Subject: FW: Director's Brief: Friday May 28, 2021

Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE - DIRECTORS BRIEF 20210528.pdf,

HHS Product Awareness Table Week 5\_31\_2021.docx

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Subject: Director's Brief: Friday May 28, 2021

#### With HHS Awareness document

#### Friday, May 28, 2021

COVID-19 Summary						
	Cumulative Total	Daily	7-Day Daily Average	Change from Prior 7-Day Period		
Cases <sup>2</sup>	33,018,965	23,511	21,627	-22.3%		
Hospital Admissions <sup>3</sup>	2,209,521	3,205	3,122	-10.1%		
Deaths <sup>2</sup>	589,547	577	438	-13.2%		
Test Volume <sup>4</sup>	443,579,898	N/A	909,846	-10.7%		
Test Positivity <sup>4</sup>	7.9%	N/A	2.6%	-12.9%		
Source: HHS Protect						

COVID-19 Vaccinations in the United States <sup>5</sup>						
	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Fully Vaccinated (% Population)	
Overall US	493,339,485	361,250,445	290,724,607	165,718,717 (49.9)	132,769,894 (40.0)	
Population ≥18 Years of Age <sup>6</sup>	N/A	N/A	N/A	159,960,365 (62.0)	130,653,567 (50.6)	
Population ≥65 Years of Age	N/A	N/A	N/A	46,792,923 (85.5)	40,627,181 (74.3)	

Data as of May 27, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID Tracker

<sup>&</sup>lt;sup>1</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

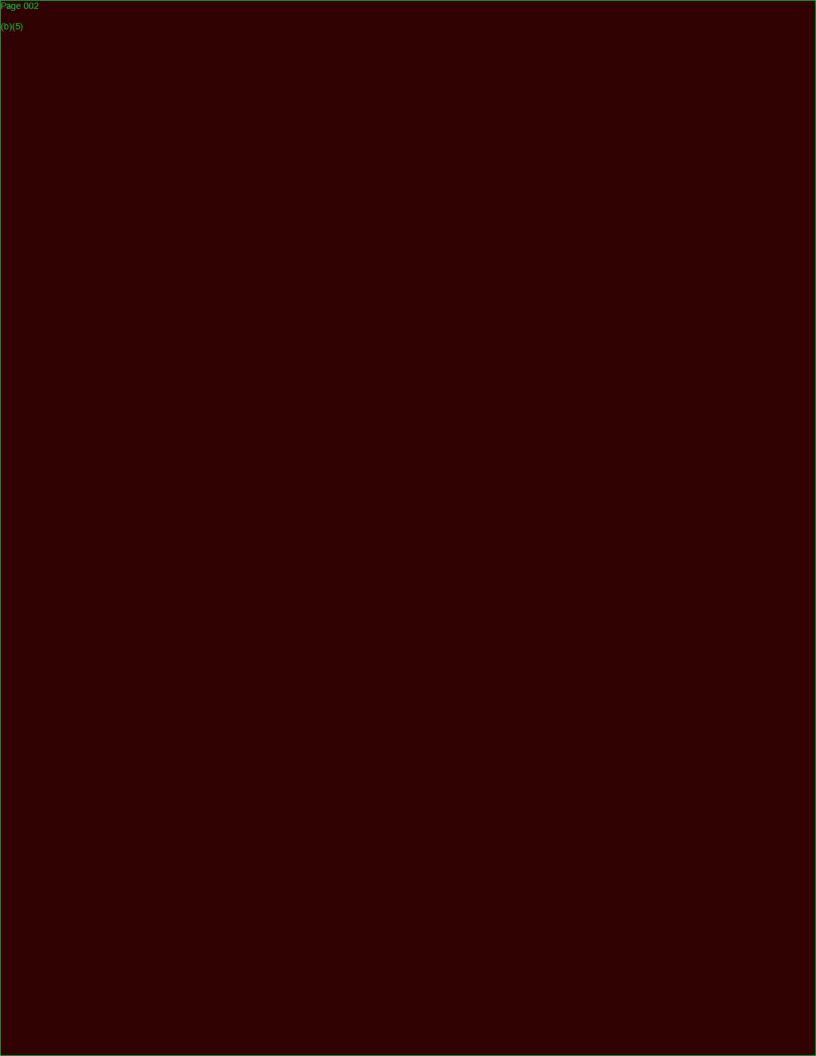
<sup>&</sup>lt;sup>2</sup> Time Period: Jan 22, 2020 – May 26, 2021; confirmed and probable cases and deaths. The total of new cases/deaths in the last 24 hours and 7-day averages do not include historical cases/deaths reported retroactively, 0f 88,582 historical cases reported retroactively, 162 were reported on the most recent submission date; 2,402 in the current week; and 1,918 in the prior week. Of 11,880 historical deaths reported retroactively, 549 were reported on the most recent submission date; 924 in the current week; and 14 in the prior week.

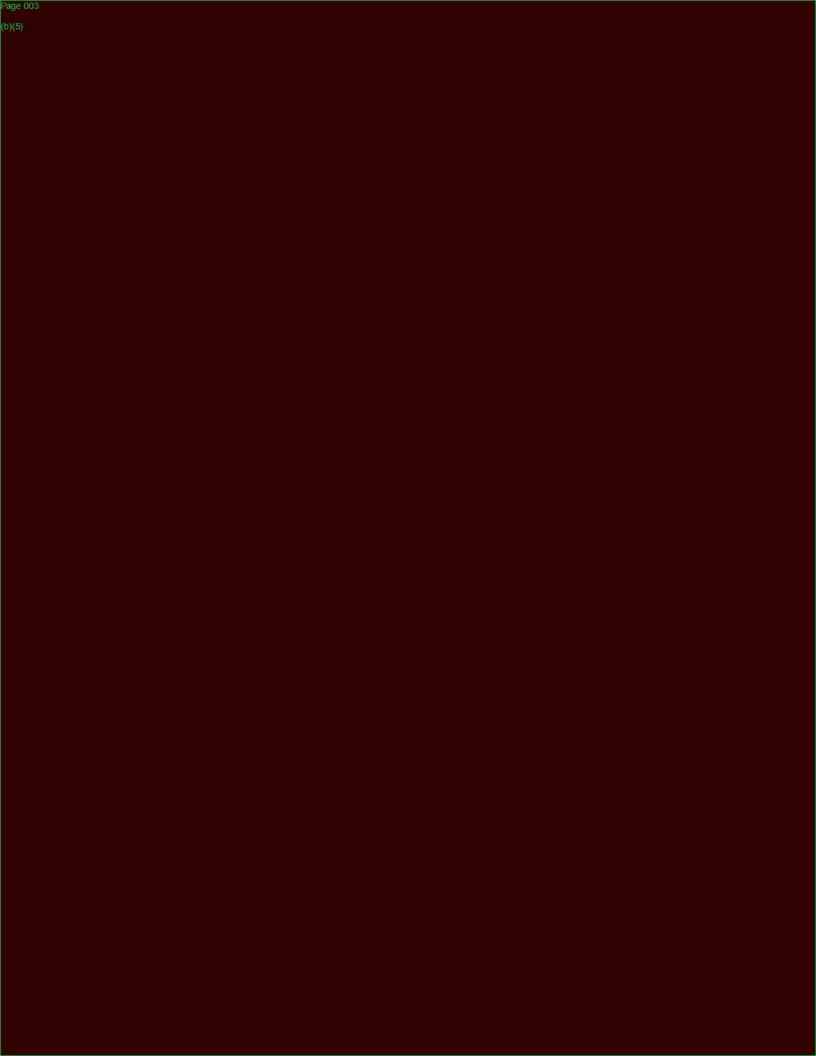
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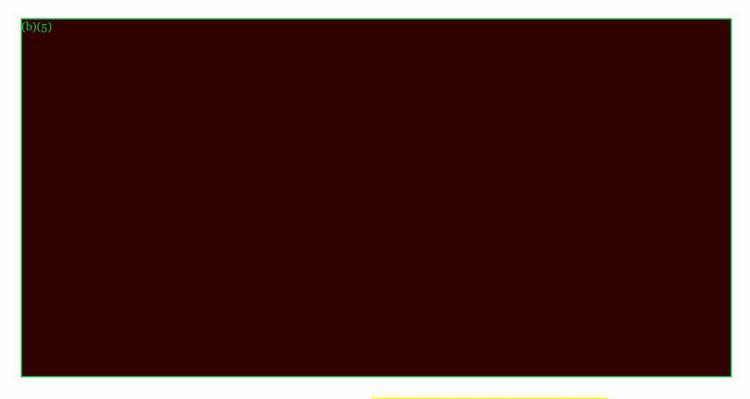
<sup>&</sup>lt;sup>4</sup> Time period: Mar 01, 2020 – May 24, 2021; Time period for test volume 7-day average and percent change: May 07, 2021 – May 20, 2021.

<sup>&</sup>lt;sup>5</sup> Includes data for US States, DC, US Territories, federal entities, and pharmacies (see table on last page for breakdown). Total doses allocated are through Jun 21, 2021.

<sup>&</sup>lt;sup>6</sup> Progress towards 70% coverage of adult (≥18 years) population with at least 1 dose by July 4, 2021: 38 days left until July 4.







- Deaths: The current 7-day moving average of new deaths (438) has decreased 13.2% compared with the previous 7-day moving average (504).\*
  - 589,547 COVID-19 deaths reported as of May 26, 2021, including 577 new deaths reported by 57 jurisdictions.<sup>†</sup>

\*Historical deaths are excluded from the daily new deaths and 7-day average calculations until they are incorporated into the dataset by their applicable date. Of 11,880 historical deaths reported retroactively, 549 were reported on May 26,2021; 924 were reported in the current week; and 14 were reported in the prior week. CDC is working with jurisdictions to obtain relevant dates and incorporate the data as soon as possible.

COVID-19 Deaths: 7-Day Moving Average, Count, and Percent Change for the Last 21 Days

Date	7-Day Average Number of New Deaths	Number of New Deaths	Percent Change in the 7-Day Moving Average of New Deaths	
5/20/2021	489	504	-13.2%	
5/21/2021	483	613	-11.6%	
5/22/2021	478	323	-9.5%	
5/23/2021	460	154	-12.8%	
5/24/2021	450	347	-14.9%	
5/25/2021	436	545	-17.7%	
5/26/2021	438	577	-13.2%	

<sup>§</sup>The 7-day average values are updated as of May 26, 2021, and may differ from values presented on previous director's bullets due to ongoing incorporation of jurisdictions' historical data.

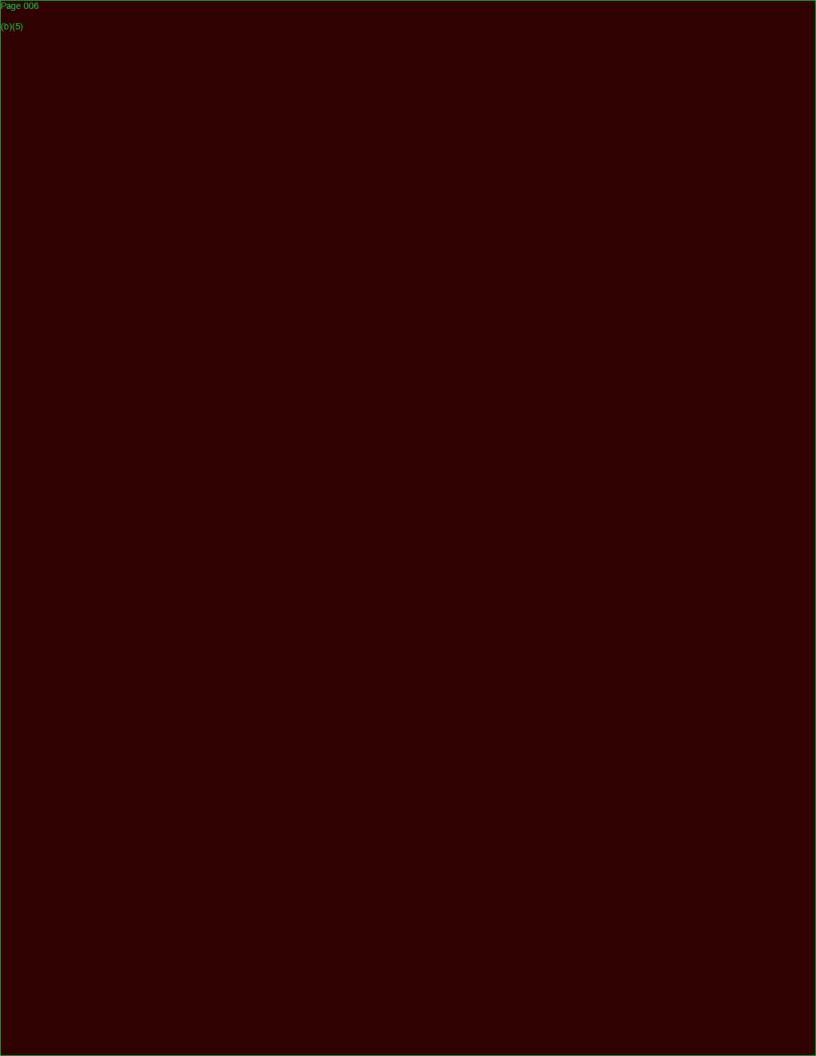
 SARS-CoV-2 National and Regional Variant Proportions: The data below show weighted estimates for specimens collected through May 8, 2021 and NOWCAST\*\* predictions for

