and histology consistent with myocarditis, but those were preliminary findings.

Jen Layden, MD, PhD
Deputy Director, Office of Science
Centers for Disease Control and Prevention
Cell phone: 404-435-2237

-----Original Message-----
From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>
Sent: Monday, June 28, 2021 10:43 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>
Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD) <akc9@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>
Subject: RE: Monday TODAY'S NEWS

Henry -

The case had been reported to VAERS. CDC has spoken with ME, but we are following protocol for f/u re the case. Additionally, CDC remains in contact with MI and has offered to assist in the investigation.

Best,
David
-----Original Message-----
From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>
Sent: Monday, June 28, 2021 10:02 AM
To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Layden, Jennifer (CDC/DDPHSS/OS/OD) <qbg5@cdc.gov>
Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD) <akc9@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>
Subject: FW: Monday TODAY'S NEWS

Any details on cdc engagement?

-----Original Message-----
From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>
Sent: Monday, June 28, 2021 10:00 AM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>
Subject: FW: Monday TODAY'S NEWS

Any details on this?

CDC reportedly probing Michigan teen's death after COVID-19 vaccination

By Shen Wu Tan - The Washington Times

Federal health officials are investigating the case of a Michigan teenager who died days after he received a COVID-19 vaccine, Fox News reported Friday.

The 13-year-old boy died three days after getting a second dose of a COVID-19 vaccine, the Saginaw County Health Department told the news agency in a statement. The department learned of the teenager's death on June 17.

"The investigation as to whether there is a correlation between his death and vaccination is now at the federal level with [the Centers for

Disease Control and Prevention," the health department said. "Meanwhile, the health department continues to encourage families to speak with their physicians to weigh their own risks and benefits of vaccination."

It is unknown whether the teenage boy had previous health problems. The news report did not specify whether the teenager received the two-dose Pfizer-BioNTech COVID-19 vaccine or the Moderna vaccine. The death has been supposedly reported to the Vaccine Adverse Event Reporting System (VAERS), a national surveillance system.

Neither the CDC nor the Saginaw County Health Department immediately responded to requests for comment.

CDC officials say deaths following COVID-19 vaccinations have been rare. More than 318 million COVID-19 doses were administered in the U.S. from Dec. 14 through June 21, and about 5,400 deaths, or 0.0017%, among those vaccinated were reported to VAERS during that time.

"Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. A review of available clinical information, including death certificates, autopsy and medical records, has not established a causal link to COVID-19 vaccines," the CDC says on its website.

However, there could be a "plausible causal relationship" between the one-shot Johnson & Johnson COVID-19 vaccine and a rare, serious blood clotting condition, which has caused deaths.

Health care providers are required by the Food and Drug Administration to report any death after a COVID-19 vaccination to VAERS.

-----Original Message-----
From: Mike Cooper <mcooper@panix.com>
Sent: Monday, June 28, 2021 9:51 AM
To: cdc@panix.com
Subject: Monday TODAY'S NEWS

TODAY'S NEWS

MONDAY, JUNE 28, 2021

CDC Director Rochelle Walensky On Coronavirus Variants And Vaccinations, National Public Radio

Half of public health workers experiencing mental health strain: study; TheHill.com

CDC says roughly 4,100 people have been hospitalized or died with Covid breakthrough infections after vaccination, CNBC.com

U.S. FDA adds warning about rare heart inflammation to Pfizer, Moderna COVID vaccines; Reuters

Vaccine-associated myocarditis tends to resolve quickly, Reuters

CDC reportedly probing Michigan teen's death after COVID-19 vaccination, WashingtonTimes.om

Bipartisan senators ask CDC, TSA when they will update mask guidance for travelers; TheHill.com

U.S. Senate Republicans press CDC to end mask mandate on airplanes, transit; Reuters

Ted Cruz joins forces with other GOP lawmakers to call for an end to mask mandates for vaccinated travelers, ahead of Independence Day; BusinessInsider.com

Senate Republicans urge CDC to lift public transportation mask mandate, TheHill.com

Ted Cruz Urges Joe Biden to 'Follow the Science' and End Travel Mask Requirement, Newsweek.com

Georgia State Looks To Boost Vaccine Rate Among Refugees, AP Georgia

U.S. average daily COVID-19 vaccination drops by over 50 pct: CDC; Xinhua

U.S. reaches 323 million doses of COVID-19 vaccine administered -CDC, Reuters

CDC reports 4,115 breakthrough COVID-19 cases involving hospitalizations or deaths, FoxNews.com

Some fully vaccinated people may still get sick if exposed to variants, CDC warns; CNN.com

Booster may be needed for J&J shot as Delta variant spreads, some experts already taking them; Reuters

'Please get your second shot,' top health official urges as Delta variant remains a pressing threat; CNN.com

States Hesitant To Adopt Digital Covid Vaccine Verification, Associated Press

`A tough slog': White House struggles to increase vaccination rates as Delta variant surges; Politico.com

Wisconsin's Johnson To Tout Claims Of Vaccine Side Effects, AP Wisconsin

Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic, research finds; CNN.com

1st Post-Pandemic Cruise Ship From US Sails Away, Associated Press

How the first cruise of the Covid era got ready to safely set sail, CNN.com

Virus-Origin Review Likely to Be Unclear, Wall Street Journal

What We Know About the Origins of Covid-19, WSJ.com

The US is concealing its research on deadly viruses -- while criticizing China's secrecy over the Wuhan lab, BusinessInsider.com

Why US labs need to be investigated for COVID-19 origins, Global Times

Celebrity Cruises to Be First to Resume Sailing From U.S., New York Times

Harris Seeks Nuance On Migration Debate During Tour of Border, New York Times

Harris views immigration problems up close, Los Angeles Times

CDC director Robert Redfield 'prayed' Trump would understand how serious COVID-19 was after contracting it, a book excerpt says; BusinessInsider.com

How Trump's blunders fueled our coronavirus nightmare, Washington Post

Hospitals Strain Under Surge in Mental-Health Cases, Wall Street Journal

ACIP approves dengue vaccine for endemic areas, tweaks flu vaccine advice; CIDRAP News

CDC Gives Maine $7M To Prep For Future Public Health Crises, AP Maine

CDC: `Don't kiss or snuggle the birds;' Salmonella outbreak linked to more than 400 infections; SILive.com

Backyard poultry Salmonella outbreak grows to 474 cases, 1 death; CIDRAP News

Avanti Frozen Foods recalls several shrimp products linked to salmonella outbreak, CNN.com

Competing events make their marks on LGBTQ+ Pride Day in New York, Reuters

HIV SOS: Action Sought For Spike In Cases In West Virginia; AP West Virginia

ACLU In West Virginia Sues Over Needle Exchange Law, AP West Virginia

Johnson & Johnson to Pay $230 Million as Part of Exit From Opioid Industry, New York Times

Johnson & Johnson settles New York opioid suit in $230 million deal, CNN.com

J&J to pay $263 mln in New York opioid settlements, avoids trial; Reuters

For Native Americans, clean water is rare; Los Angeles Times

Correction, New York Times

National Public Radio
Friday, June 25, 2021

CDC Director Rochelle Walensky On Coronavirus Variants And Vaccinations

NPR's Audie Cornish checks in with Centers for Disease Control and Prevention Director Dr. Rochelle Walensky about vaccinations, variants and the current state of the pandemic.

AUDIE CORNISH, HOST:

Fifty thousand baseball fans showed up to see the Dodgers play the Phillies last week. The Foo Fighters drew a full-capacity crowd, all vaccinated, to New York's Madison Square Garden on Sunday. And tomorrow, the first major cruise ship will set sail from Fort Lauderdale. Even as the nation returns to life as it once was, thousands of people are still dying of COVID every week. And in unvaccinated pockets of the country, the delta variant of the virus is taking hold. So here to talk about the challenges that remain, Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention. Welcome back to ALL THINGS CONSIDERED.

ROCHELLE WALENSKY: Thanks so much, Audie. Great to be here.

CORNISH: I want to talk about that delta variant. It's more contagious - potentially more dangerous strain of the coronavirus. But more importantly, it makes up to 20% of cases nationwide at this point. And that's doubled in just a few weeks. So what's your concern as this is beginning to spread?

WALENSKY: Yeah, that's exactly right. So we have been doing genomic surveillance now for a while and have a really good window as to the variants that are circulating here in the United States. About a month ago, we were seeing the delta variant at about 2- to 3%. Two weeks ago, we were seeing it at about 9- to 10%. And this last...

CORNISH: And this is assuming that we're - the testing is good enough that we know the true infection rate. I mean, do you think that's the case?

WALENSKY: Oh, that's a really good point. We have scaled up our genomic sequencing in an extraordinary fashion just in the last six months. So I do believe that we're sequencing enough to have quite a good window as to what's going on here in this country. And more recently, our - we're seeing that the delta variant makes up about 20% of virus circulating and up to 30-, 40-, 50% in some regions of the United States.

As you noted, the things that we worry about with this variant specifically is not only how quickly it is scaling up - and what we've seen in the U.K. is, you know, it really has taken over as the predominant variant, which I expect to happen - but it really is more transmissible. And early data actually suggest it may actually lead to more severe disease as well.

CORNISH: So what's your concern when you look at, say, vaccination rates among people under the age of 25? How do you convince those groups in particular that they're still vulnerable?

WALENSKY: Well, you know, anybody is vulnerable to coronavirus. And so we really do need to make sure that we get vaccine to people who are unvaccinated. We do know that younger people have not had as long of an opportunity to be vaccinated as our older people who were eligible first. And what we really do need to do is figure out ways to talk to these young folks and ensure that they understand, not just about the severity of the disease, about the morbidity and mortality related to the disease, but about the implications of long COVID.

You know, what we have seen and the data have shown us is that the young folks are not getting hospitalized or die at the same rate of older people. But young people shouldn't die at the same rate of older people. And we do have - we have seen, for example, just in the last month that there have been over 300 deaths among people ages 20 to - 12 to 29. And that is - that shouldn't happen in that demographic, which is why we really want to get people vaccinated.

CORNISH: I want to jump in here because it's not just about the vaccinated people. Studies in England - the unvaccinated, I mean. Because there are studies in England that have shown one shot isn't

enough to give full protection against the delta variant. And there's some - I think I'm reading 27 million people in the U.S. who are still only half vaccinated; either still waiting for their second shot or who maybe decided one shot was enough. What's your message to them?

WALENSKY: Right. So thank you for raising that. My message is to please get your second shot. So what we do know is you get some protection from the first shot. But really, that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this delta variant and other variants as well. And as you note, data from the U.K. show that one shot is really not working as well to stave off, especially, the delta variant and you really do need that second shot. So we are really encouraging people not only to get their first, but to get their second. And if you didn't, if you missed your second within the time window, get it whenever - get it now. But do get that second shot.

CORNISH: Is it clear how helpful that is? When you look at a country like Israel, where the variant accounts for 90% of new cases there - in cases where people had been fully vaccinated with the Pfizer vaccine. I mean, they reimposed indoor mask requirements. Looking at our map, we've got states that aren't doing that now. So what are your concerns?

WALENSKY: So I do think we have more to learn about this delta variant, but here's what I'll say. It is the case that if you're vaccinated, we believe you actually have quite good protection against the delta variant. But nothing is foolproof. What we do know is that if you have been vaccinated, you are far less likely to have severe disease, to have - to result in death and also to be able to transmit to others. So yes, perhaps we're seeing breakthrough infections at a higher rate than we would like to see, but we're also seeing that if you've been vaccinated, you have less severe disease, less transmission and less death.

CORNISH: President Biden has said the variant is unlikely to force the U.S. into another lockdown situation. Looking at a state like, say, Missouri that has low vaccination numbers and climbing cases, are you guys going to be urging local leaders to put mask mandates back in place or social distancing requirements back in place?

WALENSKY: Right. So that's a really great question. We are encouraging all local areas to look at their vaccination rates, to look at the case rates and to make their policies that - with those both in mind. It may very well...

CORNISH: So if they've got no mask mandate or no social distancing and they're like, we've only got a few people in the hospital but a low vaccination rate, is that a recipe that you want?

WALENSKY: Well, that would be - if you have low cases, then the answer there is to make sure you scale up your vaccination rates. If you also have high cases, then we might encourage states to take the mitigation strategies that we know work to decrease the number of cases and increase the vaccination rate. For the most part, CDC has said since its initial mask guidance for fully vaccinated people that if you are not vaccinated, you should continue the standard mitigation strategies

- distancing, handwashing and masking - that we know work to protect people.

CORNISH: In our final few seconds - even if you wanted to, do you think you could convince anyone to go back into lockdown? I mean, politically, it was tough.

WALENSKY: Yeah. I think my job is to make sure that the public is safe. And so we have many strategies, many tools in our toolbox now to be able to do that. Vaccine is certainly one of them. And I think we have continued work ahead of us to get into these communities and to let people - give people the information they need so that they know vaccine is the best protection for them.

CORNISH: That's Dr. Rochelle Walensky, director of the Centers for Disease Control and Prevention. Thank you for your time.

WALENSKY: Thanks so much.

(SOUNDBITE OF NATIONAL AIR AND SPACE MUSEUM, DIPLO, AND HRISHIKESH HIRWAY'S SONG, "MOTION MMXX -- I")

TheHill.com
Friday, June 25, 2021

Half of public health workers experiencing mental health strain: study

By Reid Wilson

More than half of public health workers reported experiencing symptoms of mental health conditions, according to a new study, a toll that disproportionately falls on those who spent most of their time treating patients suffering from COVID-19.

The study, to be published in the Centers for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report, found nearly a third of the 26,000 health care workers polled suffered from symptoms of depression in the last two weeks. Three in 10 reported suffering from anxiety, and more than a third say they have experienced symptoms of post-traumatic stress disorder (PTSD).

Eight percent, or about one in twelve, told researchers they experienced suicidal ideation.

All of the mental health conditions were more prevalent among public health workers under the age of 29, among those who worked more than 60 hours per week and among those who reported they were unable to take time off work.

The symptoms were particularly pronounced among those who spent most of their time in COVID-19 wards. Among public health workers who spent three-quarters of their time responding to the pandemic, nearly half reported symptoms of PTSD within the last two weeks alone and more than a third reported signs of depression and anxiety.

The CDC researchers said stress-inducing events like the coronavirus pandemic can undermine the public health workforce at exactly the time when they are most essential.

"Increases in adverse mental health symptoms among workers have been linked to increased absenteeism, high turnover, lower productivity, and lower morale, which could influence the effectiveness of public health organizations during emergencies," the researchers wrote.

The report found nearly three-quarters of all public health workers felt overwhelmed by work. One in 8 reported receiving job-related threats, in an echo of abuse hurled at health care workers early on in the pandemic. And almost a quarter said they had felt bullied, harassed or threatened because of their work.

Public health care workers are more likely to have experienced traumatic events or stressors during the pandemic than are members of the general population. More than a quarter reported losing a loved one, and more than 10 percent reported they had been diagnosed with COVID-19 themselves.

The CDC researchers surveyed 26,174 public health workers from state, tribal, local and territorial health departments over a three-week period in late March and early April of 2020, as the pandemic began.

CNBC.com
Friday, June 25, 2021

CDC says roughly 4,100 people have been hospitalized or died with Covid breakthrough infections after vaccination

Rich Mendez@richmendezcnbc

More than 4,100 people have been hospitalized or died with Covid-19 in the U.S. even though they've been fully vaccinated, according to new data from the Centers for Disease Control and Prevention.

So far, at least 750 fully vaccinated people have died after contracting Covid, but the CDC noted that 142 of those fatalities were asymptomatic or unrelated to Covid-19, according to data as of Monday that was released Friday.

The CDC received 3,907 reports of people who have been hospitalized with breakthrough Covid infections, despite being fully vaccinated. Of those, more than 1,000 of those patients were asymptomatic or their hospitalizations weren't related to Covid-19, the CDC said.

"To be expected," Dr. Paul Offit, a top advisor to the Food and Drug Administration on children's vaccines told CNBC. "The vaccines aren't 100% effective, even against severe disease. Very small percentage of the 600,000 deaths."

Breakthrough cases are Covid-19 infections that bypass vaccine

protection. They are very rare and many are asymptomatic. The vaccines are highly effective but don't block every infection. Pfizer and Moderna's phase three clinical studies found that their two-dose regimens were 95% and 94% effective at blocking Covid-19, respectively, while Johnson & Johnson's one-shot vaccine was found to be 66% effective in its studies. All three, however, have been found to be extremely effective in preventing people from getting severely sick from Covid.

The CDC doesn't count every breakthrough case. It stopped counting all breakthrough cases May 1 and now only tallies those that lead to hospitalization or death, a move the agency was criticized for by health experts.

Most Americans have received at least one shot of the two currently authorized mRNA vaccines. The U.S. has administered 178.3 million shots and fully vaccinated 46% of its population.

"You are just as likely to be killed by a meteorite as die from Covid after a vaccine," Dr. Peter Chin-Hong, an infectious disease expert at the University of California San Francisco, told CNBC. "In the big scheme of things, the vaccines are tremendously powerful."

Efficacy rates decrease slightly for variants like alpha and delta, with studies indicating 88% efficacy against the delta strain after two doses of the Pfizer vaccine. It was unclear if any of the reported breakthrough cases were caused by variants.

In Israel and the United Kingdom, concerns about the delta variant are rising after growing reports of breakthrough infections.

Even with 80% of adults vaccinated, Chezy Levy, director-general of Israel's Health Ministry, said the delta variant is responsible for 70% of new infections in the country. Levy also said that one-third of those new infections were in vaccinated individuals.

In the U.K., Public Health England released a report that found 26 out of 73 deaths caused by the delta variant occurred in fully vaccinated people from June 8 to June 14. Most of the deaths occurred in unvaccinated individuals.

"Determination of whether hospitalizations and deaths are more represented in immunocompromised patients and the type of vaccine received will be important for future guidance," Chin-Hong said.

On June 7, the CDC received reports of 3,459 breakthrough cases that led to hospitalization or death. On June 18, that number was updated to 3,729, an increase of 270 cases. Today, the number stands at 4,115.

An overwhelming majority, 76%, of the hospitalizations and deaths from breakthrough cases occurred in people over the age of 65.

"We do not have the years and years of data we have for vaccines against other airborne pathogens -- and therefore it is really essential that the CDC provides up to date reporting on breakthrough cases," David Edwards, aerosol scientist and Harvard University

professor, told CNBC.

The CDC says its numbers are "likely an undercount" of all Covid infections in vaccinated people because the data relies on passive and voluntary reporting.

-- CNBC's Berkeley Lovelace Jr. contributed to this report.

Reuters
Friday, June 25, 2021

U.S. FDA adds warning about rare heart inflammation to Pfizer, Moderna COVID vaccines

(Reuters) - The U.S. drug regulator on Friday added a warning to the literature that accompanies Pfizer Inc/BioNTech and Moderna vaccine shots to indicate the rare risk of heart inflammation after its use.

For each vaccine, the fact sheets have been revised to include a warning about myocarditis and pericarditis, FDA said.

The latest update follows an extensive review of information and the discussion by CDC's Advisory Committee on Immunization Practices meeting on Wednesday.

(Reporting by Maria Ponnezhath in Bengaluru; Editing by Chris Reese)

Reuters
Friday, June 25, 2021

Vaccine-associated myocarditis tends to resolve quickly

By Nancy Lapid

Cases of an inflammation of the heart muscle known as myocarditis have been reported after receiving COVID-19 shots, mostly in young men after the second dose of the mRNA vaccines. When myocarditis symptoms, such as chest pain and rapid or irregular heartbeats, do occur after vaccination, they usually resolve quickly, suggests a report of a small study published in the journal Circulation. Doctors tracked seven male patients, ages 19 to 39, who were hospitalized for myocarditis-like illness not long after receiving a COVID-19 vaccine manufactured by either Pfizer and BioNTech, Moderna - the two mRNA vaccines - or Johnson & Johnson. All recovered and left the hospital after two to four days of treatment. Study co-author Dr. Christopher deFilippi of the Inova Heart and Vascular Institute in Fairfax, Virginia, noted that in his health system, which represents about 2 million patients, myocarditis after COVID-19 vaccination has been a "rare event" and "fortunately so far associated with a benign outcome." The U.S. Centers for Disease Control and Prevention this week said reports of the heart condition occurred at a rate of 12.6 cases per million people who received either the Pfizer/BioNTech or Moderna vaccines, a higher rate

than would be expected in the general population. However, deFilippi's team advised that given the dangers of COVID-19, even for younger adults, "the risk-benefit decision for vaccination remains highly favorable." (https://bit.ly/35NyLRv)

WashingtonTimes.om
Friday, June 25, 2021

CDC reportedly probing Michigan teen's death after COVID-19 vaccination

By Shen Wu Tan - The Washington Times

Federal health officials are investigating the case of a Michigan teenager who died days after he received a COVID-19 vaccine, Fox News reported Friday.

The 13-year-old boy died three days after getting a second dose of a COVID-19 vaccine, the Saginaw County Health Department told the news agency in a statement. The department learned of the teenager's death on June 17.

"The investigation as to whether there is a correlation between his death and vaccination is now at the federal level with [the Centers for Disease Control and Prevention," the health department said. "Meanwhile, the health department continues to encourage families to speak with their physicians to weigh their own risks and benefits of vaccination."

It is unknown whether the teenage boy had previous health problems. The news report did not specify whether the teenager received the two-dose Pfizer-BioNTech COVID-19 vaccine or the Moderna vaccine. The death has been supposedly reported to the Vaccine Adverse Event Reporting System (VAERS), a national surveillance system.

Neither the CDC nor the Saginaw County Health Department immediately responded to requests for comment.

CDC officials say deaths following COVID-19 vaccinations have been rare. More than 318 million COVID-19 doses were administered in the U.S. from Dec. 14 through June 21, and about 5,400 deaths, or 0.0017%, among those vaccinated were reported to VAERS during that time.

"Reports of adverse events to VAERS following vaccination, including deaths, do not necessarily mean that a vaccine caused a health problem. A review of available clinical information, including death certificates, autopsy and medical records, has not established a causal link to COVID-19 vaccines," the CDC says on its website.

However, there could be a "plausible causal relationship" between the one-shot Johnson & Johnson COVID-19 vaccine and a rare, serious blood clotting condition, which has caused deaths.

Health care providers are required by the Food and Drug Administration to report any death after a COVID-19 vaccination to VAERS.

TheHill.com
Sunday, June 27, 2021

Bipartisan senators ask CDC, TSA when they will update mask guidance for travelers

By Olafimihan Oshin

A bipartisan group of senators has asked the Centers for Disease Control and Prevention (CDC) and Transportation Security Administration (TSA) when they will update their mask guidance for travelers.

In a letter, Sens. Brian Schatz (D-Hawaii), Roger Wicker (R-Miss.), Amy Klobuchar (D-Minn.), Susan Collins (R-Maine), and Jerry Moran (R-Kan.) requested information about the agency's process for updating the mask guidelines for vaccinated people, adding that they want answers by July 12.

"As there has not yet been any change in the requirement for masks while traveling, we request an update on the CDC's and TSA's process for updating the mask requirement for fully vaccinated individuals and what the science is showing about the transmission of COVID-19 for fully vaccinated individuals while traveling," the senators said in their letter.

The letter asked five questions including whether removing mask mandates for fully vaccinated people would encourage others to get vaccinated and whether lifting mask mandates for fully vaccinated people would create administrative challenges.

The senators noted they understand social distancing can be difficult on public transportation conveyances and public transportation hubs.