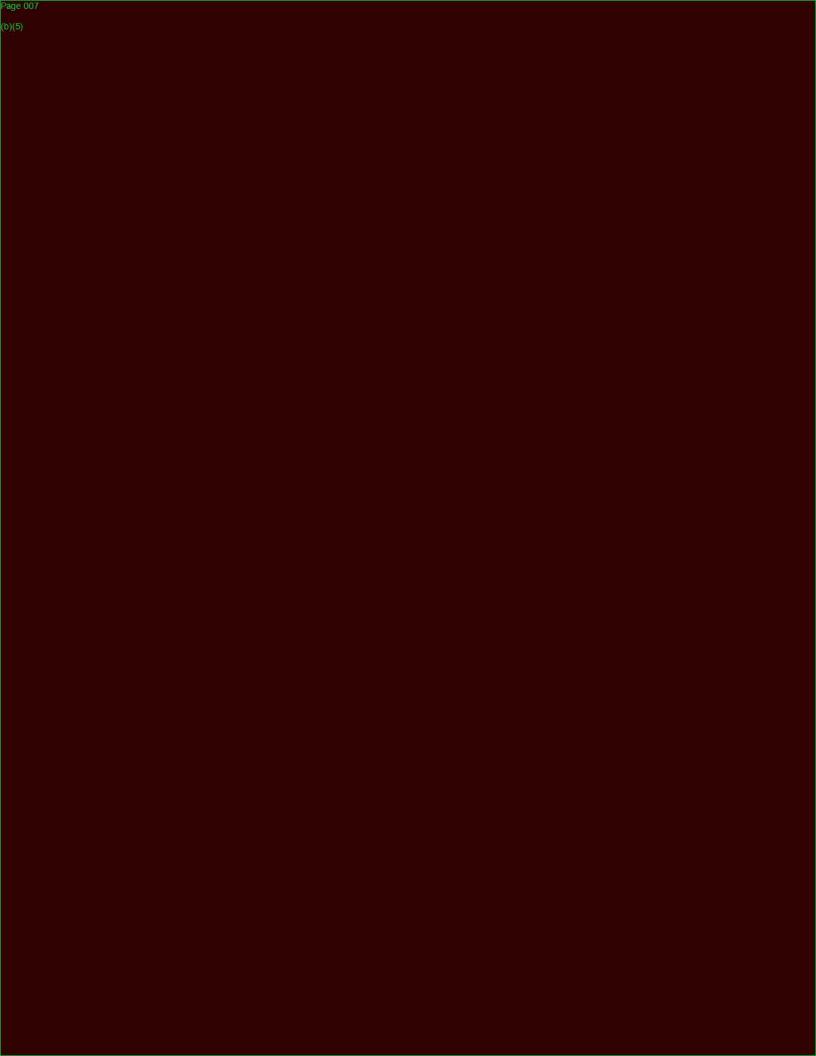
<sup>&</sup>lt;sup>†</sup>Three jurisdictions did not report data for May 26, 2021 (FSM, SC, VI).

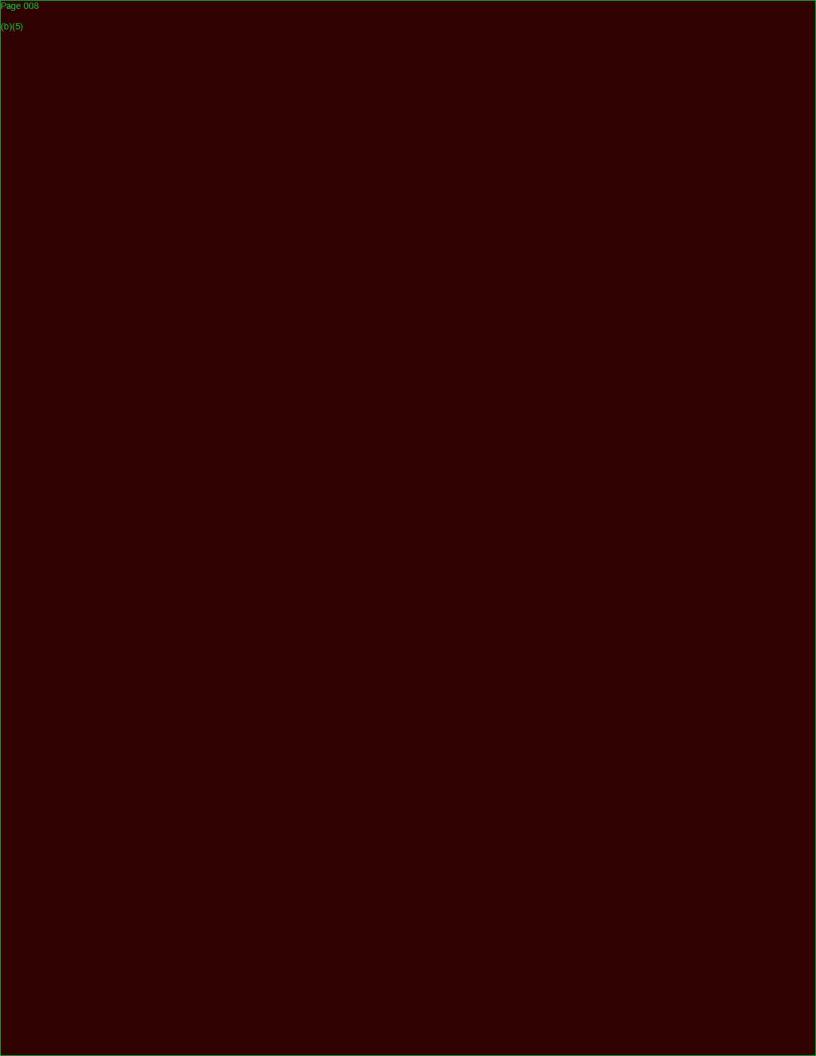
specimens collected during the two-week period ending May 22, 2021. The proportions corresponding to the bar on the far right and are enumerated in the table. Below is a summary of the predictions.

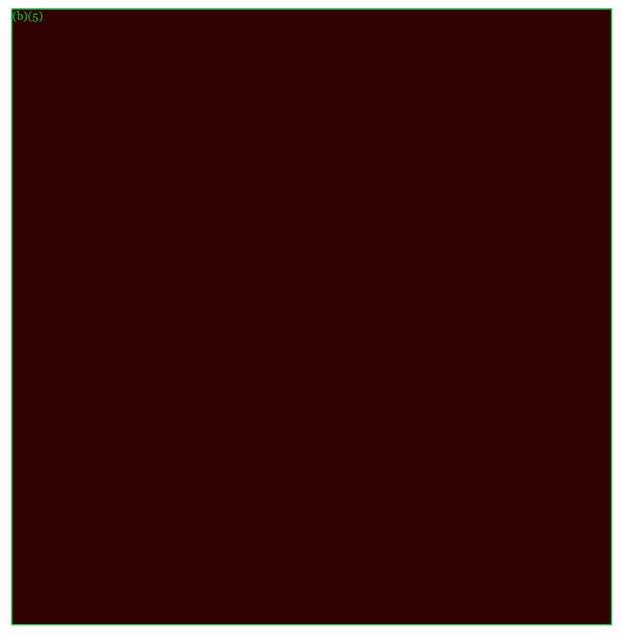


<sup>\*\*</sup> The nowcast estimates use a multinomial regression model of weighted sequencing data to estimate variant proportions and prediction intervals. The nowcast provides timely estimates while accounting for limited sequence data availability, as samples from that interval are still being processed. Nowcast estimates are projections and may differ from weighted estimates generated at later dates.









#### MMWR Releases

One MMWR Early Release related to the COVID-19 Response is scheduled for <u>Friday</u>, May 28th, with the planned embargo lifting at 11 AM. Please note that the title, content, and timing might change.

## Patterns in COVID-19 vaccination coverage by social vulnerability and urbanicity — United States, December 14, 2020–May 1, 2021

- BLUF: Disparities in county-level vaccination coverage by social vulnerability have increased as vaccine eligibility has expanded, especially in large fringe metropolitan and nonmetropolitan counties. By May 1, 2021, vaccination coverage was lower among adults living in counties with lower socioeconomic status and with higher percentages of households with children, single parents, and persons with disabilities
- Key Points:

- Data from adults living in 3,129 (99%) U.S. counties were analyzed; California counties with populations <20,000 and all Hawaii counties were excluded because of lack of available county-level vaccination
- Vaccination coverage was defined as the number of persons aged ≥18 years (adults) who had received ≥1 dose of any COVID-19 vaccine divided by the adult population.
- SVI was examined overall and by its four themes (socioeconomic status, household composition and disability, racial/ethnic minority status and language, and housing type and transportation.
- By May 1, 2021, after states opened eligibility to all adults, vaccination coverage was lower among adults living in counties with the highest overall SVI (Q4 coverage = 49.0% versus Q1 coverage = 59.3%).
- Coverage was lower in counties with higher SVI related to socioeconomic status (Q4 = 44.3% versus Q1 = 61.0%) and household composition and disability (Q4 = 42.0% versus Q1 = 60.1%), but higher in counties with higher SVI related to racial and ethnic minority residents and English proficiency (Q4 = 56.5% versus Q1 = 45.3%).
- Coverage differences between adults living in counties with the highest versus lowest SVI were −11.0% (95% CI = −13.2% to −8.9%) in large central metropolitan counties, −16.7% (95% CI = −20.7% to −12.7%) in large fringe metropolitan counties, −8.2% (95% CI = −13.1% to −3.4%) in medium and small metropolitan counties, and −12.3% (95% CI = −16.4% to −8.2%) in nonmetropolitan counties.
- Summary/abstract: Disparities in vaccination coverage by social vulnerability, defined as social and structural factors that influence health, were noted during the first 2.5 months of the U.S. COVID-19 vaccination campaign, which began during mid-December 2020. As vaccine eligibility and availability continue to expand, assuring equitable coverage for disproportionately affected communities remains a priority. COVID-19 vaccine administration and 2018 CDC Social Vulnerability Index (SVI) data were examined to ascertain whether inequities in COVID-19 vaccination coverage with respect to county-level SVI have persisted, overall and by urbanicity. Vaccination coverage was defined as the number of adults (persons aged ≥18 years) who had received ≥1 dose of any COVID-19 vaccine divided by the adult population. SVI was examined overall and by its four themes (socioeconomic status, household composition and disability, racial/ethnic minority status and language, and housing type and transportation). Counties were categorized into SVI quartiles, where quartile 1 (Q1) represented the lowest level of vulnerability and quartile 4 (Q4) represented the highest. During December 14, 2020-May 1, 2021, disparities in vaccination coverage by SVI grew over time, especially in large fringe metropolitan and nonmetropolitan counties. By May 1, 2021, vaccination coverage was lower among adults living in counties with the highest overall SVI; differences were most pronounced in large fringe metropolitan and nonmetropolitan counties. Vaccination coverage disparities were largest for two SVI themes: socioeconomic status and household composition and disability. Outreach efforts, including expanding public health messaging tailored to local populations and increasing vaccination access, could help increase vaccination coverage in counties with high SVI.

# CDC COVID-19 Response Update Report DIRECTOR'S BRIEF

## Friday, May 28, 2021



US Department of Health and Human Services Centers for Disease Control and Prevention

#### Preliminary COVID-19 COVID Case and Death Data<sup>1</sup>

Data Through	Total Cases	New Cases	Total Deaths	New Deaths
May 27, 2021	33,041,801	22,836	590,746	1,200

Source: State-level Aggregated Case and Death Counts (ACDC)

#### **COVID-19 Summary**

	<b>Cumulative Total</b>	Daily	7-Day Daily	<b>Change from Prior</b>
			Average	7-Day Period
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Source: HHS Protect		,	1.0	

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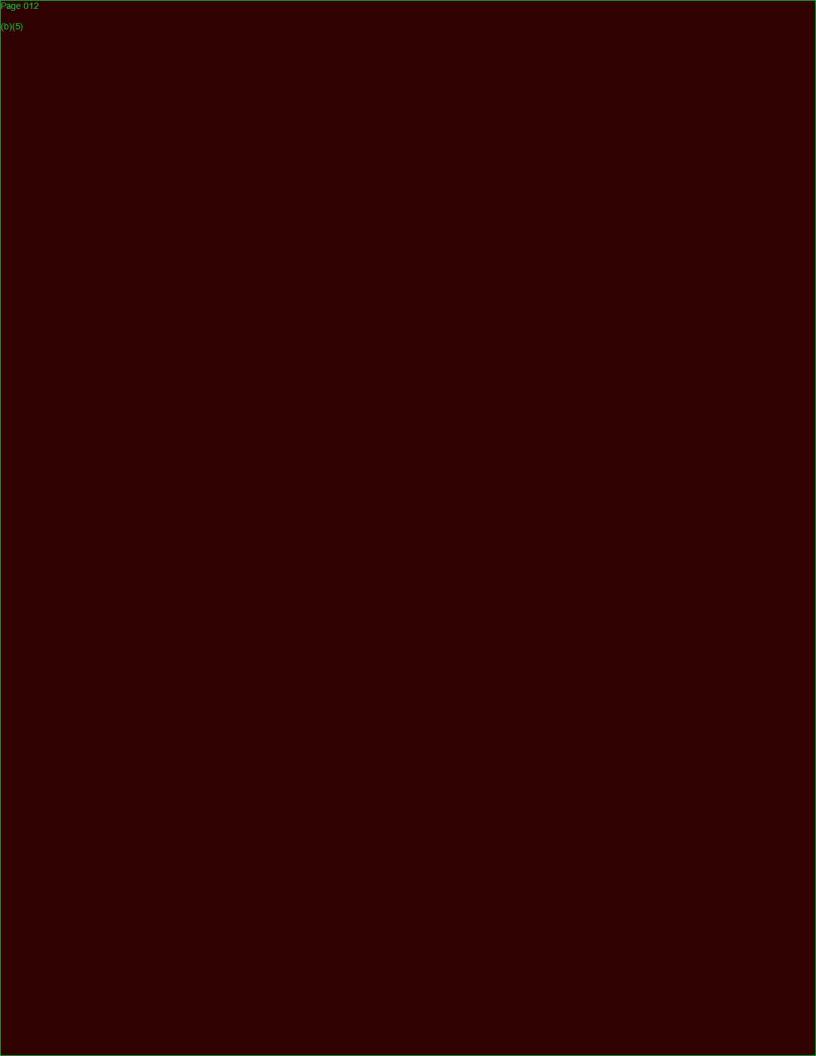
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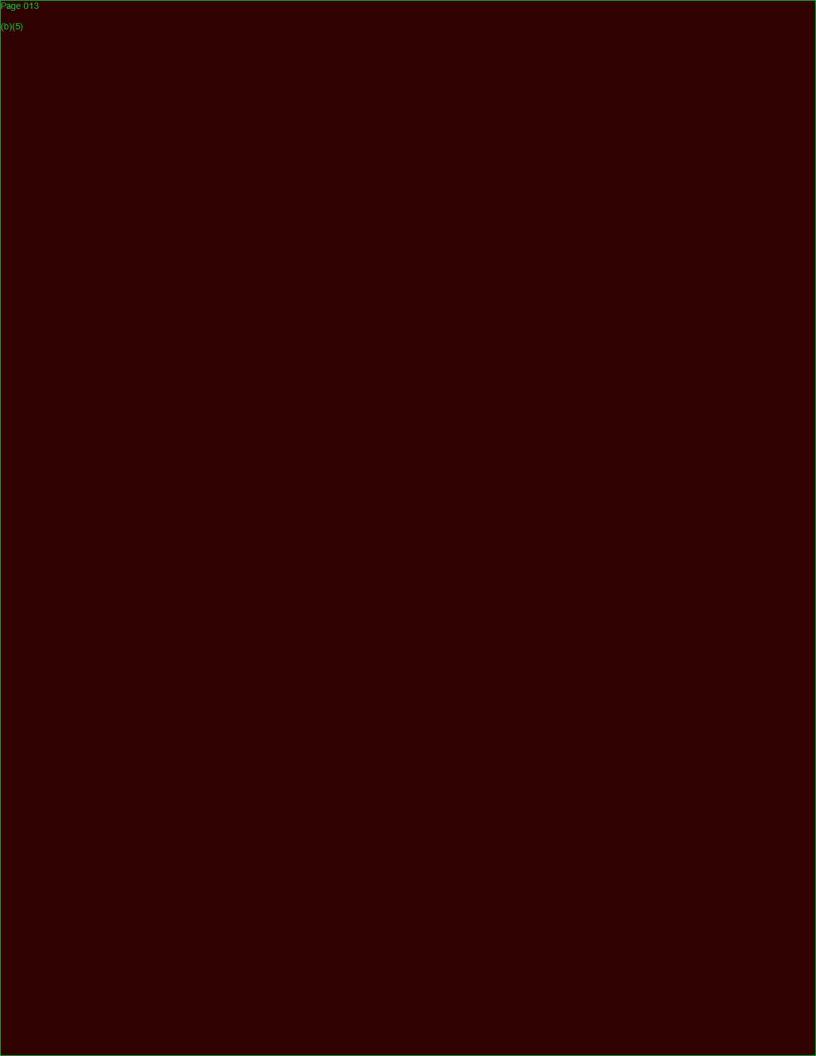
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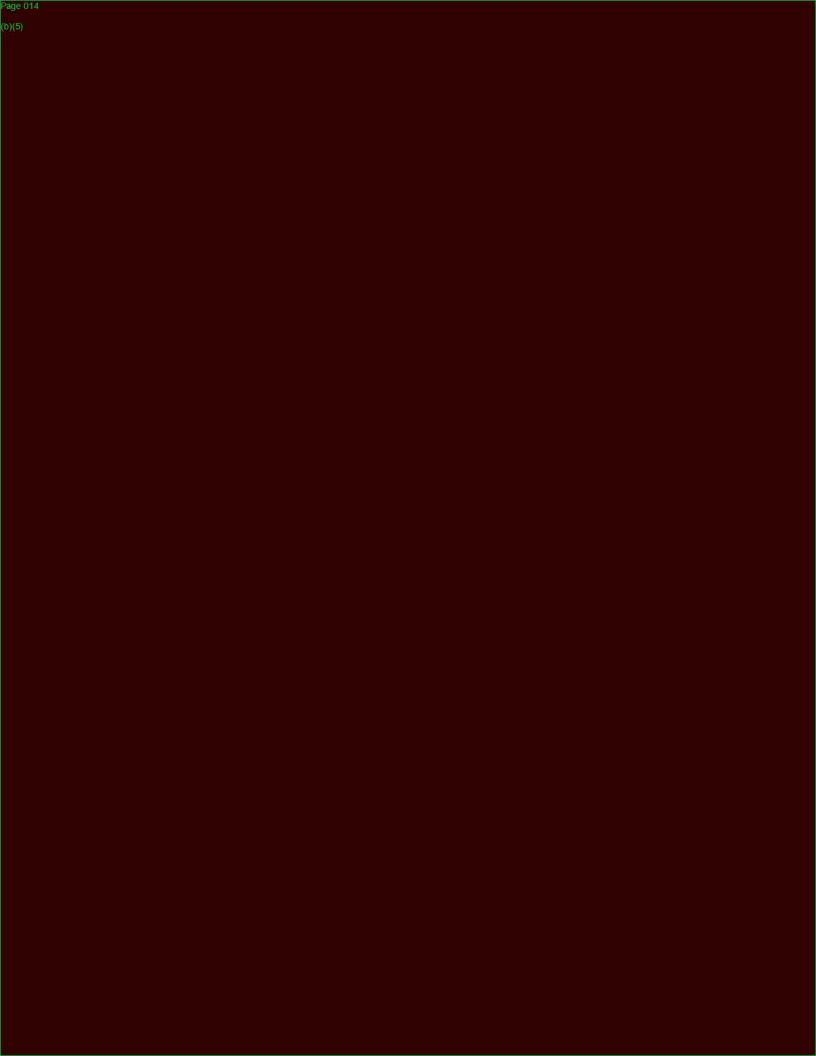
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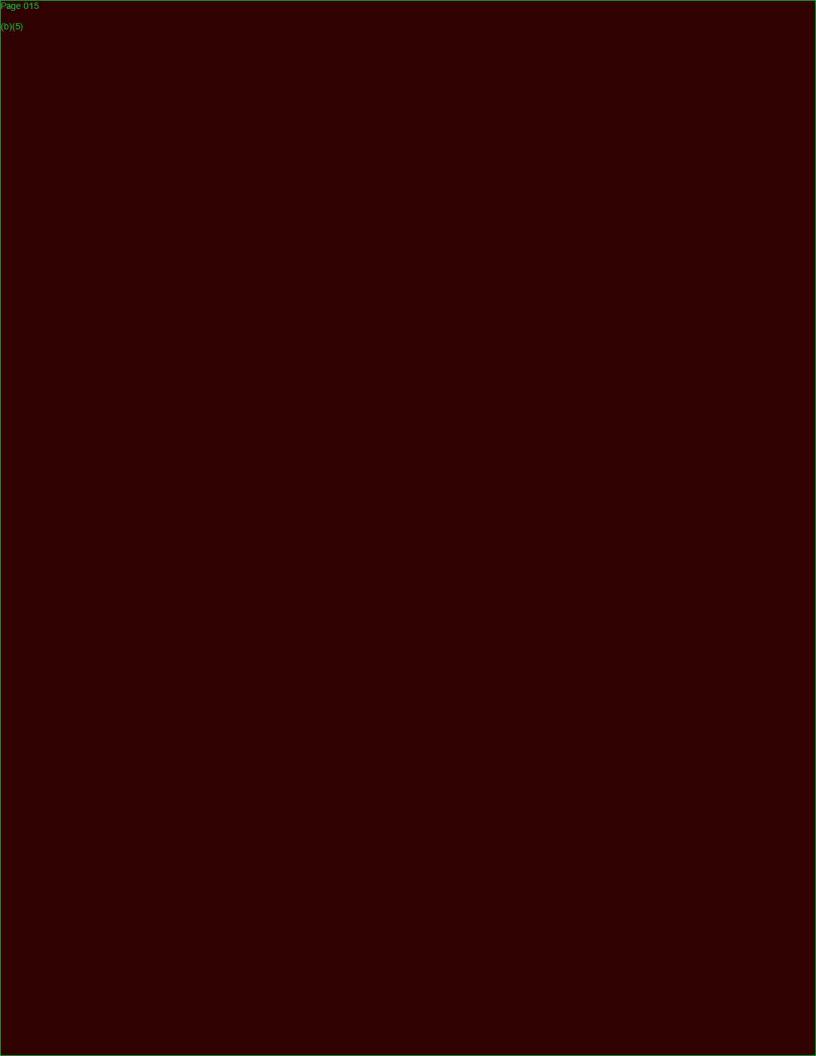
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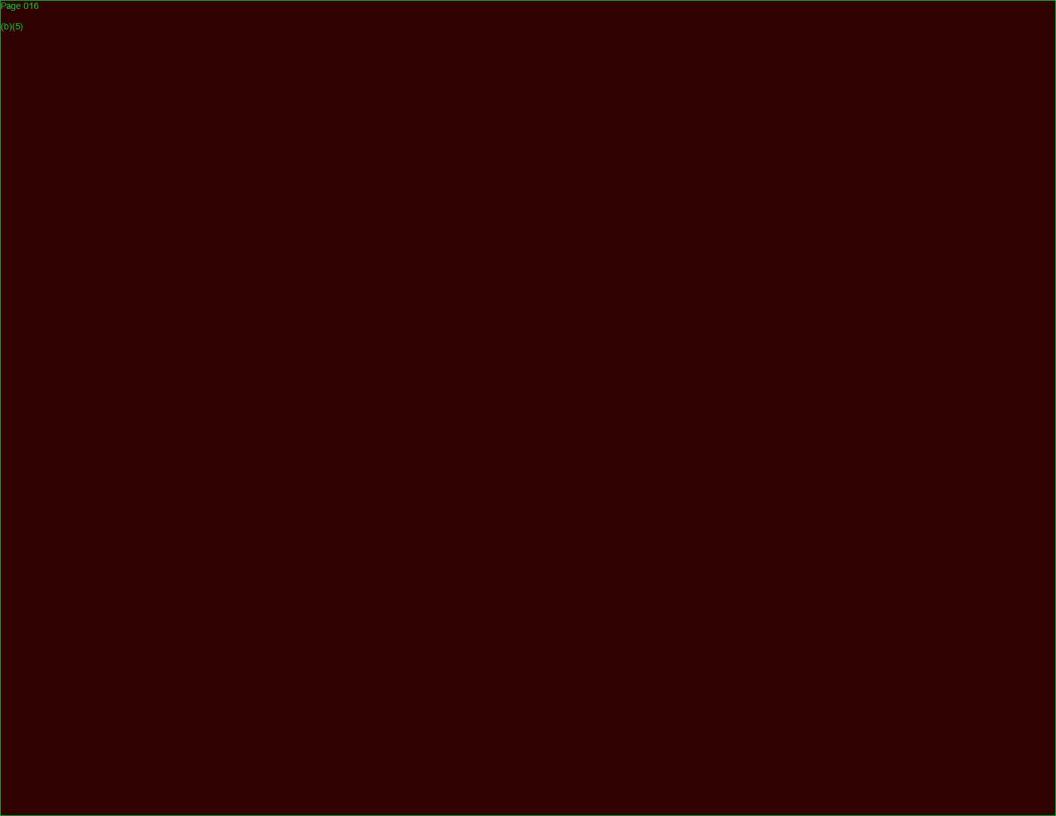
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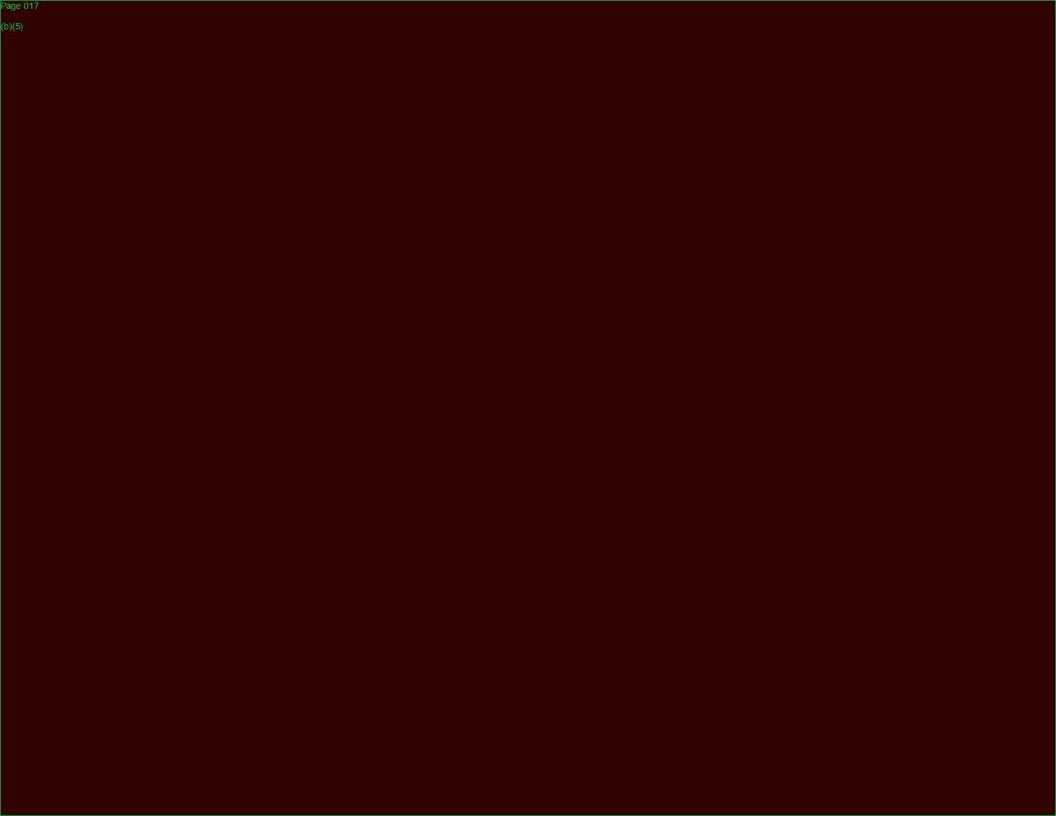