"If the requirement for wearing masks while traveling can be safely lifted and would serve the public health interest, then we believe it would benefit the traveling public. We appreciate your prompt attention to this matter and hard work in responding to the COVID-19 pandemic," the letter said.

The letter comes days after Democratic lawmakers on Wednesday shot down a bill from Republican Sens. Rick Scott (Fla.) and Mike Lee (Utah) that would have revoked the Biden administration's mask requirement on public transportation.

The Hill has reached out to the CDC and the TSA for comment.

Reuters
Friday, June 25, 2021

U.S. Senate Republicans press CDC to end mask mandate on airplanes, transit

By David Shepardson

June 25 (Reuters) - A group of Senate Republicans urged the Centers for Disease Control and Prevention (CDC) on Friday to stop requiring fully vaccinated Americans to wear masks on public transportation, including airplanes, trains and buses but also in airports and train stations.

Roger Wicker, the most senior Republican on the Senate Commerce Committee, and Ted Cruz, top Republican on an aviation subcommittee, along with Susan Collins, Jerry Moran, Cynthia Lummis and Marsha Blackburn introduced a resolution urging the CDC to lift mask requirements in place since Feb. 1.

"Over 150 million people in the United States are fully vaccinated and mask mandates have been lifted across the country. But the CDC inexplicably still hasn't lifted the mask mandate for public transportation," Cruz said. "It's long past time for President Biden and the CDC to follow the science."

The lawmakers argued the change "would incentivize a greater number of individuals to receive the COVID-19 vaccine."

A CDC spokeswoman declined to comment.

In May, the CDC said fully vaccinated Americans could stop wearing masks in nearly all indoor spaces - with transportation one of the few exceptions.

The Transportation Security Administration on April 30 extended orders to enforce face mask requirements through Sept. 13.

Sara Nelson, international president of the Association of Flight Attendants-CWA, representing nearly 50,000 Flight Attendants at 17 airlines, said the union supported the mandate to help stop the spread of the virus and protect those who don't have access to the vaccine, such as children under 12.

Since January, the Federal Aviation Administration has received 3,100 reports of unruly behavior on airlines, including 2,350 reports of passengers refusing to comply with federal face mask requirements.

On June 10, the CDC said it would no longer require travelers to wear masks in outdoor transit hubs and in outdoor spaces on ferries, buses and trolleys but left indoor requirements unchanged.

(Reporting by David Shepardson Editing by Sonya Hepinstall)

BusinessInsider.com
Saturday, June 26, 2021

Ted Cruz joins forces with other GOP lawmakers to call for an end to mask mandates for vaccinated travelers, ahead of Independence Day

Kevin Shalvey

A group of Republican senators led by Ted Cruz on Friday announced a bill seeking an end to federal mask mandates for vaccinated travelers on planes, trains, and other public transport.

Mask requirements from the Centers for Disease Control & Prevention (CDC) and Transportation Security Administration (TSA) have outlasted their purpose, the lawmakers said.

The CDC in February recommended that travellers stayed home until they were fully vaccinated, but still required everyone to wear a mask while on public transport. The same was true for the TSA, which extended its requirement until September. Airlines have their own requirements, too.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," Sen. Ted Cruz said in a statement accompanying the bill.

In addition to Cruz, the GOP effort involved Susan Collins, Jerry Moran, Roger Wicker, Cynthia Lummis, and Marsha Blackburn. It came as states across the country continued loosening restrictions on daily life.

TSA mask mandates have led to altercations in airports and on flights, where cabin crews have had to deal with unruly passengers. Flight attendants have described "unprecedented" violence. The TSA in July will restart its self-defense training for flight crews.

A frequent flier last week sued seven airlines, saying vaccinated travelers should be able to fly without masks.

The resolution, introduced in the Senate on Thursday, said the CDC could incentivize more people to get vaccines by dropping the mask requirement.

The three-page text said that getting rid of the mask mandate "would be instrumental in helping the economic recovery of the United States by boosting travel and benefitting the travel and tourism industries without sacrificing public health."

In late May, the transportation secretary, Pete Buttigieg, said the mask requirement on public transit was a "matter of safety, but it's also a matter of respect" for flight crews.

The World Health Organization in a Friday press briefing said vaccines alone won't end the pandemic. The organization urged fully vaccinated people to continue wearing masks.

Collins in a statement said she'd spoken with flight attendants about the mandate. The senator said she'd heard about "horrendous and unthinkable violence" on recent flights.

If vaccinated people on the ground no longer need masks indoors, then fliers don't need them either, Collins said.

"It makes no sense that someone can go to a restaurant without wearing a mask, but they cannot fly on an airplane without one, even though it has a far better ventilation system," she said.

TheHill.com
Saturday, June 26, 2021

Senate Republicans urge CDC to lift public transportation mask mandate

By Celine Castronuovo

A group of GOP lawmakers led by Sen. Ted Cruz (R-Texas) on Friday introduced a resolution formally calling on the Centers for Disease Control and Prevention (CDC) to lift its mask mandate for fully vaccinated individuals on public transportation.

Cruz, along with Republican Sens. Susan Collins (Maine), Jerry Moran (Kan.), Roger Wicker (Miss.), Cynthia Lummis (Wyo.) and Marsha Blackburn (Tenn.), argued that the CDC's guidance that fully vaccinated individuals do not have to wear masks in most settings should also apply when traveling on commercial planes, buses, trains and other forms of public transit.

President Biden on his first full day in office signed an executive order directing federal agencies to "immediately take action" to require masks on public transportation.

While the federal mask mandate was initially set to expire May 11, the Transportation Security Administration (TSA) has since extended it to Sept. 13.

However, Cruz and his colleagues said in their resolution Friday that "science shows that individuals fully vaccinated against COVID-19 are protected against asymptomatic infection, and thus very unlikely to spread the disease," adding that Americans "have sacrificed immensely" throughout the coronavirus pandemic.

In a press release announcing the resolution, Cruz said, "It's long past time for President Biden and the CDC to follow the science and end this mask mandate for fully vaccinated individuals.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," he added.

Collins in a statement included in the release said she had spoken with flight attendants who had expressed fears on enforcing the federal mask mandate amid multiple viral incidents showing passengers attacking or threatening workers over the safety restrictions.

"It makes no sense that someone can go to a restaurant without wearing a mask, but they cannot fly on an airplane without one even though it has a far better ventilation system," Collins argued.

The resolution comes just days after Democrats blocked a bill from Senate Republicans that would have revoked Biden's mask requirement on public transit.

GOP Sens. Rick Scott (Fla.) and Mike Lee (Utah), who had introduced the bill, cited the nation's vaccination rates in arguing against the need for a face mask requirement.

However, Sen. Patty Murray (D-Wash.), chair of the Senate Health, Education, Labor and Pensions Committee, said when blocking the bill, "This virus is still spreading, it is still mutating, it is still costing lives, and it is still leaving survivors with long-haul symptoms."

"We cannot pretend this pandemic is over," she added.

Newsweek.com
Saturday, June 26, 2021

Ted Cruz Urges Joe Biden to 'Follow the Science' and End Travel Mask Requirement

By Darragh Roche

Senator Ted Cruz (R-TX) has called on President Joe Biden to end the requirement for people who are fully vaccinated to wear face masks while traveling on trains, airplanes, buses and other vehicles.

Cruz is leading a group of Republican senators who are introducing a bill calling on the Centers for Disease Control and Prevention (CDC) to end the mask requirement for travelers.

The CDC issued updated guidance on COVID-19 mask-wearing in May, saying that fully vaccinated people could go without face coverings in most indoor and outdoor settings but masks continue to be required on forms of transportation.

Cruz issued a statement on Friday to accompany the lawmakers' resolution.

"Over 150 million people in the United States are fully vaccinated and mask mandates have been lifted across the country," Cruz said.

"But the CDC inexplicably still hasn't lifted the mask mandate for public transportation. It's long past time for President Biden and the CDC to follow the science and end this mask mandate for fully vaccinated individuals.

"Americans should be able to travel to celebrate Independence Day with their friends and loved ones without having to follow an outdated and unnecessary mandate," Cruz said.

Biden had previously set July 4 as the deadline for the administration's goal of having at least 70 percent of Americans with

one shot of the COVID vaccine but recently admitted it will not now meet that goal. However, around 65 percent of adults have been at least partially vaccinated, according to CNBC.

The CDC issued a sweeping mask mandate for public transport following Biden's executive order on the pandemic on January 21 - the day after he took the oath of office. That order came into effect on February 1.

Though CDC advice has been updated since the order on public transport was issued, the mask-wearing requirements for buses, airplanes, trains and other forms of transport remain in place.

Marty Cetron, director for CDC's Division of Global Migration and Quarantine, explained the rationale behind the decision in the 11-page written order on January 29.

"Requiring masks on our transportation systems will protect Americans and provide confidence that we can once again travel safely even during this pandemic," Cetron said.

The CDC updated its advice on June 10 to say that fully vaccinated people no longer needed to wear masks while outdoors at transportation hubs such as bus stations but that unvaccinated people should continue to do so.

Cruz, who is the ranking member of the Senate Subcommittee on Aviation Safety, Operations, and Innovation, called legal requirements for mask-wearing on airplanes "performative theater" on June 16.

Newsweek has asked the White House, Senator Ted Cruz and the CDC for comment.

AP Georgia
Saturday, June 26, 2021

Georgia State Looks To Boost Vaccine Rate Among Refugees

CLARKSTON, Ga. (AP) -- Researchers at Georgia State University will use a $500,000 grant to try to increase COVID-19 vaccination rates among refugees and other groups in the Atlanta area city of Clarkston -- one of the largest refugee resettlement communities in the U.S., the university announced.

The money from the U.S. Centers for Disease Control and Prevention will help train and deploy six outreach workers to address residents' concerns about coronavirus vaccines and encourage them to get jabbed. The workers will represent major refugee groups living in Clarkston, including the Burmese, Congolese, Afghan and Somali communities, as well as the African American community, the university said in a news release.

The school plans to use workers who are known and trusted in their respective communities and send them out within a month, Michael Eriksen, a public health professor at Georgia State who is leading the

effort, said during a phone interview Wednesday. Thousands of refugees live in the Clarkston area.

"We're really pushing this as quickly and as hard as we can," Eriksen said, citing the need for urgency because of the ongoing pandemic.

Vaccination rates in Georgia and elsewhere in the South have lagged behind the rest of the country. In some Clarkston neighborhoods, the percentage of people fully vaccinated as of June was below 30, according to researchers at Georgia State. That was lower than the state's vaccination rate.

Eriksen said many refugees receive additional conspiracy theories and false information about vaccines from people in their home countries.

They may also be struggling to overcome traumatic events that brought them to the U.S. and face language and cultural barriers -- all of which can hamper vaccine uptake.

The outreach workers will also help local clinics and the DeKalb County Board of Health schedule vaccine appointments, arrange transportation and follow up with residents to make sure they get a second dose. The goal is to increase vaccine rates in Clarkston by 50 percent by spring 2022.

The one-year grant was awarded to the Prevention Research Center located on the Clarkston campus of Perimeter College -- a two-year school in the Georgia State system.

Xinhua (China)
Saturday, June 26, 2021

U.S. average daily COVID-19 vaccination drops by over 50 pct: CDC

WASHINGTON, June 26 (Xinhua) -- The latest 7-day average number of administered vaccine doses per day decreased by 55.3 percent from the previous week, according to a weekly report of the U.S. Centers for Disease Control and Prevention (CDC).

As of June 24, the 7-day average number of administered vaccine doses reported to the CDC per day was 0.37 million, according to the report released on Friday.

About 45.8 percent of the U.S. population was fully vaccinated against COVID-19, and 53.9 percent of the population received at least one shot as of Saturday, CDC data showed.

Roughly 152.2 million people were fully vaccinated. But some states, such as Alabama, Arkansas, Louisiana, Mississippi, Tennessee and Wyoming, had low vaccination rates.

A new CDC study showed adults aged 18 to 24, as well as non-Hispanic Black adults and those with less education, no insurance, and lower household incomes, had the lowest reported vaccination coverage and

intent to get vaccinated.

The White House confirmed earlier this week that the country would not hit U.S. President Joe Biden's goal of getting 70 percent of American adults to receive at least one COVID-19 vaccine shot by July 4, the Independence Day.

Reuters
Sunday, June 27, 2021

U.S. reaches 323 million doses of COVID-19 vaccine administered -CDC

(Reuters) - The United States has administered 323,327,328 doses of COVID-19 vaccines in the country as of Sunday morning, and distributed 381,282,720 doses, the U.S. Centers for Disease Control and Prevention (CDC) said.

Those figures are up from the 322,123,103 vaccine doses the CDC said had gone into arms by June 26 out of 381,276,030 doses delivered.

The agency said 179,261,269 people had received at least one shot, while 153,028,665 in the United States are fully vaccinated as of Sunday.

The CDC tally includes two-dose vaccines from Moderna Inc and Pfizer/BioNTech, as well as Johnson & Johnson's one-shot vaccine as of 6 a.m. EDT (1000 GMT) on Sunday.

(Reporting by Maria Ponnezhath in Bengaluru; Editing by Matthew Lewis)

FoxNews.com
Monday, June 28, 2021

CDC reports 4,115 breakthrough COVID-19 cases involving hospitalizations or deaths

Cases reflect small percentage of 150 million people who are fully vaccinated

By Alexandria Hein | Fox News

The Centers for Disease Control and Prevention (CDC) has received reports of 4,115 patients with COVID-19 vaccine breakthrough cases who were hospitalized or died. Of those cases, 26% of hospitalizations were reported as asymptomatic or not related to COVID-19, and 19% of the 750 fatalities were reported as asymptomatic or not related to COVID-19.

The data, which includes information through June 21, is amid a backdrop of 150 million people who are fully vaccinated in the U.S. Nearly half of the breakthrough cases, or 49%, involve females, and 3,124, or 76%, occurred in patients ages 65 years and older.

Officials have long predicted vaccine breakthrough cases would be

reported, as "no vaccines are 100% effective at preventing illness in vaccinated people." The agency has also warned there would be a "small percentage" of vaccinated people who get sick, require hospitalization or even die from COVID-19.

"The number of COVID-19 vaccine breakthrough infections reported to CDC likely are an undercount of all SARS-CoV-2 infections among fully vaccinated persons," the agency noted. "National surveillance relies on passive and voluntary reporting, and data might not be complete or representative. These surveillance data are a snapshot and help identify patterns and look for signals among vaccine breakthrough cases."

The agency noted that "no unexpected patterns" have been identified in the reported breakthrough infections. It also states that vaccines remain effective and everyone ages 12 and older who have not received it should get one as soon as possible.

CNN.com
Saturday, June 26, 2021

Some fully vaccinated people may still get sick if exposed to variants, CDC warns

By Madeline Holcombe and Jacqueline Howard, CNN

(CNN)The US Centers for Disease Control and Prevention told CNN Friday that the agency is tracking the Delta coronavirus variant, among others -- and warned that there is a small chance a fully vaccinated person could still get infected if they're exposed.

"Current data suggest that COVID-19 vaccines authorized for use in the United States offer protection against most variants currently spreading in the United States. However, some variants might cause illness in some people even after they are fully vaccinated," CDC spokesperson Jade Fulce told CNN in an email on Friday.

While Covid-19 vaccines are effective, Fulce said no vaccine is "100% effective at preventing illness."

And with millions of people getting vaccinated against the virus, some who are fully vaccinated "will still get sick if they are exposed," Fulce said.

"However, people with breakthrough infections may get less severely ill or have a shorter illness than they would have if they had not been vaccinated."

That's why experts are especially worried about people who have not yet gotten their Covid-19 shots.

More than 53% of the US population has received at least one Covid-19 vaccine dose and more than 45% is fully vaccinated, CDC data shows.

'Please get your second shot'

As officials urge more people to get their shots, the US surgeon general warns a big obstacle stands in their way: Misinformation.

"There is so much misinformation out there about the vaccine, coming through so many channels -- a lot of it being spread on social media," Dr. Vivek Murthy told CNN's Erin Burnett. "It's inducing a lot of fear among people."

"Two-thirds of those who are unvaccinated in polls say that they either believe the myths about Covid-19 or think that they might be true," he added.

Experts, including Dr. Anthony Fauci, have estimated that 70 to 85% of people in the US will need to become immune to the virus through vaccination or infection in order to control community spread. But after initial surges, vaccination rates have now slowed across the country.

And more than 1 in 10 people who have received one dose of the Pfizer/BioNTech or Moderna vaccine have missed their second dose, according to data shared with CNN by the CDC.

That statistic is especially concerning to experts because studies have shown that the vaccines are much more effective against the Delta variant after the two-dose series is completed.

"Please get your second shot," CDC Director Dr. Rochelle Walensky said in a Friday NPR interview. "What we do know is you get some protection from the first shot, but really that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this Delta variant and other variants as well.

"If you missed your second within the time window, get it whenever, get it now, but do get that second shot," Walensky added.

Officials worried about unvaccinated Americans

The Delta variant is believed to be more transmissible and cause more severe disease than other strains. Murthy said he is worried for those who are unvaccinated as the variant spreads.

In Los Angeles County, the impact is already clear. Nearly all of the Covid-19 cases, hospitalizations, and deaths in Los Angeles County are occurring among people who are unvaccinated, county health officials said Thursday.

Out of nearly 437,000 positive coronavirus cases reported in L.A. County since December 2020, 99.6% of those were among individuals who were unvaccinated, health officials said in a press release.

"The virus is still with us," Los Angeles County Public Health Director Barbara Ferrer said at a press conference. "Even now, we need to be careful to mask and maintain distance from people outside of our households, especially if they're not yet vaccinated."

Missouri hospitals stretched thin

Missouri is the state with the largest proportion of the Delta variant of Covid-19 infections, according to the CDC. And hospitals in the state are feeling the stress of managing Covid-19 patients on top of their regular intake, one hospital leader told CNN's Ana Cabrera on Thursday.

"Both hospitals here in town are stretched," said Erik Frederick, chief administrative officer at Mercy Hospital Springfield in Springfield, Missouri.

"We saw a very rapid escalation in our in-patient census starting June 1, we went from 26 to 90 in about three weeks. To go back to last year when our peak started, it took us six to seven weeks to escalate that quickly. Today to hit 97, it really took us almost two months to hit that level which we've done in under a month."

Frederick said a return of typical hospital patients is exacerbating the issue.

"The difference between last year and this we have traditional business back we didn't have last year during the initial surge. The demand for beds is higher for both Covid and non-Covid patients. It's definitely a stretch."

Frederick said there is also a high amount of pressure on available labor.

"The staff are right back into the mix of it, and I don't think they were fully recovered from last year," he said.

Smell and taste come back, studies show

In a bit of good news, researchers reported Thursday that those who did not regain their sense of taste and smell when they cleared their Covid-19 infections should get them back after a year.

Studies confirm that many, if not most, Covid-19 patients say their sense of smell is affected -- a condition called anosmia or hyposmia.

Because smell and taste are closely linked, many people feel their ability to taste food normally is also affected when their sense of smell is disrupted.

An ongoing experiment of about 100 people who lost their sense of smell in early 2020 showed it can take months for it to come back, but it does. Some patients didn't realize or appreciate it, however, the international team of researchers reported in the Journal of the American Medical Association's JAMA Network Open.

"At eight months, objective olfactory assessment confirmed full recovery in 49 of 51 patients (96.1%)," they wrote. Two continued to have an abnormal sense of smell a year later -- one who couldn't smell much and another who had an abnormal smell sense.

"Our findings suggest that an additional 10% gain in recovery can be expected at 12 months, compared with studies with 6 months of follow-up that found only 85.9% of patients with recovery," they wrote.

CNN's Lauren Mascarenhas, Deidre McPhillips, Alexandra Meeks, Maggie Fox and Virginia Langmaid contributed to this report.

Reuters
Sunday, June 27, 2021

Booster may be needed for J&J shot as Delta variant spreads, some experts already taking them

By Michael Erman

NEW YORK (Reuters) -Infectious disease experts are weighing the need for booster shots of the Pfizer/BioNTech or Moderna mRNA-based vaccines for Americans who received Johnson & Johnson's one-dose vaccine due to the increasing prevalence of the more contagious Delta coronavirus variant.

A few say they have already done so themselves, even without published data on whether combining two different vaccines is safe and effective or backing from U.S. health regulators. Canada and some European countries are already allowing people to get two different COVID-19 shots.

The debate centers on concerns over how protective the J&J shot is against the Delta variant first detected in India and now circulating widely in many countries. Delta, which has also been associated with more severe disease, could quickly become the dominant version of the virus in the United States, Centers for Disease Control and Prevention (CDC) Director Rochelle Walensky has warned.

There is no substantial data showing how protective the J&J vaccine is against the new variant. However, UK studies show that two doses of either the Pfizer/BioNTech or AstraZeneca vaccines are significantly more protective against the variant than one.

Andy Slavitt, former senior pandemic advisor to U.S. President Joe Biden, raised the idea this week on his podcast. At least half a dozen prominent infectious disease experts said U.S. regulators need to address the issue in short order.

"There's no doubt that the people who receive the J&J vaccine are less protected against disease," than those who get two doses of the other shots, said Stanford professor Dr. Michael Lin. "From the principle of taking easy steps to prevent really bad outcomes, this is really a no brainer."

The CDC is not recommending boosters, and advisors to the agency said at a public meeting this week there is not yet significant evidence of declining protection from the vaccines.

Jason Gallagher, an infectious diseases expert at Temple University's School of Pharmacy, recently received a Pfizer dose at the Philadelphia vaccine clinic where he has been administering shots. He got the J&J vaccine in a clinical trial in November.

Gallagher said he was concerned about the UK data https://www.gov.uk/government/news/vaccines-highly-effective-against-b-1-617-2-variant-after-2-doses showing lower efficacy against the Delta variant for people who received one vaccine dose.

"While the situation has gotten so much better in the U.S., the Delta variant that's spreading ... and really quickly taking over in the U.S. looks a little more concerning in terms of the breakthrough infections with the single-dose vaccines," he said. "So I took the plunge."

Cases, hospitalizations and deaths have plummeted in the United States with 56% of the adult population fully vaccinated.

J&J said it is testing whether the immune response from its vaccine is capable of neutralizing the Delta variant in a laboratory setting, but no data is available yet.

Both mRNA vaccines showed efficacy rates around 95% in large U.S. trials, while J&J's vaccine was 66% effective in preventing moderate-to-severe COVID-19 globally when more contagious variants were circulating.

Dr. Angela Rasmussen, a researcher at the University of Saskatchewan's Vaccine and Infectious Disease Organization, said on Twitter she had gotten a dose of Pfizer's vaccine this week after receiving J&J's in April.

Rasmussen, who declined to be interviewed, encouraged Americans who received the J&J vaccine to talk to their doctors about a possible second shot.

"If you live in a community with overall low vaccination, I'd suggest you strongly consider doing so," she tweeted.

Vaccine expert Dr. Peter Hotez from Baylor College of Medicine in a tweet said adding a second J&J dose or one of the mRNA vaccines might provide broader protection, "but we need data and CDC-FDA guidance."

The U.S. National Institute of Allergy and Infectious Diseases (NIAID) is running a trial to determine the need for boosting all currently authorized shots with another dose of Moderna's vaccine. NIAID scientist Dr. John Beigel told Reuters the agency hopes to have that data by September to help inform regulators' decisions on boosters.

As long as case counts remain low in the United States, J&J recipients should wait for more data, he said.