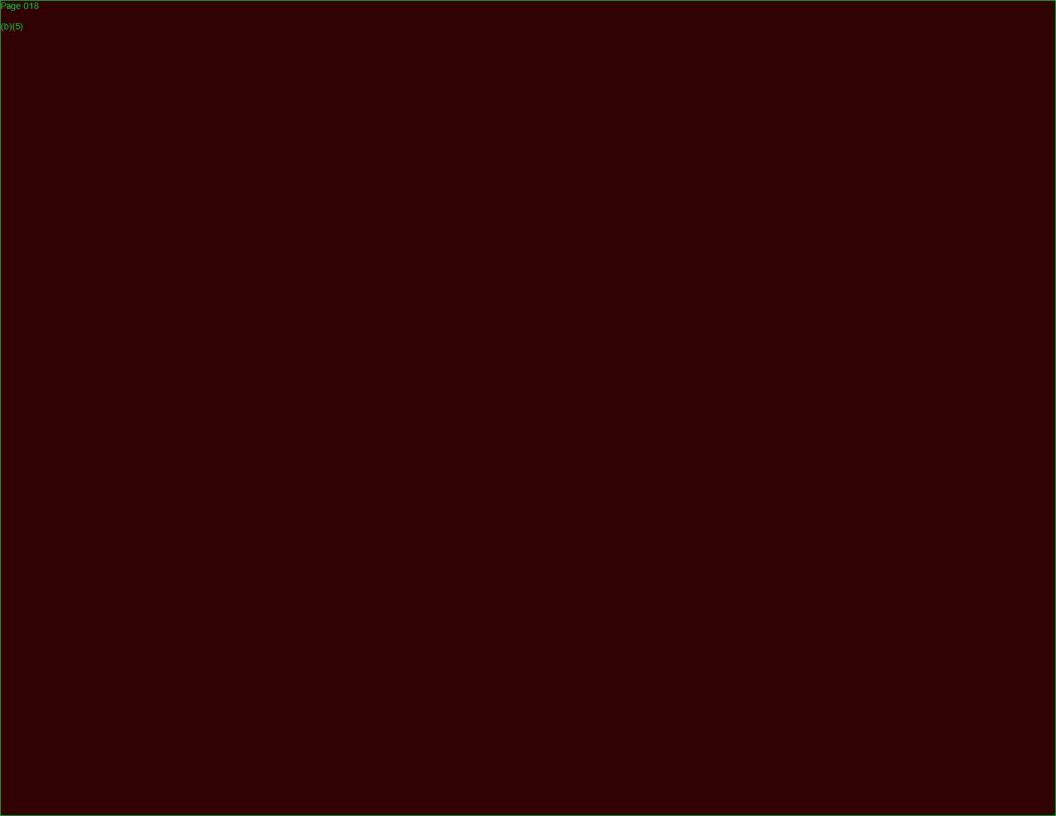


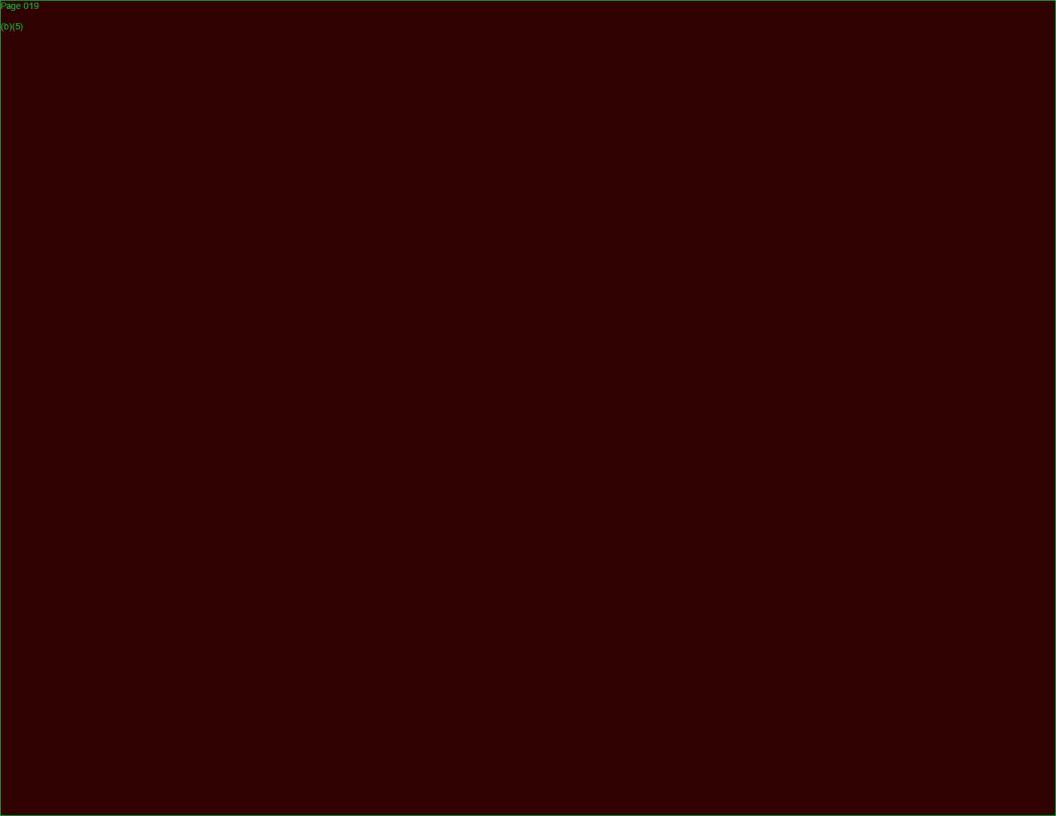












From: Goldstein, Robert (CDC/OD/OADPS)
Sent: Sat, 29 May 2021 13:30:11 +0000
To: Walensky, Rochelle (CDC/OD)

Subject: JAMA Cardiology Article

Attachments: jamacardiology\_daniels\_2021\_oi\_210042\_1621956607.12677.pdf

Here's the article (link and attached):

Prevalence of Clinical and Subclinical Myocarditis in Competitive Athletes With Recent SARS-CoV-2
Infection: Results From the Big Ten COVID-19 Cardiac Registry | Cardiology | JAMA Cardiology | JAMA Network

#### JAMA Cardiology | Original Investigation

### Prevalence of Clinical and Subclinical Myocarditis in Competitive Athletes With Recent SARS-CoV-2 Infection Results From the Big Ten COVID-19 Cardiac Registry

Curt J. Daniels, MD; Saurabh Rajpal, MBBS, MD; Joel T. Greenshields, MS; Geoffrey L. Rosenthal, MD; Eugene H. Chung, MD; Michael Terrin, MD; Jean Jeudy, MD; Scott E. Mattson, DO; Ian H. Law, MD; James Borchers, MD; Richard Kovacs, MD; Jeffrey Kovan, DO; Sami F. Rifat, MD; Jennifer Albrecht, PhD; Ana I. Bento, PhD; Lonnie Albers, MD; David Bernhardt, MD; Carly Day, MD; Suzanne Hecht, MD; Andrew Hipskind, MD; Jeffrey Mjaanes, MD; David Olson, MD; Yvette L. Rooks, MD; Emily C. Somers, PhD; Matthew S. Tong, DO; Jeffrey Wisinski, DO; Jason Womack, MD; Carrie Esopenko, PhD; Christopher J. Kratochvil, MD; Lawrence D. Rink, MD; for the Big Ten COVID-19 Cardiac Registry Investigators

**IMPORTANCE** Myocarditis is a leading cause of sudden death in competitive athletes. Myocardial inflammation is known to occur with SARS-CoV-2. Different screening approaches for detection of myocarditis have been reported. The Big Ten Conference requires comprehensive cardiac testing including cardiac magnetic resonance (CMR) imaging for all athletes with COVID-19, allowing comparison of screening approaches.

**OBJECTIVE** To determine the prevalence of myocarditis in athletes with COVID-19 and compare screening strategies for safe return to play.

DESIGN, SETTING, AND PARTICIPANTS Big Ten COVID-19 Cardiac Registry principal investigators were surveyed for aggregate observational data from March 1, 2020, through December 15, 2020, on athletes with COVID-19. For athletes with myocarditis, presence of cardiac symptoms and details of cardiac testing were recorded. Myocarditis was categorized as clinical or subclinical based on the presence of cardiac symptoms and CMR findings. Subclinical myocarditis classified as probable or possible myocarditis based on other testing abnormalities. Myocarditis prevalence across universities was determined. The utility of different screening strategies was evaluated.

**EXPOSURES** SARS-CoV-2 by polymerase chain reaction testing.

MAIN OUTCOME AND MEASURE Myocarditis via cardiovascular diagnostic testing.

**RESULTS** Representing 13 universities, cardiovascular testing was performed in 1597 athletes (964 men [60.4%]). Thirty-seven (including 27 men) were diagnosed with COVID-19 myocarditis (overall 2.3%; range per program, 0%-7.6%); 9 had clinical myocarditis and 28 had subclinical myocarditis. If cardiac testing was based on cardiac symptoms alone, only 5 athletes would have been detected (detected prevalence, 0.31%). Cardiac magnetic resonance imaging for all athletes yielded a 7.4-fold increase in detection of myocarditis (clinical and subclinical). Follow-up CMR imaging performed in 27 (73.0%) demonstrated resolution of T2 elevation in all (100%) and late gadolinium enhancement in 11 (40.7%).

**CONCLUSIONS AND RELEVANCE** In this cohort study of 1597 US competitive athletes with CMR screening after COVID-19 infection, 37 athletes (2.3%) were diagnosed with clinical and subclinical myocarditis. Variability was observed in prevalence across universities, and testing protocols were closely tied to the detection of myocarditis. Variable ascertainment and unknown implications of CMR findings underscore the need for standardized timing and interpretation of cardiac testing. These unique CMR imaging data provide a more complete understanding of the prevalence of clinical and subclinical myocarditis in college athletes after COVID-19 infection. The role of CMR in routine screening for athletes safe return to play should be explored further.

JAMA Cardiol. doi:10.1001/jamacardio.2021.2065 Published online May 27, 2021. Editorial

Supplemental content

**Author Affiliations:** Author affiliations are listed at the end of this article.

Group Information: Nonauthor contributors to the Big Ten COVID-19 Cardiac Registry appear at the end of this article.

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ARS-CoV-2, which causes COVID-19, has infected millions of people around the world, causing significant morbidity and mortality. Competitive athletes are a unique population that may be at high risk for environmental and situational transmission of disease, and once infected, may be at risk for sudden cardiac death (SCD) during training and competition. General myocarditis in asymptomatic people is a common cause of SCD, especially among those younger than 35 years. The incidence of SCD in collegiate athletes has been estimated at 1:50 000 per year. Even a small number of events in a young and apparently healthy population has devastating consequences. This often receives broad attention and, in some circumstances, may be preventable.

Typical cardiac magnetic resonance (CMR) imaging findings of myocarditis or myocardial inflammation in asymptomatic or mildly symptomatic competitive athletes after COVID-19 infection have been described, even without other cardiac testing abnormalities. <sup>12,13</sup> These reports describe variable estimates of myocarditis and myocardial inflammation prevalence (0%-15%). <sup>12,14,15</sup> Such heterogeneity highlights the potential importance of CMR in detecting subclinical myocarditis (those without cardiac symptoms) and demonstrates the need for further investigation. <sup>10,16-18</sup>

Many schools and athletic conferences have developed screening protocols for safe return to play (RTP). Available consensus documents<sup>19</sup> tie CMR and other cardiac testing to the presence of cardiac symptoms (symptoms-based screening strategy). Others require advanced testing for all athletes after COVID-19 infection. In September 2020, the Big Ten Conference mandated advanced testing for all athletes after COVID-19 infection prior to RTP, including electrocardiogram (ECG), echocardiogram, serum troponin level, and CMR imaging. <sup>20</sup> Integral to this plan, the conference also formed the Big Ten COVID-19 Cardiac Registry for valid scientific data to inform RTP decisions.

The aims of this study were to estimate the prevalence of myocarditis among athletes after COVID-19 infection, to compare differences in COVID-19 myocarditis across Big Ten Universities, to evaluate the utility of different diagnostic strategies for myocarditis screening among competitive athletes, and to review timing and results of repeat CMR imaging to inform safe RTP decisions.

#### Methods

The Big Ten COVID-19 Cardiac Registry is an observational study of athletes confirmed positive for SARS-CoV-2 by polymerase chain reaction testing. Thirteen of 14 Big Ten Universities agreed to participate (eAppendix 1 in Supplement 1). The present study was a survey (Supplement 2) of the experiences of the participating universities' athletes with COVID-19 from March 1, 2020, through December 15, 2020, with focus on those who completed CMR imaging as part of their cardiac evaluation. Detailed, deidentified information from symptom questionnaires and advanced testing was reviewed for athletes with myocarditis. Data on age and race were not collected. The Ohio State University institutional review board

#### **Key Points**

**Question** What is the prevalence of myocarditis in competitive athletes after COVID-19 infection, and how would different approaches to screening affect detection?

**Findings** In this cohort study of 1597 US competitive collegiate athletes undergoing comprehensive cardiovascular testing, the prevalence of clinical myocarditis based on a symptom-based screening strategy was only 0.31%. Screening with cardiovascular magnetic resonance imaging increased the prevalence of clinical and subclinical myocarditis by a factor of 7.4 to 2.3%.

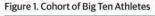
Meaning These cardiac magnetic resonance imaging findings provide important data on the prevalence of clinical and subclinical myocarditis in college athletes recovering from symptomatic and asymptomatic COVID-19 infections.

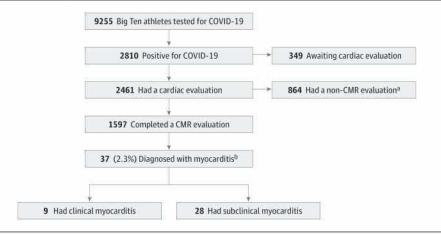
serves as the central institutional review board for the Big Ten COVID-19 Cardiac Registry and approved this survey and waiver of consent. This report follows the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

#### Survey Data

Each participating Big Ten University principal investigator reported the total number of athletes screened for SARS-CoV-2, the number with positive polymerase chain reaction results, the number completing cardiac screening with CMR imaging, and the number with findings that were consistent with myocarditis by the assessment of local clinicians. Restriction from training and competition by the local program was required for the diagnosis of myocarditis to be assigned. Those who did not complete CMR imaging as part of their cardiac evaluation or by data cut are described (eAppendix 2 in Supplement 1).