If Delta variant-driven infections and hospitalizations increase significantly, he said, "then decisions might need to be made with an absence of data. But right now, I do think it's appropriate that they

wait."

(Reporting by Michael Erman; Editing by Caroline Humer and Bill Berkrot)

CNN.com
Saturday, June 26, 2021

'Please get your second shot,' top health official urges as Delta variant remains a pressing threat

By Aya Elamroussi, CNN

(CNN)America is in a far better place now than it was six months ago in its fight against the coronavirus pandemic, with overall cases and deaths down, according to the latest data.

It shows that vaccines are effective, experts say, although they have some protection limitations when faced with more aggressive virus variants.

The Delta variant, which can spread more easily and cause even more severe disease than other strains, has been a major concern for health experts who are worried about those who remain unvaccinated.

That variant, first identified in India, has been found in 49 states and Washington, D.C., according to GISAID, an independent data sharing initiative, and the Hawaii Department of Health. South Dakota did not report cases of the variant as of Wednesday, a state health department spokesperson told CNN.

To be sure, the US Centers for Disease Control and Prevention has said there's a low chance people who are fully vaccinated may get infected with virus variants.

And any illness could be shorter or milder if one is fully vaccinated--but the keyword is "fully" because a second shot is essential for optimal protection against variants.

"Please get your second shot," CDC Director Dr. Rochelle Walensky said Friday in an interview with the National Public Radio.

"What we do know is you get some protection from the first shot, but really that second shot gives you breadth and depth of vaccine coverage to really be able to tackle this Delta variant and other variants as well."

More than one in 10 people in the US who received one dose of the Pfizer/BioNTech or Moderna vaccine have missed their second dose, according to CDC data.

"If you missed your second within the time window, get it whenever, get it now, but do get that second shot," Walensky added.

In Los Angeles County, 99.8% of the 12,234 people who died from Covid-19 since December 2020 were unvaccinated, local health data shows.

"The virus is still with us," Los Angeles County Public Health Director Barbara Ferrer said at a news conference Thursday. "Even now, we need to be careful to mask and maintain distance from people outside of our households, especially if they're not yet vaccinated."

President Joe Biden took note of the variant's dangerousness in remarks Thursday, warning that the variant is "now the most common variant in America."

"And unvaccinated people are incredibly vulnerable," he said, underscoring that the Delta variant is "more easily transmittable," and "potentially deadlier and especially dangerous to young people."

In the US overall, the Delta variant has accounted for about 21% of cases in the two weeks ending June 19, according to CDC data.

More than 151.6 million Americans are fully vaccinated, according to CDC data on Friday, which is nearly 45.7% of the total US population.

Nearly 65.8% of adults in America have had at least one dose of a vaccine as of Friday, according to the CDC. Biden's goal of 70% of adults with at least one dose by July 4 is all but likely to fall short, as officials are currently targeting mid-July.

Distribution of some antibody treatments are paused due to variants

It's not only the Delta variant that is complicating matters for health care providers.

The increase of cases due to the Gamma or P.1 variant first identified in Brazil, and the Beta or B.1.351 variant first identified in South Africa, are being cited as the reason for a pause in nationwide distribution of certain monoclonal antibody treatments from Eli Lilly, according to an announcement on Friday from the US Health and Human Services Department (HHS).

The monoclonal antibody treatment of etesevimab, as well as a combination treatment of etesevimab and bamlanivimab, don't work as well with the variants, according to the HHS statement.

In May, federal regulators had paused the distribution of these treatments to eight states where there were a high number of variant cases. Eli Lilly's single monoclonal antibody treatment bamlanivimab was put on pause in March. In April, the company had asked the FDA to revoke its emergency use authorization of the single antibody treatment, so it could focus on its combination treatment.

The Beta and Gamma variants now make up at least 11% of the cases in the US, and case numbers are increasing, according to CDC data.

Rare heart risk warning is added to 2 vaccine fact sheets

Meanwhile, the US Food and Drug Administration added a warning about the risk of the heart inflamations known as myocarditis and pericarditis to fact sheets for Moderna and Pfizer-BioNTech Covid-19 vaccines Friday.

The warning notes that reports of adverse events following vaccination suggest increased risks of both types of inflammation, particularly after the second dose.

Myocarditis is inflammation of the heart muscle and pericarditis is inflammation of tissue surrounding the heart.

Vaccine advisers to the CDC met Wednesday and said there is a likely association between the mRNA Covid-19 vaccines and rare cases of heart inflammation in adolescents and young adults.

However, the risk is rare: Following about 300 million administered doses of Pfizer and Moderna vaccines through June 11, the CDC has received roughly 1,200 preliminary reports of myocarditis and pericarditis.

Advisers urged that the benefits of vaccination outweigh the risks, and almost all the cases resolved with little treatment and patients recovered quickly.

The FDA is advising those who receive one of the two vaccines to seek immediate medical attention if they experience "chest pain, shortness of breath, or feelings of having a fast-beating, fluttering, or pounding heart after vaccination."

Both the FDA and CDC are monitoring reports of these adverse events and will follow up to assess longer-term outcomes, the FDA noted.

CNN's Lauren Mascarenhas, Jen Christensen, Jacqueline Howard, Deidre McPhillips, Jamie Gumbrecht and Travis Caldwell contributed to this report.

Associated Press
Saturday, June 26, 2021

States Hesitant To Adopt Digital Covid Vaccine Verification

By DAVID A. LIEB
Associated Press

Customers wanting to wine, dine and unwind to live music at the City Winery's flagship restaurant in New York must show proof of a COVID-19 vaccination to get in. But that's not required at most other dining establishments in the city. And it's not necessary at other City Winery sites around the U.S.

If City Winery tried doing such a thing at its places in Atlanta and Nashville, "we would have no business, because so many people are basically against it," said CEO Michael Dorf.

Across the U.S., many hard-hit businesses eager to return to normal have been reluctant to demand proof of vaccination from customers. And the public and the politicians in many places have made it clear they don't care for the idea.

In fact, far more states have banned proof-of-vaccination policies than have created smartphone-based programs for people to digitally display their vaccination status.

The Centers for Disease Control and Prevention still recommends masks when dining or gathering indoors for those who aren't fully vaccinated. But few states require it, and most businesses rely on voluntary compliance -- even in places with low vaccination rates where COVID-19 cases are climbing.

Digital vaccine verification programs could make it easier to enforce safeguards and tamp down new outbreaks.

"But that only works when you have mass adoption, and mass adoption requires trust and actual buy-in with what the state health department is doing, which is not necessarily present in all states," said Alan Butler, executive director of the Electronic Privacy Information Center, a Washington-based nonprofit organization.

Hawaii is the only state enforcing some version of a vaccine passport. It requires travelers to upload a photo or PDF of their Hawaii vaccination document or pass a pre-arrival COVID-19 test to avoid having to quarantine for 10 days.

Earlier this month, California became just the third state -- behind New York and Louisiana -- to offer residents a way to voluntarily display digital proof of their COVID-19 shots. None of those states requires the use of their digital verification systems to access either public or private-sector places.

By contrast, at least 18 states led by Republican governors or legislatures prohibit the creation of so-called vaccine passports or ban public entities from requiring proof of vaccination. Several of those -- including Alabama, Florida, Iowa, Montana, North Dakota and Texas -- also bar most businesses from denying service to those who aren't vaccinated.

"Texas is open 100%, and we want to make sure that you have the freedom to go where you want without limits," Gov. Greg Abbott said in signing a law against vaccine passports.

The prohibition doesn't apply to the demands employers make on their employees. Earlier this month, a federal judge in Texas threw out a lawsuit from 117 Houston hospital employees who challenged a workplace requirement that they get vaccinated. More than 150 were later fired or resigned for not getting their shots.

In Louisiana, under a Republican-passed bill facing a potential veto from Democratic Gov. John Bel Edwards, public facilities would not be allowed to bar unvaccinated people until the COVID-19 vaccines have

received full approval from the Food and Drug Administration. The vaccines for now are being dispensed under emergency FDA authorization.

In May, Louisiana launched a program allowing residents using the state's digital driver's license, LA Wallet, to add a record of their COVID-19 vaccination.

But its reach is still limited. About 105,000 people have activated the COVID-19 verification function. That's about 14% of those with a digital license and less than 4% of Louisiana's 3.1 million people with valid driver's licenses.

Democratic state Rep. Ted James, who wrote the bill creating the digital driver's license, said he has used the feature just once -- to show an Uber driver in Nevada that he didn't need to wear a mask. But James said he has never been asked to show it in Louisiana and doubts he ever will.

"Earlier in the year, I felt that at some point we would be limited in travel, going to certain places, unless we had the vaccine," James said. Now, "I don't foresee us ever having some type of requirement."

As a step in reopening, New York in March launched its Excelsior Pass, the first state system to provide digital proof of COVID-19 vaccination or a recent negative test. As of early June, more than 2 million people had gotten the digital pass -- about one-fifth of those who have been vaccinated.

At the City Winery, most customers bypass the Excelsior Pass and instead show their paper CDC vaccination cards to gain entry, according to Dorf, who said patrons at the 1,000-person capacity venue "appreciate going into a bubble of safety, knowing that everyone around them is vaccinated."

Though larger ticketed events, like concerts at Madison Square Garden, require proof of vaccination, most businesses don't ask.

"Think of a bar," said Andrew Rigie, executive director of the New York City Hospitality Alliance. "You have four friends that go in -- maybe two of them have it, the other two don't. You're going to turn the other two away when small businesses are struggling so much?"

Though most states have shied away from creating digital vaccination verification systems, the technology may soon become widespread nonetheless.

Vaccine providers such as Walmart and major health care systems already have agreed to make digital COVID-19 vaccination records available to customers. Apple also plans to incorporate the vaccination verification function into a software update coming this fall.

Within months, hundreds of millions of people across the U.S. will be able to access digital copies of their COVID-19 vaccination records, said Brian Anderson, chief digital health physician at the nonprofit MITRE Corp., part of a coalition of health and technology organizations that developed such technology.

People will receive QR codes that can be stored on smartphones or printed on paper to be scanned by anyone seeking vaccine verification. Those who scan the codes won't retain any of the information -- a protection intended to address privacy concerns.

The California Chamber of Commerce said it welcomes the state's new vaccine verification system as a way for employers to check on their employees. California regulations require most employees who aren't fully vaccinated to wear masks when dealing with others indoors.

Digital vaccine verification "allows an employer who really wants to make sure the workplace is vaccinated to require that without having the impossible problem of `John says he's vaccinated but he lost his vaccine card. What do we do?' This solves that issue," said Rob Moutrie, a policy advocate at the California Chamber of Commerce.

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`A tough slog': White House struggles to increase vaccination rates as Delta variant surges

By ERIN BANCO and DAVID LIM

Top Biden administration health officials trying to slow the spread of the Covid-19 Delta variant have largely given up on the possibility of reinstating mask and social-distancing rules in favor of a grassroots vaccine education campaign.

The Centers for Disease Control and Prevention, the Department of Health and Human Services and the White House Covid-19 Task Force have discussed whether to press mayors and governors in the Midwest and South, where the highly transmissible Delta variant is spreading quickly, to once again require mask mandates, according to three senior Biden health officials. But the administration ultimately concluded that many people who are not vaccinated are also those who have resisted wearing masks.

Instead, the federal government will try to convince hesitant Americans to get vaccinated by working with state officials and trusted community members to communicate the benefits of the shots, the three senior officials said. The president's team is not confident that the new campaign will change hearts and minds, the two officials said, but it is falling back on old messaging in part because top administration officials are unsure what other tactics will work.

Only about 46 percent of the U.S. population is vaccinated, and the number of doses administered has fallen by almost 300,000 per day since June 7, according to the Centers for Disease Control and Prevention.

The plateauing vaccination rate underscores the extent to which the White House is struggling to find new and better ways to convince Americans to get Covid-19 shots -- while much of the rest of the world

struggles to secure a steady supply of vaccines. And it raises questions about how the federal government will manage increasing Covid-19 cases associated with the Delta variant in the months ahead, with businesses and schools returning to normal operations.

"This is the door-to-door campaign, this is the church-to-church, this is going into the community and meeting people where they are. We're not going to convince everybody," said Scott Becker, CEO of the Association of Public Health Laboratories. "The Delta variant and its explosive growth -- I wish there was a better way to articulate the damage that it is doing and will do in those communities, but it is going to be a tough slog."

New Covid-19 infections have increased by more than 50 percent over the last two weeks in under-vaccinated states such as Missouri and Oklahoma. Many of the cases are tied to the Delta variant, which the CDC says now accounts for one-fifth of new infections nationwide.

"Based on the data that we have right now, the Delta variant is more transmissible than Alpha," the strain that has predominated in the U.S. this spring, said Summer Galloway, a senior adviser at the agency.

Preliminary data from the U.K. suggests that unvaccinated people infected with the Delta variant have an increased risk of hospitalization, she added. The CDC is studying whether the variant leads to more severe infections in undervaccinated communities. But there is good news: recent data shows the Pfizer vaccine is nearly 90 percent effective against Delta, making vaccination one of the most effective ways to stop the variant's march across the U.S.

"We really just want to encourage everyone ... to get vaccinated. What we don't want to have happen is we have a significant proportion of the population that's unvaccinated and you see an increase in the number of cases and the number of hospitalizations, the number of deaths," Galloway said. "It could lead to another surge."

In the meantime, the CDC is still encouraging people who are unvaccinated to wear masks and avoid crowded indoor gatherings, an agency spokesperson said.

The number of U.S. adults who say they will definitely not take a Covid-19 vaccine has remained steady at 13 percent, according to a Kaiser Family Foundation survey released last month. Twelve percent say they are waiting to decide if they will get vaccinated, while 7 percent say they will only opt for immunization if it is required for work or other activities.

The Biden administration in March rolled out a $1 billion advertising campaign, relying on radio and television spots to educate Americans on the benefits of vaccination and on where and when they could receive the shot. The administration partnered with 275 groups, including the Christian Broadcasting Network and Nascar, to reach areas where hesitancy or outright opposition to the vaccines is high.

The federal government has also joined up with the Ad Council -- a nonprofit organization that often partners with the federal government

on public service announcements -- and the Covid Collaborative, a group of organizations working together to combat the virus, on ads promoting Covid-19 vaccines. The CDC Vaccine Task Force is also offering "vaccine confidence consultations" to interested jurisdictions. The consultations include briefings between CDC officials and local leaders about how states can build trust in their communities around vaccination.

The three senior Biden health officials said the administration is pushing more of the responsibility of convincing the unvaccinated to get the jab to local officials, who can tap trusted community leaders to spread the word. The hope is that those local leaders will be more effective messengers than national ad campaigns or top federal officials.

Over the last two weeks, officials from the CDC, HHS and the White House Covid-19 Task Force have formulated a plan to work with local officials, including mayors, to knock on doors in areas with low vaccination rates to talk with people about signing up for the shot. Officials like President Joe Biden's chief medical adviser, Anthony Fauci, and CDC Director Rochelle Walensky also are increasing their appearances on national TV programs and with local press in the South where the Delta variant is spreading.

Fauci, for instance, has visited vaccine sites in New York and Florida this month with First Lady Jill Biden. He spent the Juneteenth holiday going door-to-door with Washington, D.C., Mayor Muriel Bowser, urging city residents to get vaccinated.

But the Biden team is still unsure how many people could be swayed by these more local appeals. The White House is now planning for what top officials see as inevitable Covid-19 surges in several states with low vaccination rates later this summer and into the fall.

Many states have already tried on their own to encourage people to get Covid-19 shots -- often through lotteries and other financial incentives. But that strategy has largely failed, and Delta Covid-19 cases continue to rise.

The CDC is now considering whether to update guidelines for schools and for domestic and international travel. Federal and state health officials are debating how and whether to recommend proof of vaccination for everything from restaurants to movie theaters to office buildings. The fear, Fauci recently told POLITICO, is that recommending proof of vaccination could cause an uproar among unvaccinated people. While federal health officials have pledged so-called vaccine passports will not be implemented at the national level, some states and private businesses have explored using vaccine passes to support safe reopening.

European Union officials have recently put pressure on U.S. diplomats overseas to open up travel to the U.S. with proof of vaccination, according to a U.S. official with direct knowledge of the matter. Germany recently issued an order that allows all U.S. residents to fly into the country if they can prove vaccination or a negative Covid-19 test.

For now, Biden administration officials say the increasing number of Delta cases is cause for worry but not overwhelming dread. The Pfizer vaccine in wide use in the U.S. works well against the variant; Moderna's vaccine uses similar technology, so the hope is that it will be similarly effective in warding off Delta. The CDC is currently in the midst of conducting studies to pin down just how well the current vaccines protect against Delta and what impact it has on the unvaccinated population, particularly children.

"We have to stay vigilant. We see this strain is affecting how much protection people get from the first dose dramatically," said Phil Febbo, chief medical officer of DNA sequencing company Illumina, which is working with the CDC to study the spread of Covid-19 variants in the U.S. "I don't think we're that far away from a different variant that goes beyond the Delta and decreases significantly the efficacy of both doses."

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Wisconsin's Johnson To Tout Claims Of Vaccine Side Effects

By SCOTT BAUER
Associated Press

MADISON, Wis. (AP) -- Republican U.S. Sen. Ron Johnson, a vocal critic of COVID-19 vaccine mandates, announced plans Friday to hold a news conference bringing together people who claim to have had adverse reactions to the vaccine, including the wife of a former Green Bay Packer player.

Johnson, who has also advocated for alternative and unproven treatments for COVID-19, said the Monday event in Milwaukee will allow people from across the country to tell their stories and concerns he said have been "repeatedly ignored" by the medical community.

Johnson, who has no medical training or expertise, hasn't been vaccinated, saying he doesn't think he has to because he had the virus last year and formed natural antibodies. He has said he's "just asking questions" and isn't against vaccines, but doctors and other critics have blasted him for spreading misinformation.

Dr. Jeff Huebner, a family doctor in Madison, said Johnson was "promoting dangerous and unfounded claims about COVID-19 vaccines" that contradict medical data and evidence.

"As a member of the Wisconsin medical community I'm gravely concerned about the impact his event and remarks will have on our ability to return to normal and protect Wisconsinites from COVID-19.," Huebner said in a statement.

Nearly all COVID-19 deaths in the U.S. now are in people who weren't vaccinated, with "breakthrough" infections in fully vaccinated people

accounting for fewer than 1,200 of the more than 853,000 COVID-19 hospitalizations in May, based on an Associated Press analysis.

YouTube this month removed an interview Johnson did with the Milwaukee Press Club during which he touted the benefits of alternative treatments for COVID-19 and suspended Johnson for a week, saying his comments violated the company's "medical misinformation policies."

Johnson, during the June 3 event, criticized the administrations of President Joe Biden and former President Donald Trump for "not only ignoring but working against robust research (on) the use of cheap, generic drugs to be repurposed for early treatment of COVID."

Johnson said Monday's event at the federal courthouse in Milwaukee will include former Green Bay Packers offensive lineman Ken Ruettgers, a member of the Packers Hall of Fame, and his wife Sheryl. Johnson said Sheryl Ruettgers will detail "severe neurological reactions that still inhibit her ability to live a normal life, including muscle pain, numbness, weakness and paresthesia" that she experienced after getting the COVID-19 vaccine this month.

Other speakers with similar stories are from Ohio, Missouri, Utah, Michigan and Tennessee.

The medical community has been consistent in stressing that the risk of side effects is exceedingly low and the benefits of getting vaccinated for the virus far outweigh the risks. Earlier this week, top U.S. government health officials, medical organizations, laboratory and hospital associations and others issued a statement touting the overriding benefit of the vaccines.

Still, certain elected officials in some states continue to push back against the vaccination recommendations.

On the same day the government and medical experts issued their statement on the vaccines' benefits, Republican attorneys general in Louisiana, Alabama and Montana wrote to a Centers for Disease Control and Prevention COVID-19 task force leader requesting a pause in recommending that children and healthy young adults get vaccinated against the disease.

The letter accused the CDC of providing "dismissive, misleading, and deadly advice" regarding incidents of heart inflammation among young people who get the vaccines.

U.S. health officials paused the Johnson & Johnson's single-dose shot for 11 days earlier this year, after 15 vaccine recipients developed a highly unusual kind of blood clot out of nearly 8 million people given the J&J shot. Experts said Wednesday that there also seems to be a link between the Pfizer and Moderna shots and some cases of heart inflammation.

Johnson's seat is up for election in 2022 and he has not yet said whether he will seek a third term.

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Associated Press writer Kevin McGill in New Orleans contributed to this report.

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Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic, research finds

By Lauren Mascarenhas, CNN

(CNN)Cases of type 2 diabetes among children more than doubled during the coronavirus pandemic at one Louisiana hospital, according to research presented Friday. The researchers say the cases increased in severity, too.

Dr. Daniel Hsia, an associate professor at Pennington Biomedical Research Center in Baton Rouge, Louisiana, and colleagues looked at the hospitalization rate for new onset type 2 diabetes among children at Our Lady of the Lake Children's Hospital.

From March to December 2019, the rate was .27% -- 8 cases out of 2,964 hospitalizations. During the same period in 2020, the rate jumped to .62% --17 cases out of 2,729 hospitalizations.

"These are very small numbers," Hsia told CNN. "We're a single hospital, but we think that we may be a microcosm of what's happening across the country."

Type 2 diabetes is by far the most common type of diabetes, and it's associated with obesity, poor diet and a lack of exercise.

Among the 25 cases of type 2 diabetes over both years, 23 were in Black children, the team noted. Black, Latinx, Asian, Native American, Alaska Native and Pacific Islander children may be at increased risk for type 2 diabetes, according to the US Centers for Disease Control and Prevention. Hsia said these existing health disparities may have worsened over the course of the pandemic.

"Risk factors for type two diabetes may worsen even more during a time like this, where they have to stay home, and they don't have access to healthy foods and physical activity, and there are sleep disturbances," Hsia said.

Children who were admitted for type 2 diabetes in 2020 had more severe symptoms than children admitted in 2019, the team said. They had higher blood sugar levels and signs of more severe dehydration -- caused when the body tries to get rid of excess glucose through urination.

Dr. Lily Chao, interim medical diabetes director at Children's Hospital Los Angeles, said she's seen the same trend in her hospital, particularly in cases of ketoacidosis, a severe complication of diabetes that occurs when the body does not have enough insulin.

"Historically, in people with type 2 diabetes, the rates vary from 5 to 10% in our hospital," said Chao. "In this past year, our rates went up to 20% of new type 2 diabetes cases presenting in that severe state." Chao noted that her hospital serves a primarily Latinx population.

"There are reports of new-onset diabetes that occur after someone's been infected with the SARS-CoV-2 virus," said Chao. "We know the Covid pandemic disproportionally affected people of color. What we don't know is how many of these cases are related to prior exposure to the virus."

A new lifestyle

Andrew Aparicio, a 17-year-old patient of Chao's, said it was about a year ago when he started experiencing stomach cramps and fatigue. At first, he thought it could be coronavirus.

"I wasn't eating. I would be sleeping most of the day and not doing anything," Aparicio said.

His father took him to the hospital, where he stayed for a week and was diagnosed with type 2 diabetes. Aparicio said the news came as a shock.

"I left the hospital pretty traumatized," Aparicio said. "What happened to me really scared me."

Aparicio said he weighed around 257 pounds at the time, "Being stuck at home all day, I would just eat. Covid kind of messed me up."

He started taking medication, scheduling workouts and eating healthier.