CMR findings consistent with myocarditis were classified based on updated 2018 Lake Louise criteria (LLC).<sup>21</sup> A positive diagnosis was determined by presence of both T1-based criteria (T1 mapping, T1-weighted imaging, or late gadolinium enhancement [LGE]) and T2-based criteria (T2 mapping or T2weighted imaging) in the same American Heart Association segment. LLC were modified by a requirement for colocalizing of Tl and T2 abnormalities to improve specificity and avoid interobserver variability. Although these criteria were agreed on in the Big Ten COVID-19 Cardiac Registry meeting, individual program clinicians determined the diagnosis of myocarditis. Diagnoses that deviated from these criteria are described in the Results section. Modified LLC also included supportive criteria such as pericardial effusion, pericardial inflammation, and left ventricular systolic dysfunction. Isolated right ventricular insertion point fibrosis was not used to diagnose myocarditis. For diagnoses consistent with myocarditis, details of the abnormal findings from CMR imaging, duration of days between COVID-19 diagnosis and CMR imaging, number and type of cardiac symptoms (chest pain, dyspnea on exertion [dyspnea], or chest palpitations), and number with abnormal findings on ECG or echocardiogram consistent with myocarditis or elevated troponin level (troponin was assessed according





- <sup>a</sup> Athletes were excluded from analysis for not completing cardiac magnetic resonance (CMR) imaging as part of cardiac evaluation and described in more detail in eAppendix 2 in Supplement 1.
- <sup>b</sup> Athletes diagnosed with myocarditis were categorized as clinical or subclinical based on presence or absence of cardiac symptoms.

to assay and local laboratory standards as normal or elevated) were collected. Data collection for myocarditis diagnoses was limited to protect personal health information. Following survey submission, results were confirmed with the local principal investigator.

#### Myocarditis Diagnosis Definitions

Myocarditis diagnoses were divided into 3 categories: (1) clinical myocarditis (cardiac symptoms present before or at the time of cardiac testing), (2) subclinical probable myocarditis (no cardiac symptoms) with abnormal ECG, echocardiogram, or troponin findings consistent with myocarditis, and (3) subclinical possible myocarditis (no cardiac symptoms) without abnormal ECG, echocardiogram, or troponin findings and only abnormal CMR imaging findings.

#### **Data Analysis**

Data from Big Ten athletes who completed all recommended cardiac testing including CMR imaging were included in this analysis. Normality of distributions were tested using the Shapiro-Wilk test. Data are reported as counts (percentage) with qualitative descriptors and as mean (SD) or median (interquartile range) for continuous variables. Clinical/ subclinical count data were analyzed using the Fisher exact test. There was variability in data collection methods among programs (eg, CMR scanners, acquisition protocols, readers, timing, etc) that may influence the detection of myocarditis and the frequency of myocarditis diagnoses across institutions. Therefore, in addition to the crude estimate of prevalence, an estimate of the percentage of athletes who received complete cardiac evaluation including CMR imaging affected by myocarditis was calculated using a generalized linear mixed-regression model (fixed effect for number of athletes with complete cardiac evaluation including CMR imaging and a random effect for institution) with a negative binomial distribution. 95% CIs were calculated using the Clopper-Pearson exact method for proportions for crude estimates and with standard methods for negative binomial distributions for the regression model. A sensitivity analysis was conducted including schools that performed CMR imaging in all

cardiac evaluations before the Big Ten Conference mandate in September 2020 for CMR testing in all athletes after COVID-19 infections to assess possible selection bias on the overall observed prevalence of myocarditis. A *P* value less than .05 indicated statistical significance. All statistical analyses were performed using R version 4.0.3 (R Foundation for Statistical Computing).

#### Results

Thirteen Big Ten Universities agreed to participate and submitted data. Through December 15, 2020, 9255 athletes had undergone COVID-19 testing and 2810 (30.4%) had tested positive. From this group of athletes with COVID-19 (1879 men [66.9%]), 2461 had completed cardiac evaluation, with 1597 (64.9%) including CMR imaging at the time of analysis and 864 (35.1%) with a non-CMR cardiac evaluation (eAppendix 2 in Supplement 1). Of those who had CMR imaging results, 37 athletes (2.3%) were diagnosed with either clinical or subclinical myocarditis (Figure 1).

#### **Myocarditis Diagnoses**

The 37 athletes were predominantly male (27) and represent 17 collegiate sports (8 women's sports). Nine athletes with clinical myocarditis reported cardiac symptoms before or at the time of cardiac testing: 8 of 9 reported chest pain, 3 of 9 had dyspnea, and 3 of 9 had palpitations. There were 28 of 37 athletes with subclinical myocarditis who reported no cardiac symptoms. Of 28 athletes with subclinical myocarditis, 8 had abnormal cardiac testing other than CMR imaging and were classified as probable myocarditis: 1 of 28 had abnormal ECG findings, 3 of 28 had abnormal echocardiogram findings, and 4 of 28 had elevated troponin levels (Table). While 5 of 9 athletes with clinical myocarditis had abnormal additional testing results (ECG, echocardiogram, or troponin), only 8 of 28 with subclinical myocarditis had abnormal additional testing. Overall, 20 of 37 athletes had subclinical possible myocarditis who had no cardiac symptoms and nondiagnostic ECG findings, echocardiogram findings, and troponin level and

Athlete	Cardiac symptoms	Troponin level	ECG findings	ECHO findings	Time from COVID-19 diagnosis, d	CMR imaging findings	Follow-up CMR imaging time and findings
Clinical n	nyocarditis						
1	Chest pain, palpitations	Elevated	Abnormal	Abnormal	46	↑T2, LGE	12 wk; Residual LGE
2	Chest pain	Elevated	Abnormal	NCM	Unknown	↑T1, ↑T2, LGE	14 wk; Residual LGE
3	Chest pain, dyspnea	Normal	Abnormal	NCM	15	↑T2, LGE	10 wk; Resolved <sup>b</sup>
4	Chest pain, dyspnea	Normal	Abnormal	NCM	13	↑T2, LGE	12 wk; Residual LGE
5	Dyspnea	Normal	NCM	Abnormal	77	↓LVEF + pericarditis	Pending <sup>c</sup>
6	Chest pain, palpitations	Normal	NCM	NCM	25	LGE	Pending <sup>c</sup>
7	Chest pain	Normal	NCM	NCM	50	LGE	Pending <sup>c</sup>
8	Chest pain	Normal	NCM	NCM	25	↑T2, LGE	14 wk; Residual LGE
9	Chest pain, palpitations	Normal	NCM	NCM	45	↑T2, LGE	12 wk; Residual LGE
Subclinic	al probable myocarditis						
10	None	Elevated	NCM	NCM	30	↑T1,↑ T2, LGE	Pending <sup>c</sup>
11	None	Elevated	NCM	NCM	14	↑T2, LGE	Pending <sup>c</sup>
12	None	Elevated	NCM	NCM	14	↑T2, LGE	12 wk; Residual LGE
13	None	Elevated	NCM	NCM	11	↑T2, LGE	4 wk; Residual LGE
14	None	Normal	Abnormal	NCM	13	↑T1,↑ T2, LGE	Pending <sup>c</sup>
15	None	Normal	NCM	Abnormal	42	↓LVEF, LGE	13 wk; Residual LGE
16	None	Normal	NCM	Abnormal	12	↓LVEF, LGE	4 wk; Resolved <sup>b</sup>
17	None	Normal	NCM	Abnormal	25	↑T1, ↑T2, LGE	Pending <sup>c</sup>
Subclinic	al possible myocarditis						
18	None	Normal	NCM	NCM	36	↑T2, LGE	13 wk; Residual LGE
19	None	Normal	NCM	NCM	20	↑T2, LGE	12 wk; Residual LGE
20	None	Normal	NCM	NCM	71	↑T2, LGE	10 wk; Resolved <sup>b</sup>
21	None	Normal	NCM	NCM	10	↑T2, LGE	10 wk; Residual LGE
22	None	Normal	NCM	NCM	14	↑T2, LGE	8 wk; Resolved <sup>b</sup>
23	None	Normal	NCM	NCM	11	↑T2, LGE	7 wk; Resolved <sup>b</sup>
24	None	Normal	NCM	NCM	11	↑T2, LGE	7 wk; Resolved <sup>b</sup>
25	None	Normal	NCM	NCM	15	↑T2, LGE	8 wk; Residual LGE
26	None	Normal	NCM	NCM	44	↑T2, LGE	6 wk; Residual LGE
27	None	Normal	NCM	NCM	21	↑T2, LGE	8 wk; Residual LGE
28	None	Normal	NCM	NCM	49	↑T2, LGE	10 wk; Resolved <sup>b</sup>
29	None	Normal	NCM	NCM	35	↑T2, LGE	6 wk; Resolved <sup>b</sup>
30	None	Normal	NCM	NCM	24	↑T2, LGE	6 wk; Residual LGE
31	None	Normal	NCM	NCM	51	LGE	4 wk; Resolved <sup>b</sup>
32	None	Normal	NCM	NCM	25	↑T2, LGE	Pending <sup>c</sup>
33	None	Normal	NCM	NCM	20	↑T2, LGE	11 wk; Resolved <sup>b</sup>
34	None	Normal	NCM	NCM	48	↑T2, LGE	Pending <sup>c</sup>
35	None	Normal	NCM	NCM	14	↑T1, ↑T2, LGE	Pending <sup>c</sup>
36	None	Normal	NCM	NCM	11	↑T2, LGE	12 wk; Residual LGE
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Abbreviations: CMR, cardiovascular magnetic resonance; ECG, electrocardiogram; ECHO, echocardiogram; LGE, late gadolinium enhancement; NCM, not consistent with myocarditis;  $\downarrow$ LVEF, decreased left ventricular ejection fraction;  $\uparrow$ TI, elevated TI by TI mapping or T1-weighted imaging based on individual institutional standards;  $\uparrow$ T2, elevated T2 by T2 mapping or T2-weighted imaging based on individual institutional standards.

Normal

NCM

NCM

19

myocarditis group with those demonstrating abnormal cardiac testing outside of CMR imaging (subclinical probable myocarditis) and those with only CMR imaging abnormalities (subclinical possible myocarditis) is reported. Abnormal ECG and abnormal ECHO findings were defined by the program as consistent with myocarditis. Elevated troponin levels were defined by institutional standards and includes both troponin I and high-sensitivity troponin.

10 wk; Resolved<sup>b</sup>

↑T2, LGE

37

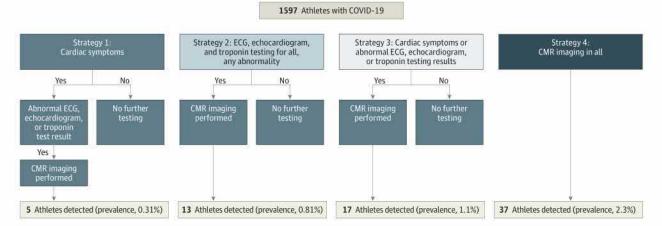
None

<sup>&</sup>lt;sup>a</sup> A total 37 athletes (27 men), from 13 Big Ten Universities and across 17 sport disciplines were diagnosed with myocarditis. Of these 37 athletes, 9 athletes had cardiac symptoms (clinical myocarditis), and 28 athletes were asymptomatic (subclinical myocarditis). Further breakdown of the subclinical

<sup>&</sup>lt;sup>b</sup> Both T1 and T2 abnormalities have resolved at follow-up CMR imaging.

 $<sup>^{\</sup>rm c}$  Athlete is in recovery from COVID-19 myocarditis, and follow-up CMR imaging has not been performed.

Figure 2. Detection and Estimated Prevalence of Myocarditis Based on Diagnostic Strategy



From 37 athletes with clinical and subclinical myocarditis, the number that would have been detected and percentage prevalence found based on strategy performed and guided by either (1) cardiac symptoms alone; (2)

electrocardiogram (ECG), echocardiogram, and troponin for all; (3) cardiac symptoms, ECG, echocardiogram, or troponin; or (4) cardiovascular magnetic resonance (CMR) imaging for all strategy.

therefore were only identified by meeting CMR imagingmodified LLC criteria or supportive criteria.

#### Diagnostic Approach

Based on a published diagnostic strategy driven by cardiac symptoms, <sup>19</sup> only 5 athletes (detected prevalence, 0.31%) of myocarditis would have been found in our cohort. A strategy using ECG, echocardiogram, and troponin findings regardless of cardiac symptoms with the addition of CMR imaging if any abnormality had been found, would have detected 13 athletes (detected prevalence, 0.81%). A strategy using CMR imaging in all athletes after COVID-19 infection regardless of cardiac symptoms or other cardiac testing results increased the prevalence to 2.3%, a 7.4-fold increase from the symptom-driven strategy and 2.8-fold increase over the ECG, echocardiogram, and troponin strategy (Figure 2).

#### **CMR Findings**

Overall, 31 of 37 CMR imaging findings reported as myocarditis met the modified LLC21 with elevated T2 and elevated T1 or LGE in the same location (American Heart Association myocardial segment). Of the 6 athletes not meeting modified LLC criteria, 3 had clinical myocarditis. One athlete reported dyspnea; echocardiogram and CMR imaging demonstrated decreased left ventricular systolic function (left ventricular ejection fraction, 35%-40%); in addition, CMR imaging showed pericardial inflammation and effusion. The 2 other athletes with clinical myocarditis reported chest pain and had CMR imaging with LGE in a pattern typical for myocarditis. Of the 3 athletes with subclinical myocarditis and CMR imaging not meeting modified LLC, 2 demonstrated significantly reduced left ventricular systolic function and LGE in patterns typical of myocarditis, thus meeting supportive LLC. In the third athlete, CMR imaging demonstrated extensive LGE in a typical pattern for myocarditis without myocardial edema on T2 mapping. Modified LLC and CMR imaging findings were not

significantly different between subclinical (25 of 28 [89.3%]) vs clinical (6 of 9 [66.7%]) (difference = 22.6% [95% CI, -7.1% to 57.7%; P = .14) (Figure 3).

In follow-up, 27 of 37 athletes (73.0%) completed repeat CMR imaging with a range of 4 to 14 weeks (mean [SD], 9.4 [3.1] weeks) from initial COVID-19 test positivity. Two patterns emerged at CMR imaging follow-up. The first was complete resolution of both T2 mapping abnormalities and LGE in 11 of 27 athletes (40.7%; range between studies, 4-10 weeks with median [interquartile range] of 8 [3.5] weeks). The second was resolution of T2 mapping abnormalities but persistence of LGE in 16 of 27 athletes (59.3%; range between studies, 4-14 weeks with median [interquartile range] of 12 [4.3] weeks) (eFigure in Supplement 1).

One of 6 athletes with clinical myocarditis showed complete CMR imaging resolution (both T2 elevation and LGE resolved), with the second CMR study performed 10 weeks after diagnosis. In comparison, 10 of 21 athletes with subclinical athletes with myocarditis (47.6%) demonstrated complete resolution of inflammation and LGE with a mean (SD) time after diagnosis of 7.7 (2.5) weeks (range, 4-11 weeks).

Additional abnormalities identified on CMR imaging included 46 athletes with LGE alone (either focal and not meeting American Heart Association segment criteria, or right ventricular insertion point LGE) without elevated T1 or T2, 34 athletes with pericardial abnormalities, and 4 athletes of pulmonary infiltrates. Detailed analysis of pattern of LGE in athletes without myocarditis was not performed.

#### Big Ten Universities and Variability

Reported findings varied among Big Ten Universities, including (1) COVID-19 positivity rate (overall, 30.4%; range, 13.0%-48.2%), (2) timing of complete cardiac testing, and (3) prevalence of myocarditis. Figure 4A shows the number of athletes with COVID-19 per program who had complete cardiac testing results available including CMR imaging (median [interquartile range], 104 [86]; range, 29-324) and those with myo-

Figure 3. Cardiac Magnetic Resonance Imaging in Athletes With Clinical and Subclinical Myocarditis D Patient A, LGE in the inferolateral wall A Patient A, T2 mapping Patient A, LGE in the basal C Patient A, postcontrast SSFP F Patient B, LGE in the anteroseptal wall G Patient B, T2 E Patient B, T2 H Patient B, postcontrast SSFP mapping mapping K Patient C, LGE in the epicardial I Patient C, T2 mapping J Patient C, postcontrast SSFP midlateral wall L Patient D, T1 mapping M Patient D, T2 mapping N Patient D, LGE in the epicardial

possible myocarditis was asymptomatic with normal electrocardiogram (ECG), echocardiogram, and high-sensitivity troponin findings. A, T2 mapping showing elevated T2 in basal-mid inferolateral wall in short axis view. B, late gadolinium enhancement (LGE) in the basal inferolateral wall in short axis view. C, Postcontrast steady state-free precession (SSFP) images showing contrast uptake in the basal-mid inferolateral wall in short axis view. D, LGE in the inferolateral wall in 3-chamber view. E-H, Athlete B with subclinical probable myocarditis was asymptomatic with normal ECG, normal echocardiogram, and elevated high-sensitivity troponin findings. E, T2 mapping showing elevated T2 in the anteroseptal wall in short axis view. F, LGE in the anteroseptal wall in 3-chamber view. G, T2 mapping showing elevated T2 in the anteroseptal wall in 3-chamber view, F. Postcontrast SSFP image showing pericardial effusion in short axis view. I-K, Athlete C with clinical myocarditis and chest pain, dyspnea, abnormal ECG, normal echocardiogram, and normal troponin findings. I, T2 mapping showing elevated T2 in the lateral wall short axis view. J, Postcontrast SSFP images showing contrast uptake in midlateral wall in short axis view. K, LGE in the epicardial midlateral wall in short axis view. L-N, Athlete D with clinical myocarditis, chest pain, abnormal ECG, echocardiogram, and troponin findings. L, T1 mapping showing elevated native T1 in midlateral wall in short axis view. M, T2 mapping showing elevated T2 in the midlateral wall in short axis view. N. LGE in the epicardial midlateral wall in short axis view. IR indicates inferior right view; IRP, inferior, right, posterior view; PLI, posterior, left, inferior view; SL, superior left view; SLA, superior, left, anterior view.

A-D. Athlete A with subclinical

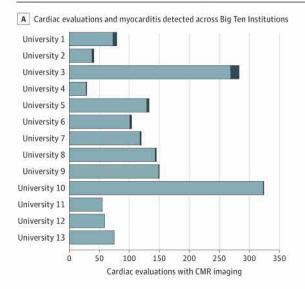
carditis. The prevalence of myocarditis per program ranged from 0% to 7.6% (overall, 2.3% [95% CI, 1.6%-3.2%]; model-based estimate, 2.1% [95% CI 1.1%-4.4%]), with 3 institutions reporting 0 cases and 10 programs reporting at least 1 case of myocarditis (Figure 4B). In the subgroup analysis including schools where CMR imaging was performed in all cardiac evaluations (n = 5), from 919 cardiac evaluations, 21 athletes were diagnosed with myocarditis, resulting in a prevalence of 2.3% (95% CI, 1.4-3.5%), consistent with the overall observed prevalence.

The timing from COVID-19 test positivity to cardiac testing and diagnosis of myocarditis ranged between 10 and 77 days (median [interquartile range], 22.5 [28.5] days) (Figure 4C).

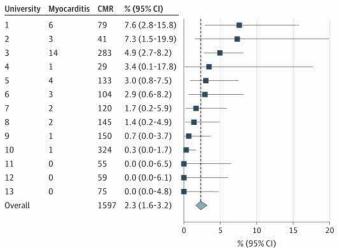
#### Discussion

In this study of aggregate data from 13 Big Ten Universities, 1597 athletes who tested positive by polymerase chain reaction for SARS-CoV-2 underwent comprehensive cardiac evaluation including ECG, echocardiogram, troponin, and CMR imaging. Of these, 2.3% had either clinical or subclinical myocarditis that restricted them from training and competitive play. Allowing for potential differences in CMR performance and distributional characteristics yielded an estimated prevalence of myocarditis of 2.1% (95% CI, 1.1%-4.4%).

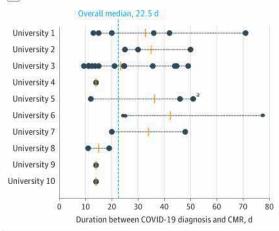
Figure 4. Cardiac Evaluations Performed in Big Ten Athletes











Cardiovascular magnetic resonance (CMR) imaging, athletes diagnosed with myocarditis, and CMR timing after COVID-19 diagnosis in Big Ten athletes with recent SARS-CoV-2 infection. A, The reported number of normal (light blue) and athletes diagnosed with myocarditis (dark blue) observed from complete cardiac evaluations including CMR imaging completed in Big Ten athletes with recent SARS-CoV-2 infection. B, The reported number of athlethes diagnosed with myocarditis, complete cardiac evaluations including CMR imaging, and the percent myocarditis with the 95% CI (calculated using the Clopper-Pearson exact method) for each participating university and the overall prevalence

(crude estimate, calculated as the quotient of all athletes with myocarditis and CMR imaging performed across all universities). C, Duration between COVID-19 diagnosis and CMR imaging for athletes who were diagnosed with myocarditis (n = 36). Data are displayed for participating institution where cases of myocarditis were observed (n = 10).

<sup>a</sup> Duration data unknown for 1 athlete diagnosed with myocarditis. Filled circles represent individual case duration, and orange horizontal lines represent the institution median duration between COVID-19 diagnosis and CMR imaging.

Myocarditis is a significant risk factor for SCD in athletes, especially at younger ages. <sup>7,9,18</sup> In an autopsy study of US Air Force recruits with SCD, physical activity was a risk factor, and the most common suspected underlying factor was unrecognized myocarditis. <sup>18</sup> In another study, lymphocytic myocarditis was a common cause of ventricular arrhythmias. <sup>10</sup> Several studies have shown that physical exertion leads to worsening disease and eventual death in mouse models of myocarditis. <sup>22-24</sup>

Myocardial injury during SARS-CoV-2 infection is well described in clinically distinct populations. <sup>25-27</sup> Early assessments in athletes with COVID-19 demonstrated myocardial in-

jury and inflammation in this otherwise healthy cohort, prompted the Big Ten Conference to integrate advanced cardiac screening into RTP protocols to reduce risk to student athletes. The Big Ten COVID-19 Cardiac Registry was formed to analyze available clinical data to identify and reduce risk to student athletes, to inform RTP decisions, and to further scientific understanding on the cardiac effect of SARS-CoV-2. Decision in the cardiac effect of SARS-CoV-2.

Our prevalence estimates differ from those of several other reports. <sup>12-15,29</sup> In addition to random error, several sources of ascertainment bias may contribute to the observed variability. Timing of CMR imaging after COVID-19 infection (eFigure

in Supplement 1), variability in CMR imaging hardware and software, technique, protocol, and expertise in interpretation may all distort estimates across programs using comparable screening protocols (eAppendix 3 in Supplement 1). Differences in screening approaches may also yield much different estimates of the prevalence of myocarditis. Our data demonstrate the increased detection of clinical and subclinical myocarditis when CMR imaging is added to previously published screening protocols. (Figure 2).

Although details regarding circumstances and in particular symptoms prior to the incident event of SCD are not known in most cases, some athletes may be asymptomatic or minimally symptomatic at the time of the event. In a recent study reviewing SCD in athletes due to autopsy-proven myocarditis, more than 50% had no reported symptoms (viral and/or cardiac), and only 16 of 74 (21.6%) reported cardiac symptoms (chest pain, palpitations, syncope) prior to the event.30 Additionally, if risk to the athlete is related to myocardial abnormalities (inflammation, edema, fibrosis), our preliminary evaluation demonstrated similar CMR findings (T2 mapping and LGE) between baseline clinical vs subclinical myocarditis and with or without abnormalities on cardiac testing (Figure 3). Beyond the acute issues and concerns, there may be benefit to establishing baseline myocardial abnormalities after COVID-19 to determine the need for follow-up studies and future risk. However, this inference would require more detailed expert CMR imaging core analysis and more cases to determine if there are myocardial inflammatory patterns and differences in LGE that would be clinically useful.

CMR abnormalities resolve for some cases, which seems clinically encouraging. Although the number of cases are too few for analysis with adequate statistical power, clinical myocarditis cases in this sample appear less likely to demonstrate resolution of LGE than subclinical cases, at least within the period of follow-up reported here. While the lack of resolution in those cases might have been expected, the limited follow-up data we present also suggests that longer intervals between initial and follow-up CMR imaging do not always result in resolution of CMR findings.

Use of CMR screening for all athletes who have had SARS-CoV-2 infection is challenging for many reasons. Data are lacking on the prevalence of CMR changes that could be related to athletic cardiac adaptation. Moreover, the LLC used in CMR diagnosis of myocarditis have been validated only in symptomatic myocarditis cases and not systematically studied in an asymptomatic cohort. All Therefore, using CMR imaging as a screening tool to detect subclinical myocarditis after a viral infection warrants further analysis and continues to be a work in progress. This will require short- and long-term outcome data to clarify the implications of these findings.

Although CMR imaging was completed as part of cardiac evaluation for fewer than 100% of the Big Ten athletes with COVID-19, selection bias associated with our estimate of myocarditis prevalence appears unlikely for 3 reasons. First, some athletes did not undergo CMR imaging because prior to the mandate, it was not required. Hence, the reason for missing CMR imaging data was independent of relation to symptoms or other testing and may reasonably be treated as uninforma-

tively censored. Second, our sensitivity analysis conducted among the 5 programs that completed CMR imaging in all athletes resulted in a prevalence of 2.3% (95% CI, 1.4%-3.5%) is consistent with the overall observed myocarditis prevalence for all programs (2.3%; 95% CI, 1.6%-3.2%). Third, the other 8 programs added complete cardiac evaluations and CMR imaging for all athletes at various times, all after the mandate. All clinical and subclinical probable myocarditis cases from these 8 programs were diagnosed after the mandate, when the programs had incorporated CMR imaging as part of the cardiac evaluation.

The data presented suggest that 1.8% of athletes with prior SARS-CoV-2 infection are both asymptomatic and have subclinical myocarditis. Importantly, inclusion of CMR imaging in the RTP protocol also has the advantage of reassuring that myocardial injury has not occurred if the CMR findings are normal. CMR imaging is highly sensitive for identifying myocardial inflammation<sup>21,34,35</sup> and in our study was able to exclude significant disease and allow safe RTP in 97.7% of athletes after cardiac screening. While there may be a concern that CMR imaging is too sensitive and therefore unduly restrict athletes from sport, such a scenario would only account for a very small proportion of the population based on our study.

In our view, the role of CMR imaging in routine screening for athletes' safe RTP should be explored further; we could then better assess the possible risk to those athletes with undiagnosed subclinical myocarditis who exercise and the benefit of ruling out significant myocardial inflammation and injury by a normal CMR.

#### Limitations

Not all athletes who tested positive for SARS-CoV-2 infection underwent CMR imaging evaluation prior to September 2020, when the Big Ten Conference mandated comprehensive cardiac testing for all athletes. It is possible that prior to this period, there could have been a selection bias in undergoing CMR imaging. However, our review of this population (eAppendix 2 in Supplement 1) and sensitivity analysis suggests that selection bias in referral to CMR imaging was not likely to influence the observed prevalence of myocarditis in this study. Sources of CMR variability as described may have influenced prevalence estimates and require standardization. LLC were developed in a different clinical population, so generalizability of these criteria to this context of SARS-CoV-2-infected population may be flawed and requires further analysis. There are several other concerns regarding using CMR imaging as a screening tool. CMR imaging may not be easily accessible to all, the volume may exceed local capacity, local expert interpretation may be insufficient, and CMR imaging could be considered costly.

Detailed, person-specific biographical data were not collected. Our survey and observational study are intended to be an institution-level analysis with a nested case series of athletes who had CMR abnormalities consistent with myocarditis to allow us to report prevalence of myocarditis. Individuallevel information and COVID-19-negative athletes will be an important addition to future CMR imaging comparative analysis. Uniform and validated evaluation of diagnostic data in core

laboratories has not occurred at this time. Thus, local evaluations of diagnostic data may be inconsistent with validated interpretations.