"Andrew's case is really inspirational," said Chao. "It is extremely difficult for many of our young people to really accomplish what he has in terms of motivation to stay as physically active as he has and to exercise that discipline."

A year later and about 120 pounds lighter, Aparicio is ready to take on his senior year of high school. He no longer needs the same level of medication to manage his diabetes and says that in a few months, he may be able to stop taking some medication completely -- a sign that he is doing much better.

"Overall, I'm both mentally and physically happy with the change I've been able to accomplish," he said. "I have a whole new lifestyle."

A growing problem

Children and teens almost never got type 2 diabetes until recently, according to the CDC, which now says the condition is a growing problem among pediatric patients.

"Getting diabetes at this age is very different than getting diabetes as an adult," said Chao. "The complications occur sooner. It is a much more progressive condition."

Hsia says additional research is needed to understand the factors

driving the increase in cases, but the lifestyle changes associated with the pandemic -- including less physical activity and more screen time -- could drive weight gain in children.

"The little weight changes and small amounts of weight gain can certainly tip the scale and cause someone to develop type 2 diabetes," Hsia said.

Doctors say symptoms to look out for include increased fatigue, thirst, urination, and sudden, unexplained weight loss.

The CDC says having a family member with type 2 diabetes, being born to a mother with diabetes while pregnant, and having conditions related to insulin resistance can place children at increased risk. The agency advises that children who are overweight and have a combination of risk factors check with their doctor about getting their blood sugar tested.

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1st Post-Pandemic Cruise Ship From US Sails Away

By ADRIANA GOMEZ LICON and MARTA LAVANDIER
The Associated Press

FORT LAUDERDALE, Fla. (AP) -- The first cruise ship to leave a U.S. port since the coronavirus pandemic brought the industry to a 15-month standstill sailed away on Saturday with nearly all vaccinated passengers on board.

Celebrity Edge departed Fort Lauderdale, Florida, at 6 p.m. with the number of passengers limited to about 40% capacity, and with nearly all 1,100 passengers vaccinated against COVID-19. Celebrity Cruises, one of Royal Caribbean Cruise's brands, says 99% of the passengers are vaccinated, well over the 95% requirement imposed by the Centers for Disease Control and Prevention.

A giant greeting was projected on a wall of one of the port buildings: "Someday is here. Welcome back."

Passengers arrived with matching T-shirts that read phrases such as "straight outta vaccination" and "vaccinated and ready to cruise."

"Words can't describe how excited we are to be a part of this historic sailing today," said Elizabeth Rosner, 28, who moved from Michigan to Orlando, Florida, in December 2019 with her fiance just to be close to the cruise industry's hub.

To comply with both the CDC's requirement and a new Florida law banning businesses from requiring customers to show proof of vaccination, Celebrity Cruises asked guests if they would like to share their vaccination status. Those who did not show or say they are vaccinated face additional restrictions.

Saturday's sailing kicks off the cruise lines' return to business with Carnival vessels already scheduled to depart from other ports next month.

"This is an emotional day for me. When I stepped on board the ship, I was proud. It's a beautiful ship," said Royal Caribbean Cruises' CEO Richard Fain, after expressing condolences to the victims of the Surfside building collapse, less than 15 miles (about 24 kilometers) south of the port.

Celebrity Cruises had unveiled the $1 billion boat in December 2018 -- betting on luxury cruising, offering a giant spa and multifloor suites. The seven-night cruise will sail for three days in the Western Caribbean waters before making stops in Costa Maya, Cozumel and Nassau.

The ship is led by Capt. Kate McCue, the first American woman to captain a cruise ship, who has more than 1 million followers on TikTok.

"You can truly feel the palpable sense of excitement and energy amongst the group as we prepare for our welcoming of our first guests," McCue said. "I've never honestly seen a group so excited to get back to work."

Industry officials are hoping all goes smooth to move past a chapter last year of deadly outbreaks on cruise ships that prompted ships to be rejected at ports and passengers to be forced into quarantine. Some passengers died of COVID-19 at sea while others fell so ill they had to be carried out of the vessels on stretchers.

The CDC extended no-sail orders repeatedly last year as the pandemic raged, and came up with strict requirements for the industry that have already been contested in court by the state of Florida. Florida Gov. Ron DeSantis says the industry generates billions for the state's economy.

On Saturday, officials at Port Everglades in Fort Lauderdale said only that port lost more than $30 million in revenue in fiscal year 2020 from the cruise shutdown.

During that hiatus, Carnival, Norwegian and Royal Caribbean, the three largest cruise companies, have had to raise more than $40 billion in financing just to stay afloat. Collectively they lost $20 billion last year and another $4.5 billion in the first quarter of 2021, according to Securities and Exchange Commission filings.

The pandemic forced Kurt and Carol Budde to cancel their beach celebration wedding aboard the world's largest ship, Symphony of the Seas, in March 2020. COVID-19 halted cruising six days before they were scheduled to tie the knot in St. Maarten. Kurt Budde's part-time gig as a travel agent also dried up.

"It's a honeymoon make-up cruise," said Kurt Budde, sporting matching shirts with the phrase "On Cruise Control."

"We are living our best lives post COVID today," he said.

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How the first cruise of the Covid era got ready to safely set sail

By Andrea Kane and Nadia Kounang, CNN

(CNN)It's anchors aweigh and full steam ahead for the Celebrity Edge. On Saturday, the cruise ship, owned by the Royal Caribbean Group, will become the first to sail from a U.S. port since the US Centers for Disease Control and Prevention brought the industry to a halt more than 15 months ago with a no-sail order that was ultimately extended a number of times. It is scheduled to sail from Fort Lauderdale on a seven-night trip that will take it around the Caribbean, with ports of call in Mexico and the Bahamas.

CNN Chief Medical Correspondent Dr. Sanjay Gupta got an exclusive early look at the procedures and safety features in place to make cruising in the Covid era possible. The question is, will they be enough to keep passengers and crew coronavirus-free?

Smooth sailing or troubled waters?

For die-hard cruise fans, this event, after several false starts, has been a long time coming. For the more skeptical, the event is tempting fate to once again reveal that cruise ships are floating petri dishes for one infectious disease or another. It will be a long while before the world forgets the high-profile saga of the Diamond Princess, which saw more than 700 coronavirus infections on board, and others like it -- a situation made worse and more dramatic by nationwide lockdowns and travel bans that left some ships literally racing toward any welcoming port.

For cruising to be possible in the Covid era, leaders in the industry convened the Healthy Sail Panel -- which included experts in the public health, infectious diseases, biosecurity, maritime and hospitality industries -- to come up with recommendations to make the experience healthier and safer for guests and crew. These wide-ranging recommendations, developed before vaccines became available, dovetail with the Covid-19 Member Policy of the industry's largest trade group, Cruise Lines International Association, and with the requirements and guidelines for cruise ships set forth by the CDC, which has been -- up to now -- deciding the circumstances under which ships can sail from the United States.

Dr. Calvin Johnson, the chief medical officer for Celebrity, told CNN neither he nor the crew are apprehensive. "I think everyone really believes in -- because they were part of it -- the protocols that we've developed, the processes we put in place," he said.

"This has been over a year of consistent, methodical, science-based, operational examinations to look at the business, how it operates, and how we can do it safely. Putting in place protocols to protect our crew, and then looking at what it will look like when our guests come

back to protect them -- and so it's been a process that brought us to this place," he said.

The industry battens down the hatches

So, what's the plan to make sailing safer? This summer at least, there will be fewer people on board; the Edge is sailing at 40% of its capacity. Because the coronavirus is spread through airborne particles, fewer people, less crowding and good ventilation can make a big difference.

"For this start-up period, we're sailing with a reduced capacity to give us all a chance to get used to the protocols and to really allow for natural social distancing," said Susan Lomax, head of global public relations at Celebrity Cruises. She said the cruise line does not plan to exceed 50% capacity on any of its trips this summer. Because of the reduced capacity, cabin occupancy will be spaced out and people will be put into cabins with windows that face outward. Crew members will get their own cabins.

Lomax said filtration experts from the University of Nebraska were asked to evaluate the ventilation/HVAC system and pronounced it "better than what hospitals have."

Linsey Marr, an environmental engineer and professor at Virginia Tech, agrees the Edge's ventilation system is more than adequate. "The combination of high air change rates and high-quality filters ... will greatly reduce the amount of virus that can build up in the air. Thus, it is unlikely that people will be exposed to elevated levels of virus in cabins and public indoor spaces," she told CNN. "If this is the case, then the biggest risk comes from being in close proximity, within the exhaled respiratory plume of an infected individual."

Yuguo Li, from the department of mechanical engineering at The University of Hong Kong, sides with Marr.

"Taking all evidence so far, I highly believe that SARS-CoV-2 is predominantly transmitted by the short-range inhalation route in inadequately ventilated spaces. We have studied about 20 outbreaks of SARS-CoV-2, and performed ventilation measurement for 10 of them, all supporting this hypothesis," Li wrote in an email. His study on the Diamond Princess was published online in April in the journal Building and Environment and his editorial appeared in the journal Indoor Air in mid-May.

"For the Diamond Princess outbreak, we showed that their cabin ventilation might be sufficient, and suspect that infections occurred in the public areas. There are two major factors in these public areas: First, in gyms and dancing floors, people perform high [energy] activities with more droplet release and higher inhalation flow, hence infection risks are high ... Second, if occupancy is not controlled in these public spaces, the ventilation per person can be even lower. In some spaces such as restaurants, people cannot wear masks," he explained.

On the Edge, other procedural changes include staggered arrival and

departure times to prevent large crowds, and a muster drill -- the mandatory safety exercise done at the start of every trip -- done virtually instead of in person, again to avoid large crowds. And, food lovers need not fear: the all-you-can-eat buffets will still be a staple of the dining experience, but instead of self-serve, crew members will lend a hand.

In the unfortunate event of an outbreak, the Edge has the capacity to manage 33 patients, and there are four ICU beds. The entire medical area is on a separate ventilation system.

Contact tracing plans that make use of the ship's CCTV have been drawn up, there are protocols for isolation and quarantining, and disinfection procedures following positive cases.

Importantly, Royal Caribbean has agreements with a number of countries to act as disembarkation ports, should there be a need to get people off the ship.

"There's no longer any 'Oh my gosh, we're sailing for days and no one will take us,' " said Lomax. "There's no reason to wait till the end of the cruise; we have the ability to go to those disembarkation ports if and as needed."

Vaccines are game changers

But everyone, from those in the cruise industry to health experts, says the real game changers are vaccines, which offer up to 95% protection against symptomatic Covid-19. Even if there are breakthrough infections, vaccines reduce the amount of virus in the body, making people less infectious to others.

"It's really the vaccines that have enabled us to return to cruising with a low enough level of risk of transmission," said Marr.

On the Edge, 100% of the crew and at least 95% of passengers are vaccinated, which considerably lowers the risk of people getting infected and sparking an outbreak.

However effective vaccines are, it's unclear whether, when and where they can be mandated on future cruises. The CDC currently advises unvaccinated people against going on a cruise -- but that's just guidance. Additionally, Florida is one of several states that has banned businesses from requiring customers to provide proof of vaccination, although upcoming cruises leaving from ports in Washington state and Alaska are expected to have vaccination requirements.

And to top it off, a federal district judge in Tampa recently concluded the CDC's restrictions on the cruise industry are likely unconstitutional and the agency is overstepping its legal authority.

So, starting July 18, the agency will no longer be able to enforce its sailing rules, including requirements that either 95% of passengers be vaccinated or that the ship successfully conduct a simulated voyage.

The judge gave the CDC until July 2 to propose more modest guidelines.

In navigating these murky, fluctuating rules, Lomax said that the Edge capped at 5% the number of cabins for people who choose not to disclose their vaccination status. They are counted as unvaccinated. People presumed to be unvaccinated will have to wear masks in public areas and will also have to undergo additional Covid-19 testing -- both to board and midway through the cruise -- at their own expense. Everybody has to be tested before disembarking in the United States.

"With 95% of passengers vaccinated, that's far more than we have in any country. And we know that the higher vaccination rates have really brought down cases. So I think it's probably reasonable for healthy vaccinated people to go on a cruise," said Marr. "The risk of an outbreak on a cruise ship, together with the measures that they're taking requiring unvaccinated people to wear masks, the overall risk of an outbreak should be quite low. And I'd be surprised if we saw something like the Diamond Princess again."

But, despite all the precautions, the experience is still not guaranteed to be 100% coronavirus-free, if the Celebrity Millennium is any example. That ship, carrying the first North American paying passengers, set sail in early June out of St. Maarten, and made several ports of call. The crew were all fully vaccinated as were more than 95% of passengers. Nonetheless, two passengers tested positive for coronavirus at the end of the trip.

"In term of vaccination, the protection is not 100%. Sufficient vaccination protects us from developing a chain of infection, i.e. sustained infection in a large population but ... that means sporadic outbreaks can still occur particularly with the new variants of concern," Li noted.

Johnson, Celebrity's CMO, said the incident was unfortunate but it shows the system is working. "It certainly got my attention," he said.

"But we also know that, if we look [at] the world around us, in every venue infections are happening every day. And so we fully anticipate that... as thorough as our efforts are and as much as we do prevent, on the front end, virus from coming on board the ship, that it can happen," he said. "It's why we have protocols, we have a process; we've trained our folks to know what to do when we do identify this. We work very quickly to identify and isolate that, and prevent and stop the spread."

But perhaps the most reassuring statement for would-be cruise goers comes from Marr, who said that she would not stop her healthy, vaccinated, 70-year-old cruise-loving mother from taking one.

CNN Health's Keri Enriquez and Michael Nedelman contributed to this story

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Virus-Origin Review Likely to Be Unclear

Biden administration warns that the hunt for clues is a challenge for U.S. spy agencies

By Michael R. Gordon and Warren P. Strobel

Biden administration officials are cautioning that a 90-day review into the origins of the Covid-19 virus may not produce a definitive explanation as intelligence agencies take on the challenge of unraveling the global pandemic.

Spy agencies conducting the review have yet to find conclusive evidence that would settle the debate over whether the virus came from human contact with an infected animal or was leaked from a Chinese government virology lab, a person familiar with the efforts said.

President Biden is due to receive a 45-day update in mid-July, and administration officials said that even partial progress might narrow differences among scientists, politicians and intelligence experts and turn up clues for further investigation.

Mr. Biden "is mindful of the fact that after 90 days we may not have an absolutely definitive answer, but he wanted a focused, intense, time-bound effort," a senior administration official said.

Experts say that knowing the origins of Covid-19 could be important in preparing for future pandemics. The virus has killed more than 600,000 Americans and nearly four million people world-wide, and disrupted the global economy.

The review is being overseen by Director of National Intelligence Avril Haines, a lawyer and former deputy director of the Central Intelligence Agency. It requires the vast intelligence community to train its resources on an area it has long treated as far less of a priority than spying on the Russian military, terrorist dangers or China's weapons buildup: the detection and analysis of global pandemics.

Ms. Haines told lawmakers this spring she had hired additional personnel to work on pandemic threats.

Absent a breakthrough, the review faces many obstacles, chief among them China's refusal to provide further access to data and scientists from the Wuhan Institute of Virology, a biosecurity lab that has studied coronaviruses. China has said the search should turn to other countries and cited the conclusion of a World Health Organization-led team of experts early this year that a lab leak was "extremely unlikely."

A daily intelligence briefing Mr. Biden received in the Oval Office in February showed the difficulties the intelligence community has had in identifying the source of the virus. Intelligence officials told Mr. Biden during that session they had numerous questions about the origin of the virus but didn't have "high confidence" in any particular explanation, more than a year after the virus was first detected in the Chinese city of Wuhan.

Mr. Biden instructed national security adviser Jake Sullivan to follow up, which he did in a meeting with intelligence officials in early March. The White House ordered a written assessment from intelligence officials. Delivered to Mr. Biden in May, the assessment showed one intelligence agency leaning toward the hypothesis that the virus leaked out of a lab and two intelligence agencies leaning toward the view that it arose naturally -- all with low or moderate confidence.

That inconclusive assessment and China's statement to the WHO that it considered the Covid-19 origins investigation in its country to be complete, led to Mr. Biden's order to mount what a senior administration official called an "all hands on deck effort" over a 90-day period.

Within Ms. Haines's office, officials said, the review is being coordinated by the National Counterproliferation Center, which oversees intelligence efforts to combat nuclear, chemical and biological proliferation.

The National Security Agency, the officials said, will look for clues in its vast stores of intercepted foreign electronic communications, most of which aren't analyzed in real time. The effort is being aided by experts from government labs, the Centers for Disease Control and Prevention, the National Institutes of Health and other parts of the Department of Health and Human Services. Experts outside the government are being consulted, as are allied intelligence agencies.

One outcome, Mr. Biden said in May, could be a list of specific questions that the U.S. would put to China as well as recommendations on what additional inquiries might be needed.

Given the possibility that the intelligence review might be inconclusive, there are already calls by leading lawmakers, some experts outside government and a grass-roots group of people affected by Covid-19 for an independent national commission.

"There has not yet been a properly organized, independent, scientific evaluation of all of the available evidence," said Philip Zelikow, the former executive director of the commission on the 9/11 terror attacks. Mr. Zelikow is heading a planning group, backed by prominent foundations, for a possible commission to investigate how Covid-19 emerged and how to prepare for future pandemics.

The Trump administration didn't organize an intensive governmentwide review into Covid-19's origins, though intelligence agencies and the Lawrence Livermore National Laboratory probed the matter, former Trump administration officials said.

WSJ.com
Saturday, June 26, 2021

What We Know About the Origins of Covid-19

Key findings from The Wall Street Journal's investigation into how the global pandemic began

By Drew Hinshaw, Jeremy Page and Betsy McKay

It is among the world's most consequential mysteries: Where did the coronavirus that killed millions of people and shattered the global economy come from?

The Wall Street Journal has covered the global quest for answers, tracking the World Health Organization, doctors and scientists in China and around the world, the U.S. intelligence community and the vast network of disease specialists, all struggling to piece together a puzzling set of disparate clues. Here are some of the key findings:

1. A WHO-led inquiry into the origins of the virus was stymied from the start.

A Journal investigation found China resisted international pressure for an investigation it saw as an attempt to assign blame, delayed the probe for months, secured veto rights over participants and insisted its scope encompass other countries as well. The WHO-led team that traveled to China in early 2021 to investigate the origins of the virus struggled to get a clear picture of what research China was conducting beforehand, faced constraints during its monthlong visit and had little power to conduct thorough, impartial research without the blessing of China's government. In their final report, the investigators said insufficient evidence meant they couldn't yet resolve when, where and how the virus began spreading.

2. China withheld data on potential early cases and delayed sharing information on animals sold at a market where the first cluster was found.

Chinese authorities refused to provide WHO investigators with raw data on confirmed and potential early Covid-19 cases that could help determine how and when the coronavirus first began to spread in China. Chinese researchers also directed a U.S. government archive to delete gene sequences of early Covid-19 cases , removing an important clue.

For months before the WHO investigators arrived, Beijing declined to disclose information about samples authorities took in the first weeks of the pandemic from animals sold at the Wuhan market linked to many early cases . During their visit, the investigators found no proof of live mammals being sold at that market and quoted market authorities saying there was no illegal wildlife traded there. A study later suggested the Wuhan market was the site of widespread trading in illegal caged wildlife , providing evidence that the virus could have spread naturally from market animals to humans.

3. The question of whether a lab accident was the cause of the pandemic remains unanswered.

Since the early days of the pandemic, questions have surrounded the Wuhan Institute of Virology and whether an accident at one of its labs could have caused the pandemic . The WHO-led team declared that a lab

accident was an extremely unlikely cause of the pandemic. But afterward, WHO Director-General Tedros Adhanom Ghebreyesus called for further investigation into the lab-leak hypothesis.

A group of leading scientists also published an open letter saying the lab hypothesis was plausible enough to merit serious consideration. Other scientists sought more information about the WIV's role in investigating a mysterious respiratory illness that afflicted six people clearing bat guano from a mine in southwest China in 2012. Three of them died, and samples the WIV took from bats in the mine were later found to contain the closest known virus on earth to the one that causes Covid-19.

Unanswered questions about the miners' illness, the viruses found at the site and the research done with them elevated into the mainstream an idea once dismissed as a conspiracy theory: that SARS-CoV-2, the virus that causes Covid-19, might have leaked from a lab in Wuhan. China denies that the virus came from the Wuhan Institute of Virology or any other Chinese laboratory.

4. International pressure for a fuller inquiry into the origins of the virus grows.

The WHO-led investigators have pushed for a second phase of research into the origins of the virus, warning that time was running out to examine blood samples and other important clues in China . Meanwhile, the Journal disclosed a U.S. intelligence report asserting that three WIV researchers became sufficiently ill in November 2019 to seek hospital care. In late May, President Biden ordered that U.S. intelligence agencies report to him within 90 days on how the virus emerged , with a focus on two scenarios--whether the coronavirus came from human contact with an infected animal or from a laboratory accident.

Meanwhile, China said further investigations should now turn to other countries, suggesting that the virus might have originated outside its borders and spread via frozen food.

5. Other efforts to trace the path of the pandemic continue.

As part of an international effort to pinpoint the origin of the Covid-19 pandemic and prevent future disease outbreaks, scientists around the world and organizations such as the American Red Cross and the U.S. Centers for Disease Control and Prevention are looking for new clues in frozen blood , searching for SARS-CoV-2 antibodies or signs of infection.

Other independent scientists are also trying to piece together a picture of how the virus could have been evolving before it exploded in late 2019. Many scientists believe that the most likely explanation is that the virus evolved and jumped from an animal to humans naturally, given evidence that two other coronaviruses spilled over to humans that way in the past two decades and signs of ample opportunity for that to occur.

At least four recent studies have identified coronaviruses closely

related to the pandemic strain in bats and pangolins in Southeast Asia and Japan, a sign that these pathogens are more widespread than previously known and that there was ample opportunity for the virus to evolve.

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The US is concealing its research on deadly viruses -- while criticizing China's secrecy over the Wuhan lab

Mattathias Schwartz

In January 2020, an obscure government panel met at the Hyatt Regency in Bethesda, Maryland, to discuss a branch of virology known as "gain of function." The goal of such research is to take infectious diseases -- including the viruses that can cause pandemics -- and alter them in ways that make them deadlier or more transmissible, in the hope of getting a jump on outbreaks. It was two days after the United States had its first confirmed case of COVID-19, but the empty seats in the Hyatt conference room were due to lack of interest, not social distancing.

The gathering "couldn't be more timely," said David Christian Hassell, a career official at the Department of Health and Human Services, as he began loading slides for his presentation. "We're seeing this virus reassort and mutate as it spreads. It's just pointing out the need for doing this kind of work."

In fact, many critics would soon be pointing to the COVID pandemic as the ultimate proof that gain-of-function research needs to be shut down. At the time, the virus was still widely viewed as a problem confined to China, where it originated. Later, as the US went into lockdown, President Trump would try to rebrand the pandemic as the "China virus." The city of Wuhan was home to a laboratory conducting "experimental investigations" into what it called the "origin, diversity, capacity to cause illness, and risk of spillover" from bat coronaviruses. If an altered virus escaped from the lab, then gain-of-function research might have accidentally caused the very sort of pandemic it's intended to prevent.

Trump's national-security adviser accused the Chinese government of engaging in a "cover-up" of what happened in Wuhan. But as the meeting in Bethesda demonstrated, the Chinese have nothing on the US when it comes to keeping secrets about dangerous viral research.