#### Conclusions

Among Big Ten athletes with recent SARS-CoV-2 infection and complete cardiac screening prior to RTP, 2.3% had evidence of clinical or subclinical myocarditis. We observed variability in prevalence across universities, and this may be based on timing of CMR imaging relative to COVID-19 infection and variability in CMR protocols and interpretation. In our study, testing protocols are closely tied to the detection of myocarditis, and cases may not have been detected without CMR imaging. Further detailed core analysis will guide

CMR screening protocols and Big Ten RTP recommendations. At present, we do not know the natural history or the shortand long-term implications to an athlete with COVID-19 clinical or subclinical myocarditis. To address these concerns, we must find ways to minimize the variability in performance among academic centers to diagnose myocarditis, perhaps through standardized evidence-based diagnostic algorithms and testing protocols, and when indicated, standardization of CMR protocols and interpretation. These unique CMR data give us a more complete understanding of the prevalence of clinical and subclinical myocarditis in college athletes recovering from symptomatic and asymptomatic COVID-19 infections. The Big Ten COVID-19 Cardiac Registry is committed to longitudinal study and elucidating the best role of CMR imaging in returning athletes to sport after COVID-19 infection.

#### ARTICLE INFORMATION

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**Author Contributions:** Dr Daniels had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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**Group Information:** Nonauthor contributors to the Big Ten COVID-19 Cardiac Registry are listed in Supplement 3.

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From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Sun, 23 May 2021 14:56:31 +0000
To: Walensky, Rochelle (CDC/OD)

**Subject:** FW: Myocarditis\_update deck 5232021\_FINAL.pptx **Attachments:** Myocarditis\_update deck 5232021\_FINAL.pptx

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>

Sent: Sunday, May 23, 2021 10:55 AM

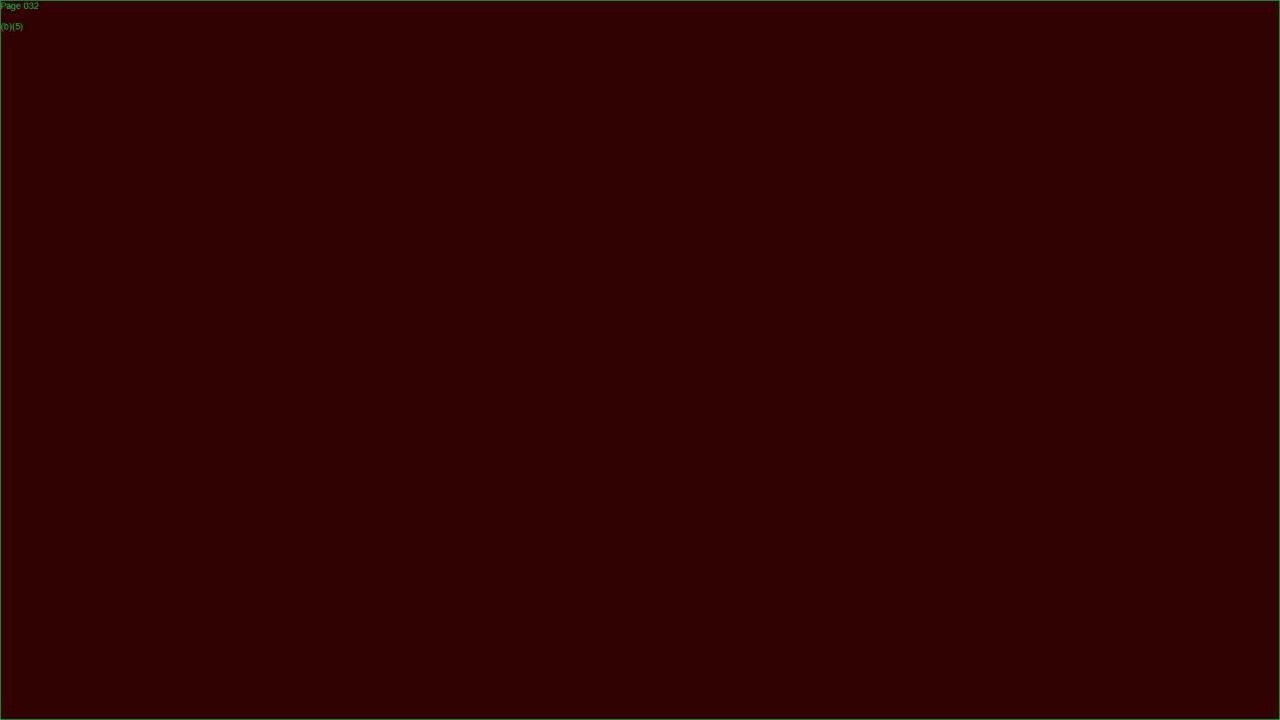
To: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

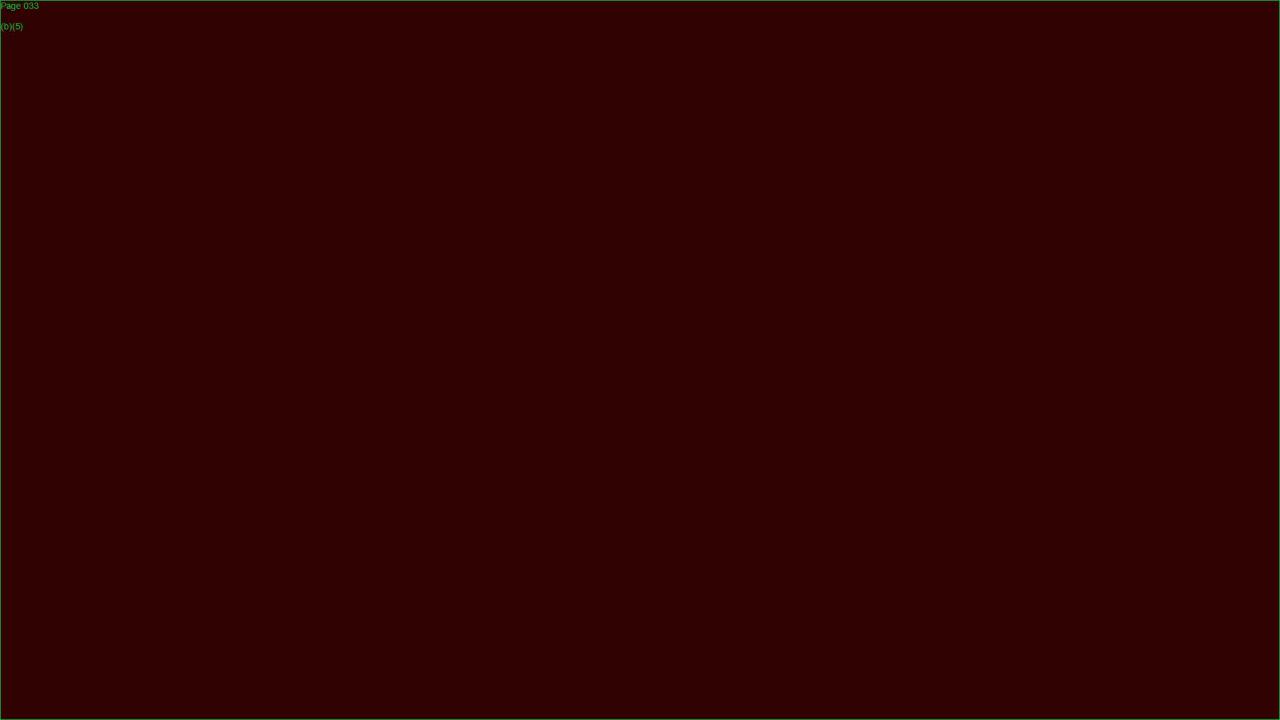
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Patel, Anita (CDC/DDID/NCIRD/OD)

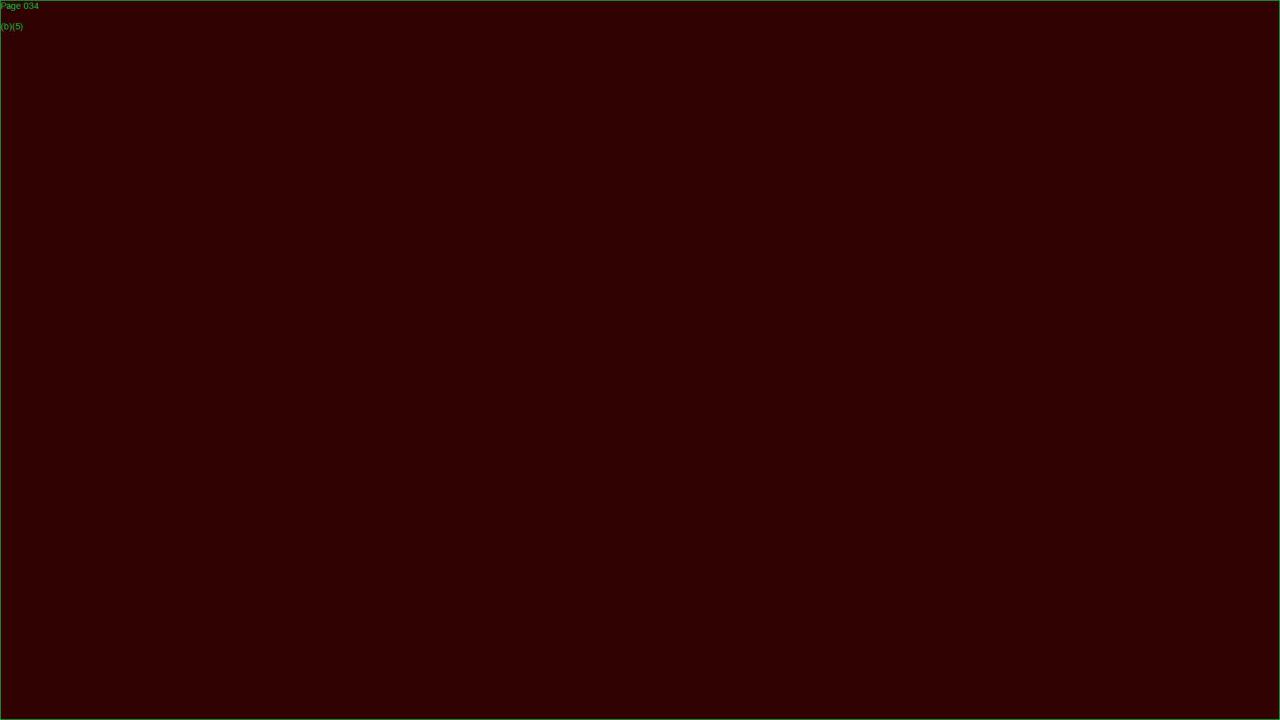
<bop1@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>