Discussion at the meeting focused on the government committee that recommends which studies get funded -- and which are too dangerous to perform. Its formal name is the P3CO Review Group. The group is cloaked in an opacity even more impenetrable than the one surrounding the military's drone-strike program or FISA's wiretapping court. Until that morning at the Hyatt, when Hassell identified himself as chair of P3CO, no one beyond a handful of officials knew who served on the panel. Only federal employees are permitted to take part in its proceedings, which

are kept confidential; neither academia nor industry is represented. Even as Trump accused the Chinese of a cover-up, Americans had no way of knowing what their own government was doing to protect them from some of the riskiest science since the development of the atomic bomb.

"This lack of transparency is unacceptable," two scientists from Harvard and Johns Hopkins argued in The Washington Post. "Making decisions to approve potentially dangerous research in secret betrays the government's responsibility to inform and involve the public when approving endeavors, whether scientific or otherwise, that could put health and lives at risk."

Officials insist that the near-total secrecy surrounding P3CO is necessary "to preserve confidentiality and to allow for candid critique and discussion of individual proposals." A spokesperson for Health and Human Services told Insider that the review group meets "as needed," and that its membership varies depending on the proposal under review.

At the Hyatt meeting, which was prompted by scientists sounding the alarm over the apocalyptic risks of gain-of-function studies, Hassell said he was open to broadening P3CO's authority and defended the integrity of its process. "This isn't some rubber-stamp group," Hassell said. "Right now, you don't see evidence of that. But it is a very tough group."

At the moment, unfortunately, we have little choice but to take Hassell's word for it. What we do know is that the group weighed in on -- and approved -- at least one gain-of-function study conducted on American soil. The research, which took place at the University of Wisconsin-Madison in 2019, sought to make the deadly H5N1 bird flu transmissible between mammals. Another study, conducted at the University of North Carolina at Chapel Hill in 2015, created a new "chimeric" hybrid that combined elements from bat and mouse coronaviruses.

We may never know for certain how the coronavirus made the jump from animals to humans. But even the slightest possibility of a lab leak should be worrisome enough to warrant a hard look at whether the benefits of gain-of-function research outweigh the risks, and who gets to make the call about which experiments move forward. Billions of people, after all, would suffer if a risky experiment inadvertently starts the next pandemic. "It is unethical to put the general public at risk," David Relman, a microbiologist at Stanford, said in a Nature roundtable, "and then minimize inclusion of the public in discussions about the appropriateness and oversight of such research."

Uncalculated risks

There's no question that tinkering with infectious diseases in the lab has saved lives. It was passing the yellow-fever virus through chicken cells, for example, that enabled researchers to create a vaccine for humans. And herpes viruses have been altered in the lab to create a treatment for cancer. Today, according to one of the funders of the Wuhan bat studies, hybrid viruses developed in the lab were used as reagents to test possible vaccines.

Michael Imperiale, a professor of microbiology and immunology at the University of Michigan, says that gain-of-function studies have made important contributions to biomedical research. The studies on H5N1 bird flu, he told me, provided vital insights into protein changes that could allow for human-to-human transmission. "The better we get at making these kinds of correlations," he said, "the further ahead we'll be in the game of anticipating dangerous pathogens."

There aren't many scientists who conduct gain-of-function research. "It's a very small part of virology," Richard Ebright, a critic of gain-of-function research who teaches molecular biology at Rutgers University, told me. "Less than 1%." And it would be wrong to suggest that biomedical research as a whole is unregulated. The federal government has a number of regulations that cover the conduct of scientific research, including special rules for 67 "select agents and toxins." Among them is SARS-CoV-2, the virus that causes COVID-19.

But what biomedicine lacks is anything approaching a consensus about risk. The potential dangers of gain-of-function research were apparent long before the events in Wuhan drew attention to them. One comprehensive survey found that over a period of 75 years, there were 1,267 documented cases of "laboratory-acquired infections," or LAIs, caused by exposure to the kind of pathogens used in gain-of-function experiments, which resulted in 22 deaths. Infections by the deadliest agents in high-security labs appear to be far less frequent -- there were only 11 self-reported LAIs over a period of seven years.

There is sharp disagreement among scientists about the risk that a deadly gain-of-function pathogen could escape from a lab. Marc Lipsitch, a professor of epidemiology at Harvard, has estimated that it would take only one year of experimenting on a flu virus to put the risk of infecting a single person at 1 in 1,000. But Ron Fouchier, who induced mutations in H5N1 avian flu to make it transmissible between ferrets, calculated that under the safety measures in his own lab, it would take a million years of research to infect a single person -- and 33 billion years before an infected lab worker spread the disease to others. "This probability," he wrote, "could be assigned the term 'negligible,' given that the age of our planet is only 5 billion years."

Whatever the overall risks, there have already been some close calls. In 2014, fears of a lab-spawned pandemic, along with the Ebola outbreak in West Africa, spurred the Obama administration to impose a two-year moratorium on government funding for gain-of-function studies. Unsecured vials of smallpox from the 1950s turned up in a storage room at the Centers for Disease Control. In another incident, the CDC mistakenly sent samples of the virulent H5N1 flu to a lab in Athens, Georgia. And in a third mishap, as many as 75 CDC employees were accidentally exposed to anthrax when they handled samples they thought were inactive.

While none of the incidents involved gain-of-function studies, they underscore the risks inherent to cutting-edge biomedical research and the difficulty of solving for human error. At the time the moratorium was imposed, 19 studies identified as possible gain-of-function research were underway in 11 states. Health and Human Services set

about devising a framework for evaluating the risks, which led to the establishment of the P3CO review group.

But even after the moratorium was lifted in 2017, the lab accidents kept coming. In 2019, the CDC briefly shut down the Pentagon's biodefense lab at Fort Detrick after numerous containment failures. And in April 2020, as the nation went into lockdown, a scientist at the University of North Carolina in Chapel Hill was forced to self-quarantine for two weeks after being bitten by a mouse that had been infected with a strain of the virus that causes COVID-19. Research at UNC -- some of which was carried out with the assistance of Shi Zhengli, who led the experiments on bat coronaviruses at the Wuhan Institute of Virology -- resulted in four incidents of potential human exposure to SARS coronaviruses. UNC confirmed to ProPublica that the viruses had been created in a lab.

Ralph Baric, who helped lead the UNC research, has denied that it involved gain of function. Zhengli, meanwhile, told The New York Times that the Wuhan lab "never conducted or cooperated in conducting GOF experiments that enhance the virulence of viruses." (She did not comment on whether the lab was trying to enhance the transmissibility of viruses, which is another key criterion for gain of function.) Dr. Anthony Fauci and the National Institute of Health, which provided funding for the Wuhan experiments, also insisted that the work did not involve any gain-of-function research. The study was "subjected to rigorous peer review and was judged to be very high priority, given how SARS-CoV had already emerged in this bat population," an NIH spokesperson told Insider.

Experts I spoke with were skeptical of the NIH's claim that the Wuhan study didn't involve gain of function, noting that the term is subject to competing definitions. But when it comes to oversight, the NIH's definition -- which is extremely narrow -- is the one that counts. The agency told The Washington Post that the Wuhan study was determined to be "outside the scope" of oversight by the P3CO committee.

It's a telling admission: What turned out to be one of the most controversial and perhaps consequential experiments in history was deemed not to require government oversight. As a result, the grant proposal was never even passed along to the P3CO review group. And there's no way to know the reasoning behind the decision, or the identities of the officials who made it.

Made in the USA

After much obstruction and foot dragging, most scientists now agree that there is a need to investigate what happened in Wuhan. At the end of May, President Biden ordered the intelligence community to conduct a 90-day review of what they know about COVID-19's origin.

It's possible, of course, that the lab-leak scenario will turn out to be wrong. If, as many scientists believe, the virus had a natural origin, then the Wuhan lab -- now vilified by everyone from Mike Pompeo to Jon Stewart -- was actually conducting critical, prescient research into a soon-to-emerge disease. The lab would be held up as a shining

example of the need for gain-of-function research, which proponents view as the last line of defense in humanity's arms race against nature. Unless we know what could be headed our way, they argue, we won't have enough time to stop it.

But the relentless focus on China-based research, and what may have gone wrong there, misses a deeper and more disturbing truth. The vast majority of virology -- including the Wuhan study and other gain-of-function research conducted outside the US -- is supported by American funding. The training, ethical guidelines, and standards for bioscience adhered to by top researchers worldwide are dominated by US institutions. If it becomes demonstrably true that a cutting-edge laboratory caused a pandemic, either now or in the future, America would deserve the blame, regardless of which country happens to be hosting those experiments. And much like the international regulatory regime around nuclear weapons, any effort to create an independent authority capable of overseeing dangerous biomedical experiments would need to be spearheaded by the US.

At the moment, though, we have no way of knowing the number or nature of studies working to change viruses in ways that could lead to the deaths of millions. Even more striking, the public has no way to know who is responsible for reviewing those studies, or how they are making their decisions about funding. Regardless of how COVID-19 emerged, we are being kept in the dark about scientific work that seeks, as its primary objective, to make the most frightening diseases more frightening.

"Everyone on earth has now experienced a pandemic in their lifetimes," Ebright told me. "Nobody wants to see another. If there's even a possibility that this category of work caused this pandemic, or could result in the next pandemic, then it needs to be regulated."

Global Times (China)
Monday, June 28, 2021

Why US labs need to be investigated for COVID-19 origins

Suspect No.1: Why Fort Detrick lab should be investigated for global COVID-19 origins tracing

By Fan Lingzhi, Huang Lanlan and Zhang Hui

The lab-leak theory, that COVID-19 was leaked from a laboratory, has once again caused a clamor since the beginning of this year, months after the argument was thrown into the trash can of conspiracy theories by an overwhelming number of scientists.

Observers found that things only get more complicated when the origins of the coronavirus - an already difficult scientific issue - is entangled in political manipulation tricks. Combing through more than 8,000 pieces of news reports related to the lab-leak theory, the Global Times found that as many as 60 percent of the coverage was from the US alone.

It is worth noting that many media outlets in the US-led Western world, which hyped the lab-leak theory, are only willing to focus on the Chinese labs though they have been thoroughly investigated by the World Health Organization (WHO), while turning a blind eye to the more suspicious American biological research institutions, such as the infamous US Army Medical Research Institute of Infectious Diseases (USAMRIID) at Fort Detrick, Maryland.

The USAMRIID was temporarily shut down in 2019 after a Centers for Disease Control and Prevention (CDC) inspection. Although this mysterious lab reported the reason for the closure as "ongoing infrastructure issues with wastewater decontamination," the explanation was not persuasive enough. The Global Times found that the lab's failure to control toxins seemed to have alarmed the Countering Weapons of Mass Destruction related institutions in the US.

Resurgence of lab-leak theory

A joint study into the origins of COVID-19 by Chinese experts and the WHO in March dismissed the "lab-leak" conspiracy theory. More evidence pointed to the fact that the virus had probably jumped from bats to humans via another intermediary animal, and it was "extremely unlikely" that it leaked from a lab, the study report said.

Nonetheless, the lab-leak theory has not disappeared; instead, especially from the beginning of May, it has been largely promoted by some US politicians and media outlets as a "plausible science." In an article published on Bulletin of the Atomic Scientists on May 5, without any evidence, science writer Nicholas Wade claimed that "proponents of lab escape can explain all the available facts about SARS2 considerably more easily than can those who favor natural emergence."

Days later, The Wall Street Journal reported on May 23 that three researchers at Wuhan Institute of Virology (WIV) "became sick enough in November 2019 that they sought hospital care," and they had "symptoms consistent with both Covid-19 and common seasonal illness." The WSJ report quoted a "previously undisclosed US intelligence report."

On May 26, President Biden stated that he had ordered the US intelligence community to "redouble" its efforts to investigate the origins of COVID-19. The US national security adviser Jake Sullivan even claimed on June 20 that China will face "isolation in the international community" if it doesn't cooperate with a further probe into the origin of the COVID-19 pandemic, Bloomberg reported that day.

Pressure from politicians and the media seems to have affected some authoritative medical scientists in the US, including Director of the US National Institute of Allergy and Infectious Diseases (NIAID), Anthony Fauci. On May 11, after Rand Paul, a Republican to the Senate, accused Fauci of helping the Wuhan lab "create" the virus, Fauci strongly denied the accusation but said he is "fully in favor of any further investigation of what went on in China."

This sudden change in attitude of some US experts is due to the political pressure they have received, a Chinese virologist told the

Global Times. "Western media like to ask the experts misguiding questions, like, 'is (lab leak) absolutely impossible?'" said the virologist who requested anonymity.

It's very difficult for experts to answer a question like that, as the possibility, although very little, still exists, the virologist said. "All they can say is, 'it's possible,'" he told the Global Times. Actually, most experts usually add "but it's highly unlikely" after "it's possible," but the media only presents the part which confirms their own bias, he said.

Big data shows the US is pushing the narrative of the COVID-19 lab-leak theory. Among the 8,594 pieces of news report related to "lab leak" that database GDELT collected since 2020, 5,079 were from the US, accounting for 59 percent. Following the US was the UK (611 pieces) and Australia (597 pieces). Almost all the coverage targeted the WIV lab.

While the US is solely focused on Chinese labs, the US seldom pays attention to the fault in its own domestic labs, some of which have even triggered virus-related accidents before. According to an August 2020 article by ProPublica, an independent newsroom that produces investigative journalism, the University of North Carolina at Chapel Hill reported 28 lab incidents involving genetically engineered organisms to safety officials at the National Institutes of Health between January 2015 and June 2020. "Six of the incidents involved various types of lab-created coronaviruses," ProPublica said in the article. "Many were engineered to allow the study of the virus in mice."

Weirdly, very few US mainstream media outlets have raised the question whether there is the possibility that COVID-19 was leaked from US labs, said the Chinese virologist. "They dare not ask that," he said.

In an article published on the independent political blog site Moon of Alabama on May 27, the author pointed out that some Westerners' hyping of the Wuhan lab leak conspiracy is similar to the trick the US played in pushing the Iraq War in 2002 - the US claimed "Saddam Hussein will soon have nuclear weapon," which was "obvious nonsense," the author said.

"The 'lab leak' theory is similar to the WMD claim - evidence-free speculation long promoted by a neoconservative leaning administration that was extremely hostile to the 'guilty' country in question," said the author.

The lab-leak theory, therefore, "isn't just about an implausible, evidence free tale of a SARS-CoV-2 lab escape," the author noted. "It is a campaign launched to depict China as an enemy of humankind."

Intl concerns on US bio-labs

The US has many bio-labs in 25 countries and regions across the Middle East, Africa, Southeast Asia and the former Soviet Union states, with 16 in Ukraine alone. Some of these labs have seen large-scale outbreaks of measles and other dangerous infectious diseases, according to media reports.

The international community has frequently expressed concern over US' biological militarization activities in other countries.

In October 2020, Deputy Chairman of the Security Council of Russia, Dmitry Medvedev, said that the US research activities in bio-labs in members of the Commonwealth of the Independent States have caused grave concern. The US not only builds bio-labs in these countries, but also tries to do so in other places across the world. However, its research lacks transparency and runs counter to the rules of the international community and international organizations.

Anatoly Tsyganok, a corresponding member of the Russian Academy of Military Sciences and associate professor of Faculty of World Politics at Lomonosov Moscow State University, told the Global Times that biological and bacteriological weapons tests on US territory are prohibited by the US Congress. He said that the US military has been and is still carrying out tests of biological and bacteriological weapons in Georgia.

This is done under the guise of providing sick people with various therapeutic vaccines conducted by the US military and American private contractors at the Richard Lugar Center for Public Health Research, Tsyganok said. Related tests have been exposed by various media outlets.

In December 2015, 30 patients at the research center who were being treated for hepatitis C died. Twenty-four of them died on the same day, and their cause of death was listed as "unknown," according to Tsyganok and Russia news outlet.

Residents of neighborhoods around these labs often complain about health problems.

Bulgarian journalist Dilyana Gaytandzhieva published a story about the Lugar center in early 2018. In her interviews for the report, most residents who lived nearby the labs complained of headaches, nausea and high blood pressure. They also said there was black smoke coming from the lab.

USA Today reported that since 2003, hundreds of incidents involving accidental contact with deadly pathogens occurred in US bio-labs at home and abroad. This may cause the direct contacts to be infected, who can then spread the virus to communities and start an epidemic.

A member of the Russian Academy of Sciences, Armais Kamalov said in an interview with TASS in early June that development of genetically-engineered viruses as biological weapons should be subject to the same worldwide ban as the testing of nuclear weapons. He mentioned US labs in Georgia and Armenia as reference.

"There are a lot of labs, which are bankrolled today by the United States Department of Defense. It's no secret that they are in Georgia, Armenia and other republics. It's surprising that access to such labs is off-limits, and we don't understand what they are doing there," he said.

What had happened in July 2019?

The terrible safety records of American biological labs around the world shows a possibility of a virus escaping from an American lab. Many point to the shutdown of Fort Detrick lab in July 2019.

In July 2019, six months before the US reported its first COVID-19 case, Army laboratory at Fort Detrick that studies deadly infectious material like Ebola and smallpox was shut down after the US Centers for Disease Control and Prevention issued a cease-and-desist order. CDC officials refused to release further information after citing "national security reasons."

The USAMRIID in Fort Detrick said in August 2019 that the shutdown was because the center did not have "sufficient systems in place to decontaminate wastewater" from its highest-security labs, the New York Times reported.

What exactly happened at Fort Detrick in the summer of 2019? Some US media previously turned to CDC to get answers, but many key contents in the report had been redacted.

In early June, a Virginia-based Twitter user got the CDC documents on the inspection of the Fort Detrick under The Freedom of Information Act (FOIA). Global Times found that most of the documents were emails between CDC officials at various departments and USAMRIID from 2018 to 2019. Although some of the emails were covered by an ABC-affiliated television station in Washington, the report did not catch much attention.

The emails revealed several violations at the Fort Detrick lab during

CDC's inspections in 2019. Four of which were labeled serious violations.

One of these serious violations, the CDC said, was one inspector who entered a room multiple times without the required respiratory protection while other people in that room were performing procedures with a non-human primate on a necropsy table.

This deviation from entity procedures resulted in a respiratory occupational exposure to select agent aerosols, the CDC said.

In another serious violation, the CDC said the USAMRIID had "systematically failed to ensure implementation of biosafety and containment procedures commensurate with the risks associated with working with select agents and toxins."

Other violations included lack of proper waste management where waste wasn't transported in a durable leak proof container, which creates the potential for spills or leaks.

The CDC documents show that it sent a letter of concern to USAMRIID, which resulted in a temporary shutdown of the Fort Detrick lab in 2019.

In an email on July 12, 2019, the CDC said the USAMRIID reported two

breaches of containment on July 1 and July 11, 2019, and this demonstrated a "failure of USAMRIID to implement and maintain containment procedures sufficient to contain select agents or toxin generated by BSL-3 and BSL-4 laboratory operations."

"Effective immediately, USAMRIID must cease all work involving select agents and toxins in registered laboratory areas until the root cause investigation has been conducted for each incident and the results have been submitted to FSAP for review," the CDC said.

The FSAP (Federal Select Agent Program) is jointly comprised of the Centers for Disease Control and Prevention's Division of Select Agents and Toxins and the Animal and Plant Health Inspection Service's Division of Agricultural Select Agents and Toxins. The program oversees the possession, use and transfer of biological select agents and toxins, which have the potential to cause a severe threat to the public, animal or plant health or to animal or plant products. Common examples of select agents and toxins include the organisms that cause anthrax, smallpox, and the bubonic plague.

Three days later, the Fort Detrick replied the email by saying that it had submitted messages in response to the immediate action, but the messages were deliberately blotted out.

The message was submitted by a director for Strategic Studies (Countering Weapons of Mass Destruction) at the USAMRIID whose name was also blotted out.

The Fort Detrick's public statement released in August 2019 said the shutdown was due to problems in decontaminating wastewater. But it's not clear whether the statement was consistent with CDC's inspection results.

The management of such high-level labs in general must be very strict with regular inspections. Various systems should be able to ensure that no potential risks can occur, and equipment failure and wastewater leakage certainly should not occur, a Chinese scientist from the WHO-China virus origins tracing team who requested anonymity told the Global Times.

The wastewater problems revealed major loopholes in the management at the Fort Detrick lab, and one has to wonder what else was leaked with the mismanaged wastewater.

"Some highly pathogenic pathogens in the laboratory were likely released. And the US military never told the public about what they were doing," the scientist said.

It is highly likely that researchers at Fort Detrick may have been infected accidentally but showed no obvious symptoms. In this way they could have brought the virus to the outside world, the scientist said.

"Under the circumstances of no obvious symptoms, 9 of the 10 individuals may not have known that they were infected and it's possible that more than 90 percent of the transmission routes had been lost when the virus was finally detected. This is also why the tracing

of virus origins is difficult to conduct," he said, noting only serological survey on a large scale could find some of the early infections.

Why not open Fort Detrick lab

Several virologists and analysts interviewed by the Global Times urged the Fort Detrick lab to open its doors for an international investigation, since international experts have already visited the Wuhan Institute of Virology.

Many Western politicians and media outlets pinned the blame of the pandemic on Wuhan, saying that Wuhan was where the virus was first detected and where the virus came from despite mounting evidence that it's not the case.

In a recent example in June, a research study run by the National Institutes of Health's All of Us Research Program found evidence of COVID-19 infections in the US as early as December 2019, weeks before the first documented infection in the country.

Wuhan recorded the earliest COVID-19 symptoms from a patient on December 8, 2019.

When asked to give more details on the study, a media person with the All of Us Research Program told the Global Times that the program "has nothing further to add" from the information it had already released.

As for why the virus was first detected in Wuhan, the anonymous scientist said that the virus was difficult to be detected at an early stage, especially in autumn and winter with more cold cases. And it would not attract attention until a large number of people were infected. That's what happened in densely populated Wuhan, the scientist said.

China's public health system is very sensitive especially after the SARS outbreak in 2003, but this is not always the case abroad, especially when the population density is low and the virus does not spread so fast, the expert said.

"The novel coronavirus was first discovered by three Chinese companies at the same time. It is very simple to detect these things, and China has lots of such third-party companies with strong medical detection ability," he said.

Without going back to earlier serum samples elsewhere now, it is going to be difficult to find the source of the virus. The retrospective studies that have been done in China have not found any evidence. It's important for the world to work together now to sort through the evidence and do early serological investigations where necessary, he said.

Zeng Guang, former chief epidemiologist of the Chinese Center for Disease Control and Prevention, told the Global Times that laboratory leak is easy to identify, as infections are bound to show signs, whether it is an operational problem or an infection of a lab staff.

The WHO experts assessed the lab-leak hypothesis when they visited Wuhan and found no evidence, and the speculation on its possibility in a Wuhan lab should have ended by now. In the meantime, we should put a question mark on other hypotheses, such as other labs around the world, Zeng said.

Zeng said the US is afraid of WHO's inspection in the same way it was done in China, Zeng said.

The US, the only country obstructing the establishment of a Biological Weapons Convention (BWC) verification mechanism, has systematic problems, Zeng said, adding that the US is afraid that the investigation into its labs would lead to more of its dirt being dug out.

Xia Wenxin contributed to this story

New York Times
Saturday, June 26, 2021, page B6

Celebrity Cruises to Be First to Resume Sailing From U.S.

By Ceylan Yeginsu

The Celebrity Edge will depart from Fort Lauderdale, Fla., on Saturday with 95 percent of its passengers all crew members vaccinated.

The Celebrity Edge is poised to set sail out of Fort Lauderdale, Fla., on Saturday, becoming the first major cruise ship to restart operations from a United States port since the pandemic all but hobbled the industry over a year ago.

The ship will sail at 35 percent capacity, with at least 95 percent of passengers and all crew members fully vaccinated, its owner, Celebrity Cruises, said in a statement. Vaccines are not mandated for the cruise because of a new Florida state law banning businesses from requiring proof of immunization, but unvaccinated guests will face more stringent coronavirus protocols.

All guests over the age of 16 who do not show proof of vaccination will be required to wear masks on board and take a series of antigen tests during the cruise at an additional cost. (Testing for vaccinated guests will be free of charge.)

"We're definitely finding that cruisers prefer to be vaccinated and to share this information with us," said Susan Lomax, associate vice president for global public relations at Celebrity Cruises.

The sailing is a major milestone for the $150 billion global cruise industry, which has been decimated by the pandemic and spent months in a battle with the Centers for Disease Control and Prevention over its requirements for the safe resumption of cruising.

Earlier this month, Celebrity Cruises tested its Covid protocols during a seven-day sailing in the Caribbean, the line's first international cruise with American passengers. All adult passengers and crew members were fully vaccinated, and they were not required to wear masks or socially distance during the sailing.

Halfway through the cruise and following two shore excursions on the islands of Barbados and Aruba, a vaccinated couple tested positive for the virus and were immediately put into isolation. Other passengers who had come into contact with them were required to quarantine and get tested.

Before the ship reached its final destination, all passengers on board were tested, and no further positive cases were identified. Celebrity said the handling of the incident demonstrated that the company's virus protocols worked in preventing the spread of the virus.

Other major lines, including Carnival Cruise Line and Royal Caribbean, are preparing to restart U.S. operations in July. As of July 18, cruise ships departing from and arriving in Florida will not be required to follow C.D.C. guidance, after a judge ruled last week that the order was based on "stale data" and failed to take into account the prevalence of effective vaccines.

New York Times
Saturday, June 26, 2021, page A18

Harris Seeks Nuance On Migration Debate During Tour of Border

Advocates pushed the vice president to end Title 42, a Trump-era rule that allows the government to expel migrants for public health reasons.

By Katie Rogers

WASHINGTON -- Vice President Kamala Harris on Friday made her first visit to the southern border since she took office, hitting back at Republican criticism and meeting with advocates who pushed her on why the Biden administration had not yet ended restrictive Trump-era policies on migration.

"We can take all of these perspectives into account and have meaningful good public policy if we just stop the rhetoric," Ms. Harris told reporters after a four-hour visit to El Paso. "You can't just react to a problem without solving it at its roots. Let's just agree to that."

During her trip, she confronted an issue that has bedeviled the administration for months and is now tied to her own political future after President Biden put her in charge of addressing the root causes of migration. But for all of the questions she took from reporters, immigration advocates and even a group of detained migrant children -- whom she met behind closed doors -- the vice president had few answers.

In one private meeting, she heard from immigration advocates who said they did not understand why the Biden administration had yet to deliver

on promises to roll back Trump-era policies like Title 42. Several pressed Ms. Harris to end that rule, which allows the government to expel migrants, including asylum seekers, for public health reasons.

"We were very forceful about that," Fernando Garcia, the executive director of the Border Network for Human Rights, who attended the meeting, said in an interview. "She asked how we think it could happen. She was looking for some answers."

The Biden administration is working to phase out Title 42, but on Friday, Alejandro N. Mayorkas, the secretary of homeland security who accompanied Ms. Harris to El Paso, told reporters that the Centers for Disease Control and Prevention would ultimately decide.

"It's a public health decision," Mr. Mayorkas said. "It's based on the well-being of the American public."

The agency, however, has directed questions about the policy to the White House.

In some ways, the trip was notable for what Ms. Harris did not do: visit a tent complex at nearby Fort Bliss, where migrant children are being held. (As she traveled to Texas, the Biden administration announced that Xavier Becerra, the secretary of health and human services, would head there next week.)

"She'll check off the box of going down to the border," Representative Henry Cuellar, a Texas Democrat who wrote a letter to the vice president last week urging her to visit the border, said in an interview. Mr. Cuellar said his letter went unanswered.

Ms. Harris stopped at Customs and Border Protection's processing center, where she received a briefing from officials and asked questions about the technology used to process people who crossed the border illegally.

She also said she had met with young girls detained at the Paso del Norte port of entry, a meeting that had not been announced and was kept private. Ms. Harris said the girls reminded her that the issue should not be reduced to partisan politics.

"They were asking me questions: 'How do you become the first woman vice president?'" Ms. Harris said. "It also reminds me of the fact that this issue cannot be reduced to a political issue. We're talking about children, we're talking about families, we are talking about suffering."

Human rights and immigration advocates have assailed the Biden administration for not doing enough in its first six months to reopen the border to asylum seekers, reunite unaccompanied children with families and provide the appropriate facilities to hold detained migrants. In a report released last week, the human rights group Amnesty International said that the Biden administration had failed to fulfill some of its early pledges.

"Rebuilding an immigration system takes time, but nearly half a year

in, the administration still needs to deliver promised change," the report read. "No matter the situation or who heads the administration, the government cannot get out of its human rights obligations."

Still, some Democrats praised Ms. Harris, saying her trip showed a dedication to finding solutions, including a push for bipartisan immigration overhaul, an effort that has eluded modern presidents.

"Her attendance today in El Paso is an indication of her caring and commitment to meaningful immigration reform," said Senator Richard J. Durbin, the chairman of the Judiciary Committee, who stood next to her on the tarmac in El Paso. "And I want to join her in saying that Congress needs to do its part."

The visit came together quickly after Ms. Harris was criticized on her trip to Mexico City and Guatemala, where Lester Holt of NBC grilled her about why she had not been to the border. She responded by calling the visit a "grand gesture" and pointed out that she had not been to Europe yet, either -- answers that confounded her critics and members of the administration.

Though her office denied politics played a part, the El Paso stop does carry some significance. The city is a major port of entry and has complicated ties to former President Donald J. Trump, who will travel to the border with Gov. Greg Abbott of Texas days after Ms. Harris.

As president, Mr. Trump called El Paso "one of our nation's most dangerous cities," castigating it as overrun by immigrants and crime. It typically ranks among the safest cities in the United States. In 2019, after 22 people were killed at a Walmart and the white suspect warned of a "Hispanic invasion," Mr. Trump was greeted with protests when he met with the victims' families.

On Wednesday, a group of House Republicans said they would join Mr. Abbott and Mr. Trump on their trip, a move intended to add more pressure on the Biden administration, which has struggled to chip away at Mr. Trump's "zero tolerance" immigration policies while warning migrants not to make the journey to the United States.

The number of unaccompanied minors crossing the border has hit a record high under the Biden administration, and officials have struggled to quickly move them out of cramped facilities and into the care of family members. A surge in the apprehensions of single adults -- some 121,000 last month -- has offset a small decline in the number of unaccompanied minors and families traveling north, according to Customs and Border Protection data.

As she prepared to leave El Paso, Ms. Harris was asked about criticism that she had stopped by El Paso instead of the lower Rio Grande Valley, which is considered the center of the current surge in migration. The vice president, who spent her visit pleading for partisan politics to be omitted from the conversation about immigration, pointed to Mr. Trump to make her case.

"It is here in El Paso that the previous administration's child

separation policy was implemented," she said. "We've seen the disastrous effects of that right here in this region."

Zolan Kanno-Youngs and Eileen Sullivan contributed reporting.

Los Angeles Times
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Harris views immigration problems up close

Criticism continues after she meets with border agents, migrant children in El Paso.

By Noah Bierman and Molly Hennessy-Fiske

Kamala Harris made her first trip as vice president to the U.S.-Mexico border Friday, meeting with border agents and migrant children as she toured a processing center in El Paso and became more closely tied to one of the Biden administration's diciest political problems.

Her visit comes after months of Republicans' criticism that she and President Biden hadn't seen firsthand the effects of an immigration system overwhelmed by an increase in migrant families and unaccompanied children seeking entry into the United States.

Even as Harris traveled around the El Paso area, critics on both sides of the immigration debate lambasted her for avoiding some more problematic spots along the border, where children and families are experiencing long delays and often dangerous conditions as they wait to have their fates determined.

The migrant children she met "are filled with optimism," Harris said as she left Texas for a weekend at her Brentwood home. "But they are without their family -- young children. They're being processed through the system."

"This issue cannot be reduced to a political issue," she added. "We're talking about children. We're talking about families. We're talking about suffering. And our approach has to be thoughtful and effective."

Harris was accompanied by Homeland Security Secretary Alejandro N. Mayorkas, who has been to the border previously. Health and Human Services Secretary Xavier Becerra plans to visit a nearby facility Monday -- a federal tent city for hundreds of children at the Army's Ft. Bliss, where there have been outbreaks of COVID-19 and lice, reports of sexual abuse and other unsafe conditions.

During her visit, which lasted about four hours, Harris blamed the Trump administration for leaving her and Biden with "a tough situation," which she asserted was improving.

"We're not exactly where we want to be yet, but we've seen extreme progress," she said, noting that wait times for unaccompanied children in El Paso had been reduced.

Despite months of taunts from Republicans that she was avoiding the border, Harris told reporters that "it was always the plan to come here" as part of her work on immigration diplomacy with Central America. She had been to the U.S.-Mexico frontier numerous times as a senator and as California's attorney general.

"We have to deal with causes and we have to deal with the effects," she said. Her recent trip to Mexico and Guatemala, she added, was about probing the causes of residents' decisions to migrate north, while her border visit is intended to allow her to see "the effects of what we have seen happening in Central America."

Harris said the border stop reinforced her belief that deterring people from leaving their home countries will require long-term, consistent investment in Central American countries to reduce poverty there.

In addition to touring the processing center, Harris met privately with five migrant girls ages 9 to 16. Aides said the girls drew pictures and told the vice president what they wanted to be when they grew up. Harris also went to a nearby inland entry port where asylum seekers arriving from Mexico, including unaccompanied children, are initially screened.

The Biden administration is facing tough policy decisions as it tries to balance efforts to deter migrants and to develop a more humane system of processing those who have made the journey.

Mayorkas told reporters traveling on Air Force Two that his office is still reviewing how quickly to rescind a Trump-era policy, initiated amid the pandemic, that allows agents to turn away migrants by citing a public health law known as Title 42.

Mayorkas said the decision on whether to end the policy would be based on the assessment of the Centers for Disease Control and Prevention, based on public health data and the threat of spreading COVID-19.

Harris' role in immigration policy dates to March, when Biden asked her to examine ways to reduce migration through Mexico from Honduras, Guatemala and El Salvador by attacking its root causes, including corruption, poverty and gang violence -- problems that have been exacerbated by devastating hurricanes and the pandemic.

The vice president visited the capitals of Guatemala and Mexico earlier this month to confer with their leaders, encourage investment and discourage corruption in the region. But those diplomatic activities were overshadowed by questions raised back in the United States about why she wasn't visiting the border.

On Friday, Sen. Ted Cruz (R-Texas) tweeted of Harris' trip: "93 days too late," adding: "It only took more than half a million illegal immigrants entering the U.S., more than 400,000 pounds of drugs seized, dozens of U.S. Senators and House members traveling to the southern border for Border Czar Kamala Harris to finally visit the southern border."

White House officials said Harris did not go to Texas in response to the partisan pressure, which includes former President Trump's recent announcement that he would visit a border site with GOP members of Congress next week.

Republicans say the Biden administration is looking at the wrong causes for the increase in migrants. They say the reason they're coming is because Biden has relaxed some of Trump's hard-line policies.

Republicans have decried Biden's early order to halt border wall construction while his administration reviews the legality of how Trump funded his signature project.

More than 200 miles of barrier were in some stage of construction in Texas, which is the least-fenced border state, when Trump left office, according to U.S. Customs and Border Patrol.

Texas Gov. Greg Abbott, a Republican who plans to host Trump next week, has vowed that his state will continue to build the wall, though it's not clear he has the authority to see that it's done.

Liberal groups and immigrant advocates have their own issues with the administration, complaining that officials have been too slow to roll back Trump's policies, including the use of Title 42, and to fix conditions for children at Ft. Bliss.

"There is a long way to go," said Shaw Drake of the ACLU of Texas in El Paso, a staff attorney and policy counsel for border and immigrants' rights.

From the administration's vantage, El Paso was an appealing destination for Harris. The largest city on the long Texas border, it's a military outpost but also a Democratic college town and a bastion of liberal activism for immigrant rights. It is also home to Democratic Rep. Veronica Escobar, who was traveling with the vice president.

El Paso also was the first place where the Trump administration began separating children and parents who crossed the border -- one of the former president's most reviled policies.

Rep. Henry Cuellar, a Texas Democrat who had urged Harris to visit the border, said El Paso is "politically safer to go to than the Rio Grande Valley, where you can see unaccompanied kids, family units, and where you get most of the single adults that are coming in."

Migrant numbers fell sharply in 2020 amid the pandemic, when the U.S., like many countries, restricted entry. This year the numbers began to increase.

Some progressive activists in the Rio Grande Valley also expressed disappointment that Harris and Mayorkas were visiting El Paso, where far fewer asylum-seeking families have been forced by U.S. policies to wait across the border in Mexico.

Karla Vargas, an attorney with the Texas Civil Rights Project, based in the Rio Grande Valley east of El Paso, said: "We would have hoped they

would have tried to also visit this area to see how difficult it is for the families waiting here. We welcome them trying to address this. We hope it is not just showmanship."

Times staff writer Molly O'Toole contributed to this report.

BusinessInsider.com
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CDC director Robert Redfield 'prayed' Trump would understand how serious COVID-19 was after contracting it, a book excerpt says

Yelena Dzhanova

Robert Redfield, the director of the Centers for Disease Control and Prevention, prayed that former President Donald Trump would take the coronavirus more seriously after being diagnosed with it, according to a new book by two reporters from the Washington Post.

An excerpt of the book, "Nightmare Scenario: Inside the Trump Administration's Response to the Pandemic That Changed History," illustrates the White House's chaotic response to Trump's October 2020 COVID-19 diagnosis and hospitalization at the Walter Reed Medical Center. The book, written by Yasmeen Abultaeb and Damian Paletta, is due for release on June 29.

Over the weekend that Trump announced that he and then first lady Melania had the virus, Redfield prayed for a recovery, the excerpt says. Redfield also prayed that it would be a wake-up call for the president, who for months at this point had flouted or mocked COVID-19 safety restrictions like mask-wearing.

He also held giant rallies with thousands of mask-less people in attendance to drum up support for his 2020 re-election bid.

Redfield "prayed that Trump would tell Americans they should listen to public health advisers before it was too late," the excerpt says.

Just days after his hospitalization, Trump walked the White House South Lawn. Watching the event unfold on television, Redfield prayed again, this time that the former president would "show some humility" and "remind people that anyone could be susceptible to the coronavirus -- even the president, the first lady and their son. That he would tell them how they could protect themselves and their loved ones."

But Trump didn't do that. Instead, he took off his mask and gave the cameras a thumbs up, the excerpt says.

In a video taken just over the weekend while at Walter Reed, Trump appeared to be visibly paler than usual. He released a video from the hospital, saying he felt "much better now." In the video message, Trump appeared to have no trouble speaking and breathing.

During the moment he addressed the cameras on the South Lawn, he was

likely still contagious.

"He made a military salute as the helicopter departed the South Lawn, and then strode into the White House, passing staffers on his way and failing to protect them from the virus particles emitted from his nose and mouth," the excerpt says.

That's when Redfield began to understand the hospitalization changed neither Trump nor his response to the coronavirus, according to the excerpt.

Washington Post
Sunday, June 27, 2021, page B1

How Trump's blunders fueled our coronavirus nightmare

Nightmare Scenario
Inside the Trump Administration's Response to the Pandemic That Changed History
By Yasmeen Abutaleb and Damian Paletta
Harper. 478 pp. $30

By William Hanage

Early in the pandemic, an outbreak of the novel coronavirus on the Diamond Princess cruise ship had spread out of control. The passengers included many Americans, prompting urgent questions about whether they should be repatriated and where they should be quarantined. Among the most eye-popping and jaw-dropping revelations in a new book by Washington Post reporters Yasmeen Abutaleb and Damian Paletta, "Nightmare Scenario," is the claim that President Donald Trump suggested sending them to Guantanamo Bay.

It shouldn't need saying, but a military compound used to house terrorism suspects is not a suitable place for the quarantine, isolation and treatment of mostly elderly citizens, already known to be a group vulnerable to severe infection. The alleged reason for the suggestion was the president's obsession with keeping the numbers of cases in the United States low. While energies were consumed with the Diamond Princess and other cruise ships, the virus quietly entered the country and started to spread, even as the Centers for Disease Control and Prevention struggled to develop a test capable of establishing that fact.

This episode illustrates two of the common factors that tie together the many missteps documented in the book. One is the wasting of time and energy on narrow issues such as cruise ships, or the discredited treatment hydroxychloroquine, rather than accepting that the situation was bad and going to get much worse without the hard work of pandemic management. The other is the conviction that the negative press coverage was the problem, not the virus itself.

Over and over again, whenever public health and public relations came into conflict, public health lost out. Trump's complaints directed at

"the Doctors" kept coming back to the same charge - negativity - including a remarkable, petulant presidential Oval Office outburst roughly halfway through the book. "I am sick and tired of how negative you all are. . . . I spend half of my day responding to what Tony Fauci has to say, and I'm the president of the United States!" Later in the same exchange, Trump told coronavirus response coordinator Deborah Birx: "Every time you talk, I get depressed. You have to stop that." As if the pandemic could be defeated by the power of positive thinking, and Birx should just cheer up and promote policies that she knew would lead to more illness and death than the alternatives.

In general, the book is not strong or detailed on the scientific nuts and bolts. This is not a place to come if you want to understand the nitty-gritty of why the CDC's test development went so very awry. But Abutaleb and Paletta are on the money when it comes to the challenges in formulating policy advice on the basis of science that was not fully settled. As they write, "The task force members . . . had to make the best decisions they could and update their guidelines as the scientific understanding grew."

The point is illustrated well by the politicization of masks. Amid early concerns about an exponential wave of infections flooding into the health-care system, experts including Fauci, director of the National Institute of Allergy and Infectious Diseases, argued against mask use, concerned that hoarding by the public would leave health-care workers deprived of vital personal protective equipment (PPE). This advice would later change as evidence accumulated showing that mask-wearing by a large fraction of the population is an effective intervention. This shift was interpreted as a political flip-flop, rather than science in progress, and adopted as ammunition by those adamantly opposed to masks. Mask use became irrevocably politicized, and attempts to convince doubters foundered amid an epidemic of cherry-picked evidence.

Shortages of PPE were in fact a serious concern early in the pandemic, because of an incoherent approach that set states and even individual health-care networks against one another. In just one example of many, the book alleges that the work of a "Shadow Task Force" run by Jared Kushner diverted "30 percent of 'key supplies' from the Strategic National Stockpile to operate forty-four drive through testing sites for five to ten days."

That the response was chaotic and dysfunctional will not be news, but according to this account there were opportunities to take a different course. Some officials emerge with credit, although it must be noted that, as with all tales of palace intrigue, the story is inevitably shaped by the sources. As time went on more efforts were put into finding ingenious reasons to deny the seriousness of the pandemic rather than to respond to it, with the nadir being the appointment of Scott Atlas as special coronavirus adviser to the president, to give the advice Trump wanted to hear.

This casting of reality as whatever you want to believe led to a sort of choose-your-own-pandemic, in which decisions were pushed ever downward to governors, mayors or individuals. Some of these were well resourced, others not, but all less well than they would have been with

adequate federal support. Members of the coronavirus task force resorted to broadcasting their own advice as widely as possible, either in meetings with local officials or through the media, so those who were willing to hear and act on it could benefit. The divided, inconsistent messaging set up the disastrous fall and winter, when deaths peaked at well over 4,000 each day.

We will be examining the mistakes and missteps of 2020 for decades, probably centuries. This book will be one of the places future historians will start, if far from where they will finish. The epilogue expresses hopes that in the next pandemic, "the nation rallies together." Unfortunately the partisan divisions in the United States are deep, illustrated by reluctant vaccine uptake in Republican strongholds. This book will not change that, although it reminds us of the dangers of relying on policy-based evidence rather than evidence-based policy. You cannot intimidate an earthquake or bully a hurricane to do your bidding, and a virus cannot be fired.

Pandemics have a way of making history. From the Black Death to the 1918-19 flu to HIV, infectious-disease outbreaks convulse societies in a way matched only by how readily humans forget them once they are over. Abutaleb and Paletta describe in sobering detail how the Trump White House chose to forget about the current pandemic while it was still going on.

William Hanage is an associate professor of epidemiology at the Center for Communicable Disease Dynamics at the Harvard T.H. Chan School of Public Health.

Wall Street Journal
Monday, June 28, 2021, page A7

Hospitals Strain Under Surge in Mental-Health Cases

By Robbie Whelan

PITTSBURGH -- Before the coronavirus pandemic took hold, psychiatrist Garrett Sparks usually treated about a dozen patients on his overnight shift in the emergency department at Western Psychiatric Hospital, this city's biggest mental-health hospital. On a recent Thursday evening, he saw 21 cases.

As the night began, an agitated man sitting on a couch in a space reserved for acute cases loudly demanded turkey sandwiches. Parents of a 7-year-old who had been kicked out of school for emotional outbursts came in, saying their child's behavior was spiraling and he was becoming more aggressive. A few hours later, police brought in a 17-year-old boy who had tried to commit suicide by jumping from a bridge.

"It seems like everyone has been holding their breath for a year, and now, it's just a total explosion of everything, both in terms of high volume but also the severity of cases," Dr. Sparks said. "You see a lot more people who were, pre-pandemic, kind of overwhelmed and stressed,

and now they have full-on anxiety disorders or depression."

In the coronavirus pandemic, a wave of mental-health crises has grown into a tsunami. As the country appears to be emerging from the worst of the Covid-19 crisis, emergency departments say theyare overwhelmed by patients who deferred or couldn't access outpatient treatment, or whose symptoms intensified or went undiagnosed during the lockdowns.

Doctors say it could be years before we see the full impact of the pandemic on mental health, but a host of studies indicate how strained the system has become. Emergency visits for patients seeking help for overdoses and suicide attempts rose 36% and 26%, respectively, between mid-March and mid-October of last year, the U.S. Government Accountability Office said in March. U.S. Centers for Disease Control and Prevention surveys have found that 38% of respondents reported symptoms of anxiety or depression between April of last year and February, up from about 11% in 2019.

Children have been hit particularly hard. School closures have allowed serious mental-health issues to go unnoticed, because teachers and school psychologists are a primary source of referrals, doctors say. Even before the pandemic, the country faced a shortage of mental-health professionals to serve juveniles; the American Academy of Pediatrics last year estimated the need for child psychiatrists at 47 per 100,000 people, roughly four times the number in practice.

Emergency-room visits for mental-health crises among 12- to 17-year-olds increased 31% between 2019 and 2020, the CDCreported in June. Among the same group, emergency-room visits for suspected suicide attempts rose 22% last summer compared with the previous year, and 39% this past winter compared with the previous winter.

At the University of Pittsburgh Medical Center, which includes Western Psychiatric, pediatric-outpatient volume surged 30% in the first four months of 2021 compared with the year earlier.

"We have more kids waiting for care than we ever have before," said Abigail Schlesinger, the hospital's chief of child and adolescent psychiatry. "We're in the mental-health emergency phase of this pandemic."

Mental-health crisis cases are ending up in emergency rooms in higher numbers in part because outpatient facilities, including private psychiatrists' offices, therapy practices and crisis centers, are saturated with patients whose mental-health problems have worsened during the pandemic, doctors and hospital administrators say.

"For us, it's definitely a lot of people who either had pre-existing conditions or have neglected to address their new onset of emotional imbalance," said Damir Huremovic, a psychiatrist at North Shore University Hospital on Long Island. "Many developed anxiety or insomnia, and they tried to see a provider but no one was taking new patients, and then things sort of just snowballed."

For patients dealing with depression, anxiety or eating disorders, physicians recommend getting out of the house, seeing people and

establishing a normal routine, said Jeanne Noble, an emergency physician at the University of California, San Francisco.

"That's the exact opposite of what's happened with the school closures and lockdowns," Dr. Noble said.

The pandemic has taken its toll on mental-health providers, too. In his downtime, Dr. Sparks trains for marathons, listens to audiobooks, and sees a therapist to treat his own longstanding depression.

"You can only take so much when you're sleep-deprived, exhausted, and juggling other people's problems like balls on fire for so many nights in a row," he said.

CIDRAP News
Friday, June 25, 2021

ACIP approves dengue vaccine for endemic areas, tweaks flu vaccine advice

The vaccine advisory group to the Centers for Disease Control and Prevention (CDC) yesterday unanimously voted to recommend Sanofi's dengue vaccine (Dengvaxia) for children ages 9 to 16 years who live in areas such as Puerto Rico where the disease is endemic.

The vaccine is given in three doses and requires a test to confirm that a child has had a previous dengue infection. Vaccination in someone who has never been exposed to dengue before can lead to a more severe future infection through a phenomenon called antibody-dependent enhancement.

An Advisory Committee on Immunization Practices (ACIP) working group has been studying the issue and drafted the recommendation, which the whole group discussed and voted on yesterday, according to Stat. The experts acknowledged that the rollout of the vaccine would be challenging, owin to lab testing before vaccination. Also, members discussed challenges regarding provider access to tests to assess previous exposure to dengue and to ensure that kids receive all three doses. However, the group was swayed by the benefits and manageable risks.

The Food and Drug Administration (FDA) approved Dengvaxia in May 2019 for children ages 9 to 16 who have had at least one lab-confirmed dengue infection.

In separate discussions, ACIP fine-tuned its flu vaccine recommendations, according to American Academy of Pediatrics (AAP) News. The committee green-lighted co-administration with COVID-19 vaccines and added guidance about flu vaccine timing for certain groups--such as for children ideally by the end of October. Also, ACIP said nonpregnant adults should avoid immunization in July and August because of concerns over waning immunity, and women in their third trimester should be vaccinated as soon as the vaccine is available to protect their babies.

On another topic, the group said children receiving pre-exposure rabies vaccination can receive two rather than three doses, similar to a change recommended earlier this year for adults.

AP Maine
Sunday, June 27, 2021

CDC Gives Maine $7M To Prep For Future Public Health Crises

PORTLAND, Maine (AP) -- The federal government has given Maine a $7 million boost to help prepare for another public health crisis.

Republican Sen. Susan Collins and independent Sen. Angus King said the Maine Department of Health and Human Services has received the money from the U.S. Centers for Disease Control and Prevention. About $1.8 million of the money is for preventing and controlling emerging diseases and the rest is for preparing and responding to public health emergencies.

The senators said the state "must not lose sight of other public health initiatives that protect the health and safety of the community" while it continues responding to the coronavirus pandemic.

SILive.com
Monday, June 28, 2021

CDC: `Don't kiss or snuggle the birds;' Salmonella outbreak linked to more than 400 infections

By Joseph Ostapiuk | jostapiuk@siadvance.com

STATEN ISLAND, N.Y. -- The Centers for Disease Control and Prevention (CDC) said a salmonella outbreak linked to backyard poultry has now sickened nearly 500 people in the U.S.

The outbreak has caused 474 illnesses in 46 states, and more than 100 hospitalizations, the CDC announced late last week. One death has been reported in Indiana. Data from the agency shows that 15 people in New York have been sickened by salmonella germs.

Since May 20, the CDC said an additional 311 illnesses have been reported, and the agency said it is likely that the actual number of sick people is much higher, since many people recover without medical care and are not tested for salmonella.

About one-third of sick people are young children under the age of five, the CDC said.

Currently, backyard poultry is considered the "likely source" of the outbreak. Even if backyard poultry look clean, salmonella germs can spread in areas where the animals live and roam -- easily spreading from their environment to humans through physical contact.

To avoid infection, the CDC recommends washing your hands for 20 seconds after touching poultry or poultry supplies, and to also avoid letting children under the age of five touch the birds.

"Don't kiss or snuggle the birds, as this can spread germs to your mouth and make you sick," the CDC said.

Salmonella can cause a multi-day illness that includes diarrhea, fever and stomach cramps. Children under five and adults over the age of 65 are more susceptible to severe salmonella illness.

CIDRAP News
Friday, June 25, 2021

Backyard poultry Salmonella outbreak grows to 474 cases, 1 death

A US Salmonella outbreak linked to backyard poultry has grown by 311 cases, to 474 illnesses, and the CDC has reported the first outbreak death, according to a CDC update yesterday.

Three more states are affected (46 total) and a new serotype has been added (Salmonella Mbandaka) since the CDC's first notice of the outbreak on May 20, and 41% of isolates have shown some degree of antibiotic resistance, the agency noted. Of 334 people with information available, 103 (31%) have been hospitalized, up from 34 on May 20. An Indiana patient has died.

Illness-onset dates range from Dec 15, 2020, to Jun 4, 2021, and 58% of case-patients are female. Patient ages range from less than 1 to 97 years, with a median age of 31, and 139 patients (30%) are children younger than 5 years.

Of 271 people interviewed, 209 (77%) reported contact with backyard poultry before getting sick.

"Epidemiologic and laboratory data show that contact with backyard poultry is making people sick," the CDC says. "The true number of sick people in an outbreak is likely much higher than the number reported, and the outbreak may not be limited to the states with known illnesses."

The agency recommends no close contact, such as snuggling, with backyard poultry, and to buy the animals from hatcheries that take steps to reduce Salmonella. Those who raise backyard birds should always wash their hands with soap and water immediately after touching poultry, their eggs, or their surroundings.

Newsweek.com
Sunday, June 27, 2021

Whole Foods, Safeway and Other Stores Recall Shrimp for Salmonella

Contamination

By Scott McDonald

Several lots of frozen cooked shrimp have been recalled nationwide at major grocers, including Whole Foods, Safeway, Meijer and Hannaford. The U.S. Food and Drug Administration (FDA) stated the recalled shrimp has been found to contain Salmonella contamination.

The eight recalled brands include Chicken of the Sea and the supermarket house brands.

The Centers for Disease Control and Prevention (CDC) stated that six people have been infected with the contamination so far--four in Nevada and two more in Arizona. There were two hospitalizations and zero deaths. The last onset illness was April 25.

All recalled shrimp were distributed by Avanti Frozen Foods of India, and the affected lots were distributed between December 2020 and February 2021.

Salmonella was first found in an import sample during January, the FDA stated. Though that particular sample was destroyed in March, illnesses began sprouting up in April from the contaminated lots sold three months earlier.

"As of (Friday, June 25), there are six clinical isolates from ill people that are genetic matches to the salmonella collected from the import sample. Five of the six ill people were interviewed to determine the foods they ate before becoming sick, and all five ill people report eating shrimp," the FDA stated.

The shrimp that caused the reported sicknesses have already passed their expiration dates and have been pulled from the shelves. Here are the affected products still on the shelves and their lot numbers:

* Censea, tail off -- 2-pound pouch; Codes 140313D, 140314D, 140315D, 140316D; expiration dates 5/7/2022 -- 5/10/2022.
* Chicken of the Sea, tail on -- 16-ounce tray; Codes 91AS/02UN/216 and 91AS/03UN/217; expiration dates 5/1/2022 and 5/2/2022.
* Honest Catch, tail on -- 1-pound pouch; Code 3150-GFF; expiration date 11/9/2022.
* CWNO, tail on -- 7-pound pouch; Codes 91AS/06UN/220D, 91AS/07UN/221C, 91AS/23HN/206B, 91AS/24HN/207; expiration dates 1/23/2022; 1/24/2022; 2/6/2022; and 2/7/2022.
* Hannaford, tail on -- 1-pound pouch; Codes. AVF 30920 EF and AVF 31020 EF; expiration dates 10/25/2022 and 10/26/2022.
* Waterfront Bistro (Safeway house brand), tail on -- 16-ounce tray; Codes 20305 and 20306; expiration dates 10/30/2022 and 10/31/2022.
* Open Acres, tail on -- 1-pound pouch; Code 02572 0307 11 and 02572 0308 11; expiration dates 11/2/2022 and 11/3/2022.
* 365 (Whole Foods store brand), tail on -- 2-pound pouch; Codes 91AS/29HN/212B and 91AS/30HN/213; expiration dates 4/29/2022 and 4/30/2022.
* Meijer, tail on -- 1-pound pouch; Codes 29720 49982, 29820 49982, 30220 50736, 30320 50736, 30520 49486, 30620 49486, 30920 50737,

31020 50737; expiration dates 10/22/2022, 10/23/2022, 10/27/2022, 10/28/2022, 10/30/2022, 10/31/2022, 11/3/2022, 11/4/2022.

Healthy people who come in contact with Salmonella could experience nausea, vomiting, diarrhea or bloody diarrhea, abdominal cramping and fever. More serious problems could include arterial infections, endocarditis, arthritis, muscle pain, eye irritation, and urinary tract symptoms.

Should any person have these symptoms after handling the product, they should contact their health care provider.

The CDC says that roughly 1.3 million people get sick on an annual basis from Salmonella contamination.. There are about 26,500 hospitalizations and 420 deaths annually.

CNN.com
Saturday, June 26, 2021

Avanti Frozen Foods recalls several shrimp products linked to salmonella outbreak

By Rachel Trent, CNN

(CNN)If you eat frozen cooked shrimp at home, you may want to check your freezer.

A salmonella outbreak has been linked to certain frozen cooked shrimp products distributed nationwide, according to the US Centers for Disease Control and Prevention.

Salmonella was found in a sample of Avanti Frozen Foods' shrimp collected as part of the FDA's Imported Seafood Compliance Program, the CDC said.

In a statement on the FDA website, Avanti said that out of "an abundance of caution" it recalled some of its frozen cooked shrimp products sold under the brand names 365, Censea, Chicken of the Sea, CWNO, Hannaford, Honest Catch, Meijer, Open Acres and Waterfront Bistro.

Six people got sick from this outbreak and two of those were hospitalized, according to the CDC. The agency says the illnesses happened in Nevada and Arizona, but the outbreak may have affected other states.

The products in question were distributed from late December to late February.

Only products bearing certain codes are affected by the recall. Anyone who has purchased one of those can return them to where they bought them for a refund.

Salmonella can cause fever, diarrhea, nausea, vomiting and abdominal

pain, the FDA said. The organism can cause serious and sometimes deadly infections in young children, frail or elderly people, and others with weakened immune systems.

The CDC said symptoms usually start six hours to six days after swallowing the bacteria and most people recover without treatment after four to seven days.

Reuters
Sunday, June 27, 2021

UPDATE 1-Competing events make their marks on LGBTQ+ Pride Day in New York

By Peter Szekely

(Recasts to reflect that events have begun, adds details and comments)

NEW YORK, June 27 (Reuters) - For the second consecutive year, the lingering pandemic consigned New York's annual Pride march to the virtual world on Sunday, even as its alter-ego, the Queer Liberation March, took its edgier message through the streets of Manhattan.

The NYC Pride march, the city's marquee LGBTQ+ event now in its 51st year, became a made-for-TV production as a cautionary measure to prevent coronavirus infections, which have dropped sharply as the number of people vaccinated has grown.

Only a small number of guests were invited to the group's three-block areas where floats and musical acts paraded for the cameras, but organizer Sue Doster said "something in the millions" of viewers were expected to tune in.

Guests included Brandon Wolf, a survivor of the June 2016 mass shooting at the Pulse, a gay nightclub in Orlando, Florida, who has since become an advocate for LGBTQ rights legislation.

"Six days after the shooting, we had a funeral service for my best friend and I made a promise to him that day that I would never stop fighting for a world that he would be proud of," he told ABC, which aired the event.

"We've made incredible progress in equality across the country, but trans people are under attack," he added.

HIV/AIDS expert Dr Demetre Daskalakis, one of the event's grand marshals, urged all LGBTQ+ community members to get tested frequently for the virus.

"At the end of the day, HIV is just a virus, and we have the ability to prevent it and to treat it," said Daskalakis, who is director of the Division of HIV/AIDS Prevention at the Centers for Disease Control and Prevention.

MARCHING FOR 'LIBERATION AND JUSTICE'

Meanwhile, thousands of people organized by the Reclaim Pride Coalition, whose parade began as a protest to the Pride march two years ago, marched more than 30 blocks down New York's Seventh Avenue with rainbow flags and signs that included "Liberation and Justice."

Coalition cofounder Jay W. Walker said the group was hoping to draw up to 70,000 marchers.

Under sunny skies with muggy conditions that felt like 90 degrees Fahrenheit (32 degrees Celsius), a racially mixed crowd of men and women chanted "No Justice, No Peace," and other slogans, some critical of the New York Police Department.

After linking last year's message to the Black Lives Matter movement, Walker said this year's theme is returning to the coalition's standard: "None of us are free until all of us are free."

Although the group had urged marchers to wear masks, few did. Last year's march produced no discernable spike in new coronavirus cases, he said.

Both events commemorate the June 28, 1969, uprising at the Stonewall Inn, a gay bar in Manhattan's Greenwich Village, when patrons fought back during a police raid. The defiant stand gave birth to the modern LGBTQ rights movement.

The two groups have differed over their policies on police participation in their events, which the Reclaim Pride Coalition opposes. But Heritage of Pride last month also decided to bar uniformed police officers from its future parades. Doster said many of its Black, brown and trans members feel threatened by their presence. (Reporting by Peter Szekely in New York Editing by Grant McCool and Matthew Lewis)

AP West Virginia
Saturday, June 26, 2021

HIV SOS: Action Sought For Spike In Cases In West Virginia

By JOHN RABY
Associated Press

CHARLESTON, W.Va. (AP) -- Dozens of volunteers formed the letters "HIV SOS" at a health event Saturday as activists seek a public health emergency declaration in a city with one of the nation's highest spikes of such cases.

Kanawha County, which includes Charleston and has 178,000 residents, had two intravenous drug-related HIV cases in 2018. The number grew to 15 in 2019 and 39 last year, according to state data. There have been 14 such cases so far in 2021.

After volunteers wearing red T-shirts formed the plea for help along the Kanawha River near downtown Charleston, Joe Solomon, co-founder of

the nonprofit group Solutions Oriented Addiction Response, called on the City Council and Mayor Amy Shuler Goodwin to act on the HIV crisis and overdoses from prescription pain pills.

"In Charleston and Kanawha County, there's a family butchered by the overdose crisis every other day," Solomon said. "All we're asking is for (them) to take one day to declare a public health emergency. We need to treat this like the emergency that it is."

Earlier this year, Dr. Demetre Daskalakis, the CDC's chief of HIV prevention at the Centers for Disease Control and Prevention, called Kanawha County's outbreak "the most concerning in the United States." He warned it could take years to address the surge and that the case count possibly "represents the tip of the iceberg."

Earlier this week the CDC presented preliminary findings of an investigatio n that showed emergency departments and inpatient medical personnel in Kanawha County rarely conducted HIV testing on intravenous drug users.

Republican Gov. Jim Justice in April signed a bill to introduce more stringent requirements to needle exchange programs like those offered by Solomon's group. The move came over the objections of critics who said it would restrict access to clean needles amid the spike in HIV cases.

The bill requires licenses for syringe collection and distribution programs. Operators would have to offer an array of health outreach services, including overdose prevention education and substance abuse treatment program referrals. Participants also must show an identification card to get a syringe. Advocates view the regulations as onerous.

The American Civil Liberties Union on Friday filed a lawsuit challenging the new law.

AP West Virginia
Friday, June 25, 2021

ACLU In West Virginia Sues Over Needle Exchange Law

CHARLESTON, W.Va. (AP) -- The American Civil Liberties Union of West Virginia on Friday filed a lawsuit opposing a law that would instate stringent requirements on needle exchange programs in the state.

Republican Gov. Jim Justice signed the bill in April over the objections of critics who said it will restrict access to clean needles amid a spike in HIV cases.

The bill requires licenses for syringe collection and distribution programs. Operators would have to offer an array of health outreach services, including overdose prevention education and substance abuse treatment program referrals. Participants also must show an identification card to get a syringe. Advocates see the regulations as

onerous.

Supporters said the legislation would help those addicted to opioids get connected to health care services fighting substance abuse. Some Republicans lawmakers had said the changes were necessary because some needle exchange programs were "operating so irresponsibly" that they were causing syringe litter.

The ACLU-WV went to court to prevent it from taking effect on July 9.

The group called it "one of the most restrictive state laws governing syringe exchange services in the nation" and that it would likely lead to more HIV cases and the spread of other bloodborne illnesses.

The restrictions "will cost lives and deprive West Virginians of numerous constitutional rights, including due process and equal protection among others," ACLU-WV legal director Loree Stark said in a statement. "The bill should be declared unconstitutional and stopped."

The governor's office did not return an email seeking comment.

The law would take effect amid one of the nation's highest spikes in HIV cases related to intravenous drug use. The surge, clustered primarily around the capital of Charleston and the city of Huntington, is being attributed at least in part to the cancellation in 2018 of a needle exchange program.

It led to an investigation by the Centers for Disease Control and Prevention that this week found emergency departments and inpatient medical personnel rarely conducted HIV testing on intravenous drug users in Kanawha County.

Previously, city leaders and first responders complained that the program in Kanawha County led to an increase in needles being left in public places and abandoned buildings, and it was shut down.

The CDC describes syringe programs as "safe, effective, and cost-saving."

New York Times
Sunday, June 27, 2021, page A25

Johnson & Johnson to Pay $230 Million as Part of Exit From Opioid Industry

The settlement agreement came just days before opening arguments in a sweeping trial of several defendants, including the company.

By Sarah Maslin Nir

Johnson & Johnson will pay New York State more than $230 million in a settlement that also ensures the company will permanently stay out of the opioid business in the United States, the state attorney general's office announced on Saturday.

The settlement comes at a time when the opioid industry is facing over 3,000 lawsuits across the nation for its contribution to an epidemic of prescription and street opioid abuse that has killed more than 800,000 Americans in the last 20 years, according to the Centers for Disease Control and Prevention.

And it came just days before opening arguments in a sweeping New York trial in which the company was to be among the defendants. That trial will be the first of its kind to go before a jury, and the first to target the entire opioid supply chain, from the drugmakers who manufactured the pills to the distributors that supplied them to a pharmacy chain that filled prescriptions for them.

"The opioid epidemic has wreaked havoc on countless communities across New York State and the rest of the nation, leaving millions still addicted to dangerous and deadly opioids," Attorney General Letitia James said in a statement. "Johnson & Johnson helped fuel this fire, but today they're committing to leaving the opioid business -- not only in New York, but across the entire country."

In a statement, Johnson & Johnson said that the settlement was not an admission of liability or wrongdoing and that "the company's actions relating to the marketing and promotion of important prescription pain medications were appropriate and responsible."

It has not sold opioids in the United States since last year, when it ceased production of its last opioid product; and it stopped supplying opioid ingredients to other manufacturers in 2016.

Johnson & Johnson is the parent company of Janssen Pharmaceutical Companies, one of the defendants in the New York trial that will be removed from the case because of the settlement. The company will also pay an additional $33 million as reimbursement for New York's attorney fees and costs. The payments for the total will be made over nine years.

The money is not intended to compensate people harmed by the opioid crisis, but rather for what is known as abatement, mitigating harm and preventing future crises with things like education and addiction treatment programs.

The funds will be distributed to the counties subject to an allocation agreement with the state that is currently being finalized, according to Jayne Conroy, lawyer with Simmons Hanly Conroy, who is representing Suffolk County in the case.

The sprawling opioid case about to begin in New York was filed by the attorney general and by Nassau and Suffolk Counties on Long Island, and is being argued jointly. It includes claims that the companies, like Janssen, misled the public by initially denying the drugs were highly addictive, and aggressively marketed them as such, ignoring warnings of abuse as they chased profits.

The drugs that Janssen developed included a fentanyl patch and a tablet that was crush-resistant, marketed under names like Duragesic and Nucynta, which, according to Johnson & Johnson, accounted for less than

one percent of total opioid prescriptions in the United States. It stopped marketing its opioids in 2016 in the United States and later discontinued the fentanyl patch. In 2020, it ceased production of the pill in the United States as well.

For years, Johnson & Johnson had supplied 60 percent of the ingredients that make opioids to companies that used them to make drugs like Oxycodone, contracting with poppy growers in Tasmania. In 2016, they sold the business that supplied the materials.

Johnson & Johnson has struggled under waves of bad publicity. It suffered a defeat in an opioid trial in 2019 when an Oklahoma judge ordered it to pay the state $465 million for its role in the public nuisance created by opioid addiction. It has been ordered to pay millions in courts that have found products like its talcum powder and hip implants to be harmful. Most recently, its coronavirus vaccine has been plagued by a troubled rollout.

The one-shot vaccine was initially seen as a vital tool in combating Covid-19, the disease caused by the coronavirus. But a host of concerns with production and the drug itself has seen the company's product account for just about 12 million of the more than 320 million doses administered in the United States so far, according to C.D.C. data.

In April, federal health officials paused use of the Johnson & Johnson vaccine after cases of a rare blood-clotting disorder emerged as a side effect. In June, a mix-up in a Baltimore factory resulted in the government ordering the disposal of 60 million potentially contaminated vaccine doses.

The exit of Johnson & Johnson from the New York case means that two of the country's biggest drugmakers will now be absent from the trial when opening arguments begin on Tuesday. Purdue Pharma, the maker of OxyContin, owned by members of the billionaire Sackler family and the company most publicly linked to the opioid epidemic, is also no longer standing trial.

Though initially named in the case, as were some individual Sacklers, Purdue filed for bankruptcy nearly two years ago as it faced thousands of opioid-related lawsuits. The bankruptcy process has paused cases against the drugmaker and the Sacklers.

In addition, in the weeks before opening arguments were to be made before a six-person jury and a New York Supreme Court justice, Jerry Garguilo, three of the four pharmacy chains -- Walmart Inc., Rite Aid Corp. and CVS -- were severed from the case; one of them, CVS, confirmed it had reached a settlement agreement with the counties, the terms of which are not yet final and public. Walmart and Rite Aid did not respond to emails requesting comment.

Walgreens remains one of the defendants that will face a jury next week.

Ms. Conroy, who is representing Suffolk County, cautioned that Saturday's announcement did not mark the end of the case. "While this settlement is good news, there still remains a crucially important

trial starting next week," she said in a statement.

"We remain focused on ensuring the other defendants who played a major role in creating the opioid crisis are held accountable for their actions," she said.

Jan Hoffman contributed reporting.

CNN.com
Saturday, June 26, 2021

Johnson & Johnson settles New York opioid suit in $230 million deal

By Danielle Wiener-Bronner, CNN Business

New York (CNN Business)Johnson & Johnson has agreed to a $230 million settlement with New York state, resolving complaints from the state's attorney general over the pharmaceutical company's role in the opioid epidemic.

"Johnson & Johnson helped fuel this fire," New York Attorney General Letitia James said in a statement Saturday. "While no amount of money will ever compensate for the thousands who lost their lives or became addicted to opioids across our state ... these funds will be used to prevent any future devastation."

The settlement money will go toward opioid education, prevention and treatment, James added. Johnson & Johnson is set to pay out the funds over the course of nine years. The company may also be responsible for another $30 million if New York passes a law that creates an opioid settlement fund.

In a statement, Johnson & Johnson (JNJ) said that "the settlement is not an admission of liability or wrongdoing," adding that it "remains committed to providing certainty for involved parties and critical assistance for communities in need."

The settlement also prevents Johnson & Johnson from manufacturing or selling opioids in the state, or promoting opioids or opioid-related products. The company had already decided to discontinue the production and sale of pain medication in the United States last year, a spokesperson said.

About 247,000 people died from overdoses involving prescription opioids in the United States from 1999 to 2019, according to the Centers for Disease Control and Prevention. The crisis has had a financial toll, as well -- a notice of claim filed last summer in bankruptcy court by nearly every US state and many territories said that opioid manufacturers have cost the American economy $2.15 trillion.

A New York lawsuit against the makers and distributors of opioids is going to trial next week. Johnson & Johnson was set to be a defendant but will no longer be a part of the trial due to the settlement agreement.

News of the settlement comes as lawsuits against major pharmaceutical companies over their role in the opioid epidemic play out in court. In May, a landmark trial involving three major prescription opioid distributors began in federal court in West Virginia. California's trial against opioid manufacturers began in April.

-- CNN's Lauren del Valle contributed to this report.

Reuters
Saturday, June 26, 2021

UPDATE 1-J&J to pay $263 mln in New York opioid settlements, avoids trial

By Jonathan Stempel

(Adds details of settlements, upcoming trial, New York attorney general comment, background)

NEW YORK, June 26 (Reuters) - Johnson & Johnson said on Saturday it will pay $263 million to resolve claims it fueled an opioid epidemic in New York state and two of its largest counties.

The settlements remove the drugmaker from a jury trial scheduled to begin on Tuesday on Long Island, where several big opioid makers and distributors are also defendants.

Johnson & Johnson did not admit liability or wrongdoing in settling with New York state, and with Nassau and Suffolk counties. The $229.9 million state settlement also calls for J&J to stop selling the painkillers nationwide.

"The opioid epidemic has wreaked havoc" across the nation, New York Attorney General Letitia James said in a statement. "Johnson & Johnson helped fuel this fire."

She said her focus remains "getting funds into communities devastated by opioids as quickly as possible."

J&J said the settlements were consistent with its prior agreement to pay $5 billion to settle opioid claims by states, cities, counties and tribal governments nationwide.

The healthcare company and the largest U.S. drug distributors - AmerisourceBergen Corp, Cardinal Health Inc and McKesson Corp - have proposed paying a combined $26 billion to end thousands of opioid lawsuits.

J&J has also been appealing an Oklahoma judge's 2019 ruling that the New Brunswick, New Jersey-based company pay that state $465 million for its deceptive marketing of opioids.

Tuesday's opioids trial is one of several scheduled for this year, with others underway in California and West Virginia.

Drugmakers AbbVie Inc and Teva Pharmaceutical Industries Ltd and several distributors are among the defendants. Pharmacy chain Walgreens Boots Alliance Inc is also a defendant, though it was sued only by the counties.

Walmart Inc, Rite Aid Corp and CVS Health Corp were severed from the trial during jury selection. CVS has settled with Nassau and Suffolk counties. Settlement terms have not been disclosed.

The U.S. Centers for Disease Control and Prevention has said nearly 500,000 people died from opioid overdoses from 1999 to 2019. (Reporting by Jonathan Stempel in New York; Additional reporting by Nate Raymond in Boston; Editing by Bill Berkrot)

Los Angeles Times
Monday, June 28, 2021, page A2

For Native Americans, clean water is rare

Crumbling pipes and faulty sanitation systems leave many on reservations struggling for access

By Celina Tebor

When the clean water system failed last week at the Warm Springs Reservation in Oregon, thousands of residents relied on members of nearby communities to come to their aid with bottled water.

It was not the first time clean water had been difficult to find at Warm Springs, two hours southeast of Portland, or at many other Native American reservations across the United States.

The nonprofit U.S. Water Alliance says 58 out of every 1,000 Native American households lack access to indoor plumbing.

Many Native American communities don't have access to clean water because of faulty, outdated or nonexistent pipes or sanitation systems that result in residents being forced to use bottled water or to boil water to kill viruses, bacteria and parasites.

Sen. Ron Wyden (D-Ore.) in February introduced a bill aimed at funding facilities for drinking water and sanitation in tribal communities. The bill calls for the Environmental Protection Agency to connect, expand or repair public water systems on reservations, at a cost of about $150 million by 2026.

" 'Boil water' notices and crumbling pipes are not acceptable," Wyden said during Interior Secretary Deb Haaland's nomination hearing. "Congress must do more to bring urgently needed resources to build sustainable tribal water infrastructure that has been neglected for far too long."

About 130,150 out of 409,535 homes of Native Americans surveyed by the

government organization Indian Health Service needed sanitation facility improvements involving water, sewer or solid waste systems at the end of fiscal year 2018. The cost to improve those systems is estimated at $2.67 billion, according to the IHS.

In the 1960s, the federal government funded sanitation programs for tribes after the general American public began to become aware of poor living conditions on reservations.

The Sanitation Facilities Construction Act, passed in 1959, led to a sharp decrease in gastrointestinal and infectious respiratory disease in both Native American infants and white infants who lived near reservations, according to a Journal of Public Economics study.

According to the U.S. Water Alliance, Native American households are 19 times more likely than white households to lack indoor plumbing. Black and Latino households are twice as likely as white households to lack indoor plumbing.

Federal funding for reservations is not meeting needs, said Randall Akee, a UCLA professor of public policy and American Indian studies and chair of the university's America Indian Studies Interdepartmental Program.

"It's just woefully underfunded at the federal level, and tribes for a long, long time have not had the resources to fully develop these resources themselves," Akee said. "And frankly, it's a responsibility of the federal government -- a trust responsibility of treaties and hundreds of years of commitments. There has been a failure to fully live up to those commitments."

A problem for tribes across the U.S.

The Hopi tribe in Arizona has up to three times the amount of arsenic in its water that the EPA says is safe to drink. Many Native households in rural Alaska use a 5-gallon bucket as a toilet because they don't have running water. And the Navajo Nation, the biggest reservation in the U.S., faces a diabetes crisis because soda is more accessible and cheaper than clean drinking water.

Bidtah Becker is a member of the Navajo Nation, which spans northeastern Arizona, southeastern Utah and northwestern New Mexico. She helped lead a report on access to clean water for tribes in the Colorado River Basin and has studied its effects on her own community and other tribes. She estimates that 30% to 40% of homes on the Navajo Nation lack piped water.

The federal Centers for Disease Control and Prevention and the Alaska Native Tribal Health Consortium have found links between low water service and respiratory infections. Studies from the CDC, the consortium and the IHS have also found links between a lack of access to clean water and skin and gastric infections.

"The other thing that people often don't think of with access to clean water is that it affects the economics of your community," Becker said. "If you don't have pipes to go to homes, you don't have pipes to go to

laundromats or gas stations or stores. Clean water is integral to creating a healthy economy."

The cost of new infrastructure

Almost one-quarter of Native Americans lived below the poverty level in 2019, and fixing or building water infrastructure isn't cheap, nor is it easy or quick.

The IHS determined that there were 130,153 homes needing sanitation improvements in Native American communities at the end of fiscal year 2018 and identified 1,837 communitywide projects to assist those homes. The agency aims to bring sanitation systems to a level that complies with laws for water supplies and pollution control while requiring only routine maintenance.

About 28% of these projects are considered "infeasible" by the government, because they're too expensive. The IHS estimates the cost of all feasible projects across the country at $985 million.

According to the IHS report, the cost to bring sanitation to this level in Alaska was higher than the cost in every other community combined, at nearly $1.4 billion (for feasible and infeasible projects). Alaska is home to two-thirds of the nation's federally recognized tribes, with 229. Almost 16% of the state's population is American Indian or Alaska Native.

Jackie Qatalina Schaeffer is the community development manager for the tribal health Consortium's Division of Environmental Health and Engineering. Her role at the nonprofit is to work with rural Alaskan tribes, helping them access water and sanitation services.

Communities that don't have those services typically have access to a central watering point consisting of a hose connected to a building that provides showers, utility sinks andsometimes commercial washers and dryers, Qatalina Schaeffer said.

Residents can collect clean drinking water at the watering point, she said. They then haul the water by ATV, snowmobile or hand to their homes. They use either an outhouse or a "honey bucket," a 5-gallon bucket with a lid, as a toilet.

The average rural Alaskan living without piped water uses 3 gallons of water a day for bathing, drinking and cooking, compared with 156 for the average American.

Alaska's rural villages present particular challenges when it comes to providing water and sanitation systems.

"In Alaska, rural is not just 'away from a city,' " Qatalina Schaeffer said. "Rural is disconnected by any road systems. The only access to these communities is via small aircraft."

The average rural Alaskan village has a population of 400 to 500. It costs $40 million to $60 million to implement a communitywide water and sanitation system. While the infrastructure is often funded by the

government, the burden of operation and maintenance falls on the community -- a burden most cannot afford.

Community support when pipes fail

Dan Martinez, emergency manager at Warm Springs, said the reservation's entire water system needs to be overhauled, at a cost of about $40 million. And while the federal and state governments provide emergency funds to the reservation, those often cover only the cost of quick fixes to a water system that he said needs to be rebuilt from the ground up.

While the reservation works toward a long-term solution for its water issues, Warm Springs relies on neighbors to help when the pipes fail.

"We rely on donated water from outside sources, which has been something that's happening on a daily basis," Martinez said. "We rely not so much on the government but on our neighbors and religious groups and donations from outside sources to give out drinking water."

Gilbert Brown, who grew up on the north end of the reservation and now lives in Portland, helps haul water donations from a Portland coffee shop to Warm Springs.

"Last year, the pipes kept breaking, and [the reservation] kept going on boil notices," he said. "People had to come bring water, and I was asked to help. And here we are again."

New York Times
Saturday, June 26, 2021, page A19

Correction

An article on June 20 about the Centers for Disease Control and Prevention misidentified the act of Congress that funded electronic medical-record systems. It was the American Recovery and Reinvestment Act of 2009, not the Affordable Care Act of 2010.

From: (b)(6)
Sent: Tue, 17 Aug 2021 22:52:21 +0000
To: Woodcock, Janet (FDA/CDER);Marks, Peter (FDA/CBER);Hinton, Denise (FDA/OC);asmonto@umich.edu;Walensky, Rochelle (CDC/OD);sean.mccluskie@hhs.gov;Cohn, Amanda (CDC/DDID/NCIRD/OD)
Subject: Reject MRNA Covid Vaccine approvals

To:
Janet Woodcock, Peter Marks, Rear Admiral Denise Hinton, Arnold Monto, Rochelle Walensky, Xavier Becerra, Captain Amanda Cohn
Re: Covid Vaccine
All,
I very strongly oppose the FDA's path to approval for these MRNA vaccines. These vaccines have already caused too much harm to the general population in the way of thousands of deaths and hundreds of thousands harmed with blood clotting and neurological damage, and it also looks like it now promotes antibody dependent enhancement which can make the vaccine much worse.
Please vote NO to this insanity and stop the vaccination program. You will be held accountable for your actions.
If you want to make a difference, support the use of therapeutic drugs that will help humanity, not destroy it.
Thank you,

(b)(6)

From: Bloomquist, Christie
Sent: Fri, 20 Aug 2021 12:08:20 +0000
To: Walensky, Rochelle (CDC/OD)
Subject: Update on AstraZeneca COVID Response
Attachments: AZD7442 PROVENT P3 HLR_FINAL 20082021.docx

Dear Dr. Walensky,

I am pleased to let you know that AstraZeneca announced this morning in the attached press release that the AstraZeneca long-acting antibody combination, AZD7442 has positive high-level results from the PROVENT Phase III pre-exposure prophylaxis trial. The trial showed that AZD7442 achieved a statistically significant reduction in the incidence of symptomatic COVID-19, the trial's primary endpoint.

Below is information from the press release, which is attached:

- AZD7442, a combination of two long-acting antibodies (LAAB), reduced the risk of developing symptomatic COVID-19 by 77% (95% confidence interval (CI): 46,90) compared to placebo.
- The LAAB was well tolerated and preliminary analyses show adverse events were balanced between the placebo and AZD7442 groups.
- AZD7442 was optimized using AstraZeneca's proprietary YTE half-life extension technology, which could afford up to 12 months of protection from COVID-19. The half-life extension more than triples the durability of its action compared to conventional antibodies.
- AZD7442 is delivered by intramuscular injection.
- Preliminary "invitro" findings from investigators at Oxford University and Columbia University demonstrate that AZD7442 neutralizes recent emergent SARS-CoV viral variants, including the Delta variant.
- Regulatory submission preparation is underway for potential emergency use authorization or conditional approval.

Please let me know if you have any questions or would like more information,

Thank you,
Christie

Christie Bloomquist
Vice President, Corporate Affairs, North America

AstraZeneca|North America
801 Pennsylvania Ave, NW; Suite 830
Washington, DC 20004
T: (b)(6)
(b)(6)

News Release

Regulatory News Service

20 August 2021 07:00 BST

AZD7442 PROVENT Phase III prophylaxis trial met primary endpoint in preventing COVID-19

77% reduced risk of developing symptomatic COVID-19

First long-acting antibody combination to prevent COVID-19

Positive high-level results from the PROVENT Phase III pre-exposure prophylaxis trial showed AstraZeneca's AZD7442 achieved a statistically significant reduction in the incidence of symptomatic COVID-19, the trial's primary endpoint.

AZD7442, a combination of two long-acting antibodies (LAAB), reduced the risk of developing symptomatic COVID-19 by 77% (95% confidence interval (CI): 46, 90), compared to placebo. The trial accrued 25 cases of symptomatic COVID-19 at the primary analysis.

There were no cases of severe COVID-19 or COVID-19-related deaths in those treated with AZD7442. In the placebo arm, there were three cases of severe COVID-19, which included two deaths.

AZD7442 is the first antibody combination (non-vaccine) modified to potentially provide long-lasting protection that has demonstrated prevention of COVID-19 in a clinical trial.

The trial included 5,197 participants in a 2:1 randomisation AZD7442 to placebo. The primary analysis was based on 5,172 participants who did not have SARS-CoV-2 infection at baseline. More than 75% of participants had co-morbidities, which include conditions that have been reported to cause a reduced immune response to vaccination.

The LAAB was well tolerated and preliminary analyses show adverse events were balanced between the placebo and AZD7442 groups.

Myron J. Levin, MD, Professor of Pediatrics and Medicine, University of Colorado School of Medicine, US, and principal investigator on the trial, said: “The PROVENT data show that one dose of AZD7442, delivered in a convenient intramuscular form, can quickly and effectively prevent symptomatic COVID-19. With these exciting results, AZD7442 could be an important tool in our arsenal to help people who may need more than a vaccine to return to their normal lives.”

Mene Pangalos, Executive Vice President, BioPharmaceuticals R&D, said: “We need additional approaches for individuals who are not adequately protected by COVID-19 vaccines. We are very encouraged by these efficacy and safety data in high-risk people, showing our long-acting antibody combination has the potential to protect from symptomatic and severe disease, alongside vaccines. We look forward to sharing further data from the AZD7442 Phase III clinical trial programme later this year.”

AZD7442 was optimised using AstraZeneca's proprietary YTE half-life extension technology, which could afford up to 12 months of protection from COVID-19, and is delivered by intramuscular injection.

Preliminary 'in vitro' findings from investigators at Oxford University and Columbia University demonstrate that AZD7442 neutralises recent emergent SARS-CoV-2 viral variants, including the Delta variant.[1-6]

AstraZeneca will prepare regulatory submission of the prophylaxis (PROVENT and STORM CHASER) data to health authorities for potential emergency use authorisation or conditional approval of AZD7442. Full results from PROVENT will be submitted for publication in a peer-reviewed medical journal and presented at a forthcoming medical meeting.

PROVENT

PROVENT is a Phase III, randomised, double-blind, placebo-controlled, multi-centre trial assessing the safety and efficacy of a single 300mg dose of AZD7442 compared to placebo for the prevention of COVID-19. The trial was conducted in 87 sites in the US, UK, Spain, France and Belgium. 5,197 participants were randomised in a 2:1 ratio to receive a single intramuscular (IM) dose of either 300mg of AZD7442 (n = 3460) or saline placebo (n = 1,737), administered in two separate, sequential IM injections.

The primary efficacy endpoint was the first case of any SARS-CoV-2 RT-PCR positive symptomatic illness occurring post dose prior to day 183. Subjects will continue to be followed for 15 months.

Participants were adults 18 years-old and over who would benefit from prevention with the LAAB, defined as having increased risk for inadequate response to active immunisation (predicted poor responders to vaccines or intolerant of vaccine) or having increased risk for SARS-CoV-2 infection, including those whose locations or circumstances put them at appreciable risk of exposure to the SARS-CoV-2 virus. Participants at the time of screening were unvaccinated and had a negative point-of-care SARS-CoV-2 serology test.

Approximately 43% of participants were 60 years and over. In addition, more than 75% had baseline co-morbidities and other characteristics that are associated with an increased risk for severe COVID-19 should they become infected, including those with immunosuppressive disease or taking immunosuppressive medications, diabetes, severe obesity or cardiac disease, chronic obstructive pulmonary disease, chronic kidney and chronic liver disease. Approximately 73% were White/Caucasian, 17% Black/African American, and 3% Asian. Approximately 15% of participants were Hispanic.

AZD7442

AZD7442 is a combination of two LAABs - tixagevimab (AZD8895) and cilgavimab (AZD1061) - derived from B-cells donated by convalescent patients after SARS-CoV-2 virus. Discovered by Vanderbilt University Medical Center and licensed to AstraZeneca in June 2020, the human monoclonal antibodies bind to distinct sites on the SARS-CoV-2 spike protein[7] and were optimised by AstraZeneca with half-life extension and reduced Fc receptor and complement C1q binding. The half-life extension more than triples the durability of its action compared to

conventional antibodies and could afford up to 12 months of protection from COVID-19 following a single administration.[8-11] The reduced Fc receptor binding aims to minimise the risk of antibody-dependent enhancement of disease - a phenomenon in which virus-specific antibodies promote, rather than inhibit, infection and/or disease.[12]

AZD7442 is being studied in a comprehensive clinical trial programme for both prevention and treatment of COVID-19 in over 9,000 participants. Ongoing trials include TACKLE COVID-19[13], a Phase III treatment trial in an outpatient setting and collaborator treatment trials in outpatient and hospitalised settings. AZD7442 is being assessed in both IM and intravenous administration routes.

AZD7442 is being developed with support from the US Government, including federal funds from the Department of Health and Human Services; Office of the Assistant Secretary for Preparedness and Response; Biomedical Advanced Research and Development Authority in partnership with the Department of Defense; Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, under Contract No. W911QY-21-9-0001.

AstraZeneca is working with governments around the world to make AZD7442 accessible to high-risk populations as another valuable option in the fight to end COVID-19, should it prove to be effective and well tolerated.

Data published in *Nature* in July 2020 showed that in preclinical experiments, the LAABs were able to block the binding of the SARS-CoV-2 virus to host cells and protect against infection in cell and animal models of disease.[14]

Under the terms of the licensing agreement with Vanderbilt, AstraZeneca will pay single-digit royalties on future net sales.

AstraZeneca

AstraZeneca (LSE/STO/Nasdaq: AZN) is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialisation of prescription medicines in Oncology, Rare Diseases, and BioPharmaceuticals, including Cardiovascular, Renal & Metabolism, and Respiratory & Immunology. Based in Cambridge, UK, AstraZeneca operates in over 100 countries and its innovative medicines are used by millions of patients worldwide. Please visit astrazeneca.com and follow the Company on Twitter @AstraZeneca.

Contacts

For details on how to contact the Investor Relations Team, please click here. For Media contacts, click here.

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Adrian Kemp
Company Secretary
AstraZeneca PLC

From: (b)(6)
Sent: Tue, 10 Aug 2021 16:58:57 -0400 (EDT)
To: Walensky, Rochelle (CDC/OD)
Subject: Are you complicit in Murder??

Dear Rochelle Walensky,

Below please view the faces of those unfortunate individuals from the US and elsewhere who have paid the ultimate price for getting "vaccinated". This is just a small sampling of those who died or suffered adverse effects from the "vaccines". Think of how their loss has traumatized their loved ones. Anything you do in compliance with your job that would assist in the full FDA approval of these injections makes you complicit in the deaths of thousands more innocent people, including children.

Click on the link below and scroll down to see all the faces of the thousands who have already given their lives, for no reason.
The survival rate of the virus, covid-19, is between 97% and 99.75%, not to mention that there are very effective and cheap medications that have been on the market for decades that have successfully knocked this virus down in a short span of time, which are now inaccessible to the public, and doctors are not able to prescribe them for their patients.
Ivermectin, hydroxychlloroquin, and other effective treatments make taking an experimental "vaccine" unnecessary and highly risky. But why are they disappearing from the market, as well as certain supplements which protect us??

Not to mention the importance of natural immunity which is much better at attacking a host of viruses, rather than just one. Many people have already had covid-19 and recovered and developed antibodies. It is not recommended for them to get this synthetic injection due to the fact that they can get ADE - Antibody Dependent Enhancement which can cause increased severity of the symptoms.

The mRNA injection is a poisonous attack on the population and should be STOPPED immediately.

The purpose of this mRNA technology is to deliver genetic information to parts of your body to overwrite or erase genetic information that's already there. That alone should raise a red flag. We don't yet know if these injections could reverse into DNA

to be transmitted to future generations. The legal implications are beyond comprehension.

Nor do we know what the adjuvants are that have been added to the injection. We have heard about PEG, polyethylene glycol
which is an allergen responsible for causing anaphylaxis (4759 reports as of July 30,2021) and cardiovascular collapse.
We also know that the injection is resulting in onset of autoimmune diseases, cancer and fertility issues.

And we also know that the spike protein is a toxin itself which disrupts the blood-brain barrier raising the risk of neurological damage
and heart damage, which can never be reversed.

The entire trial period for this vaccine has not been completed yet and should not be approved or administered to the population
until it has. It still has 2 more years to go. Not to mention that normally it takes 5-10 years and up to 12.5 years to properly test vaccines.

What you may be a party to is criminal negligence at the least. Imposing or mandating this vaccine on human beings is a violation of the
Nuremberg Code which prohibits medical experimentation on human beings.

Please give careful consideration to what's been said here. Your face or one of your loved ones could be the next ones added to this
tragic hall of fame. Scroll down to see sampling.

https://healthimpactnews.com/2021/uncensored-a-review-of-the-first-8-months-of-the-covid-19-injections-a-memorial-for-those-who-paid-the-ultimate-price/

Sincerely,

(b)(6)