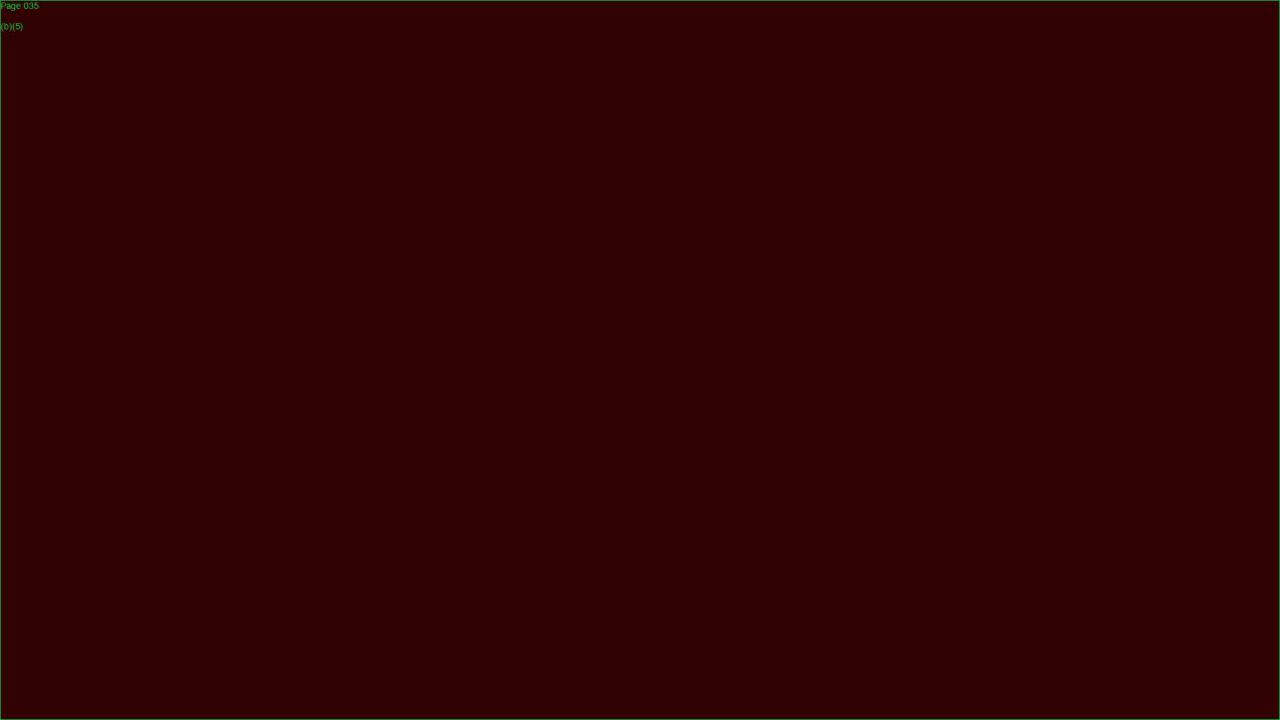
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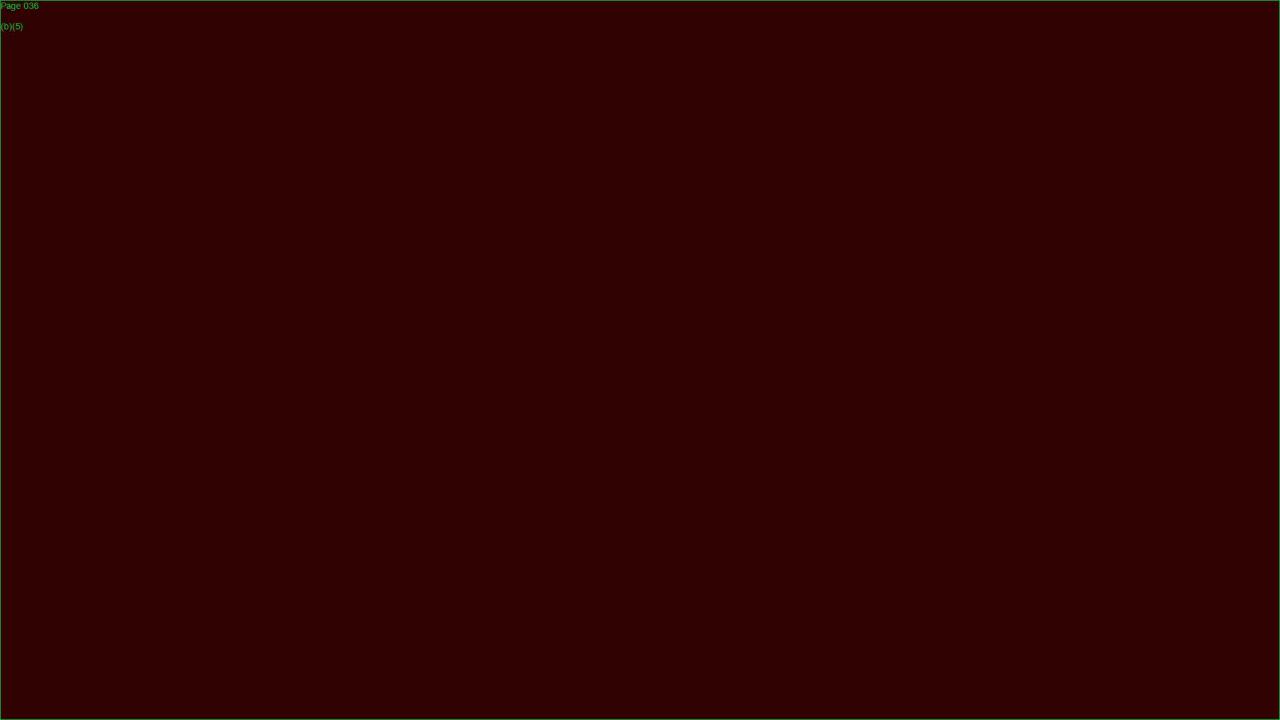
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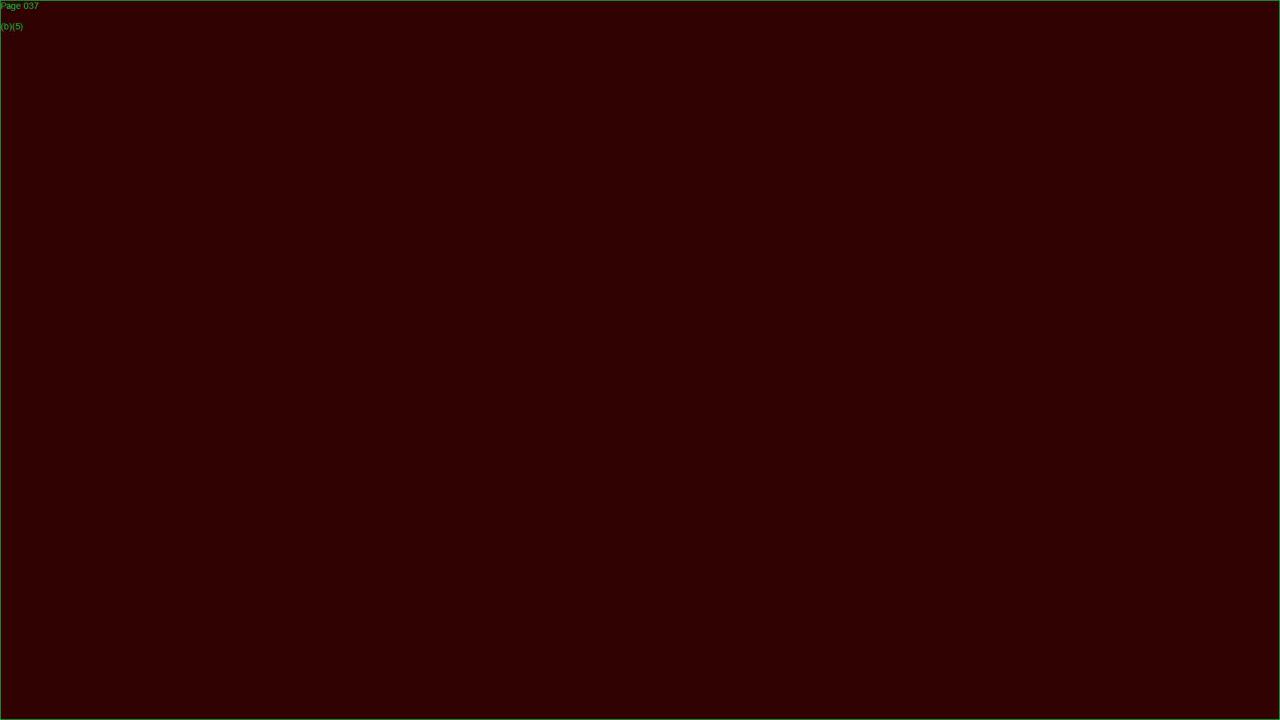


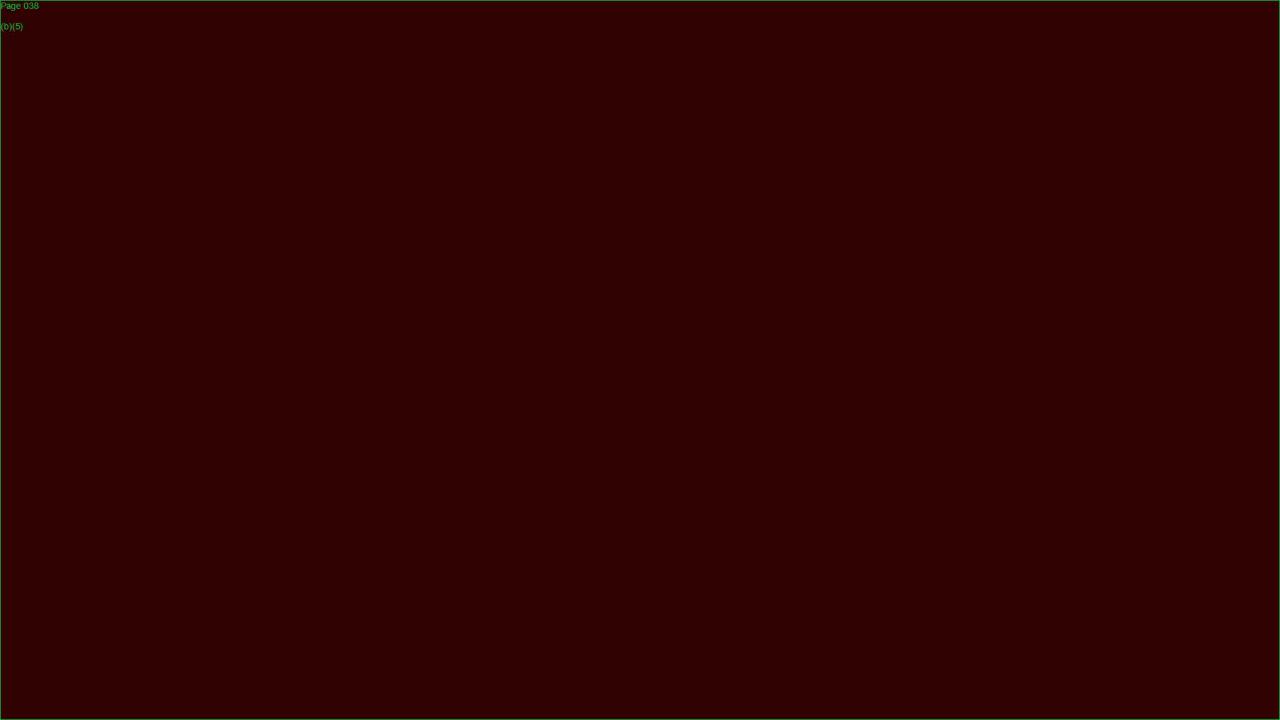


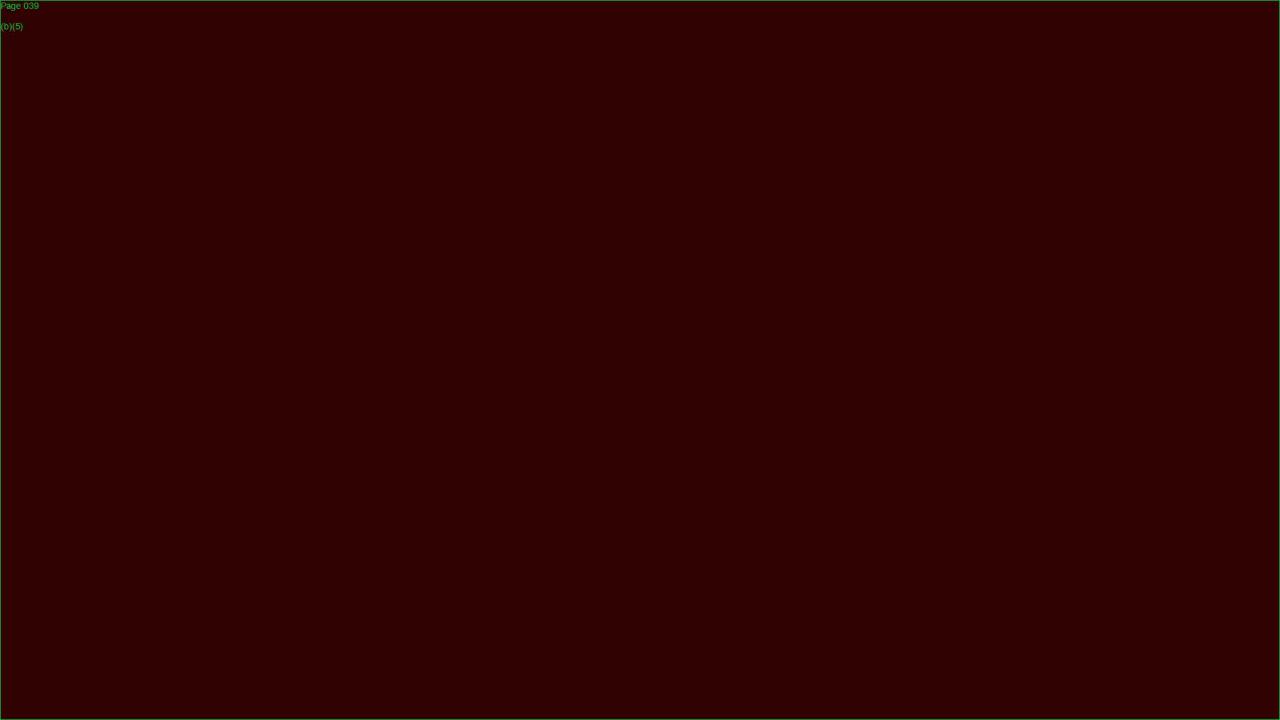


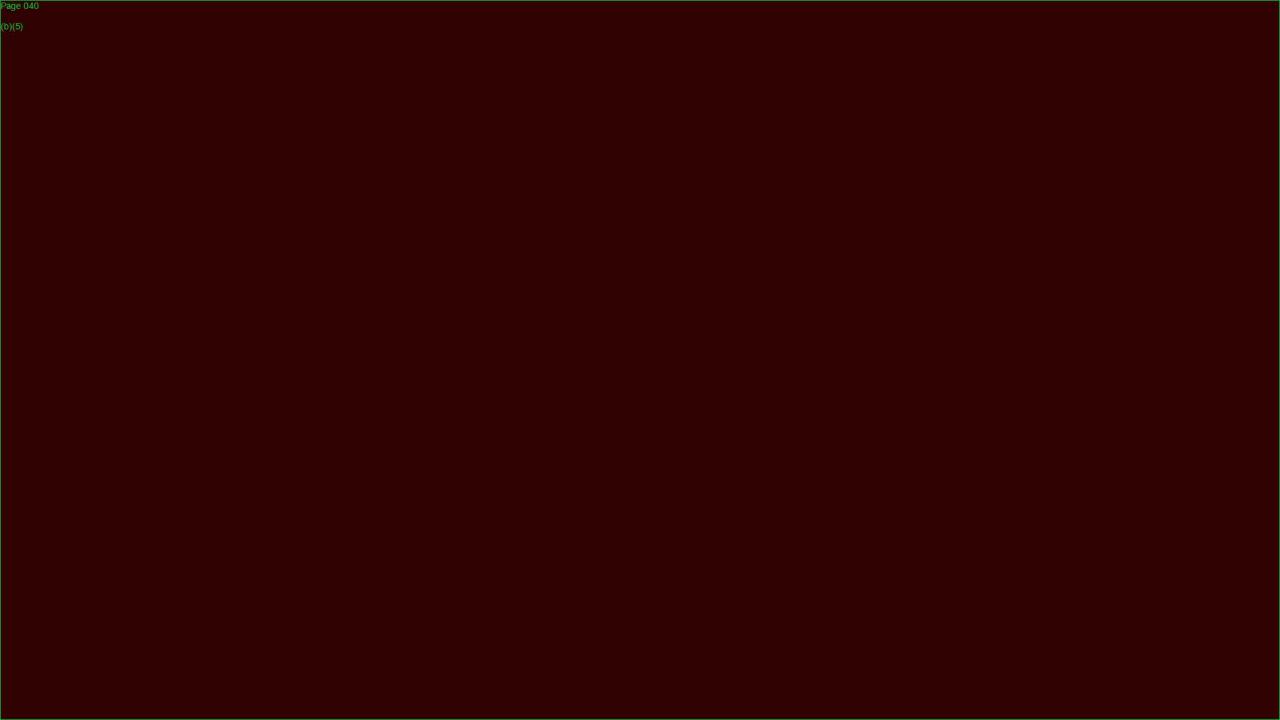


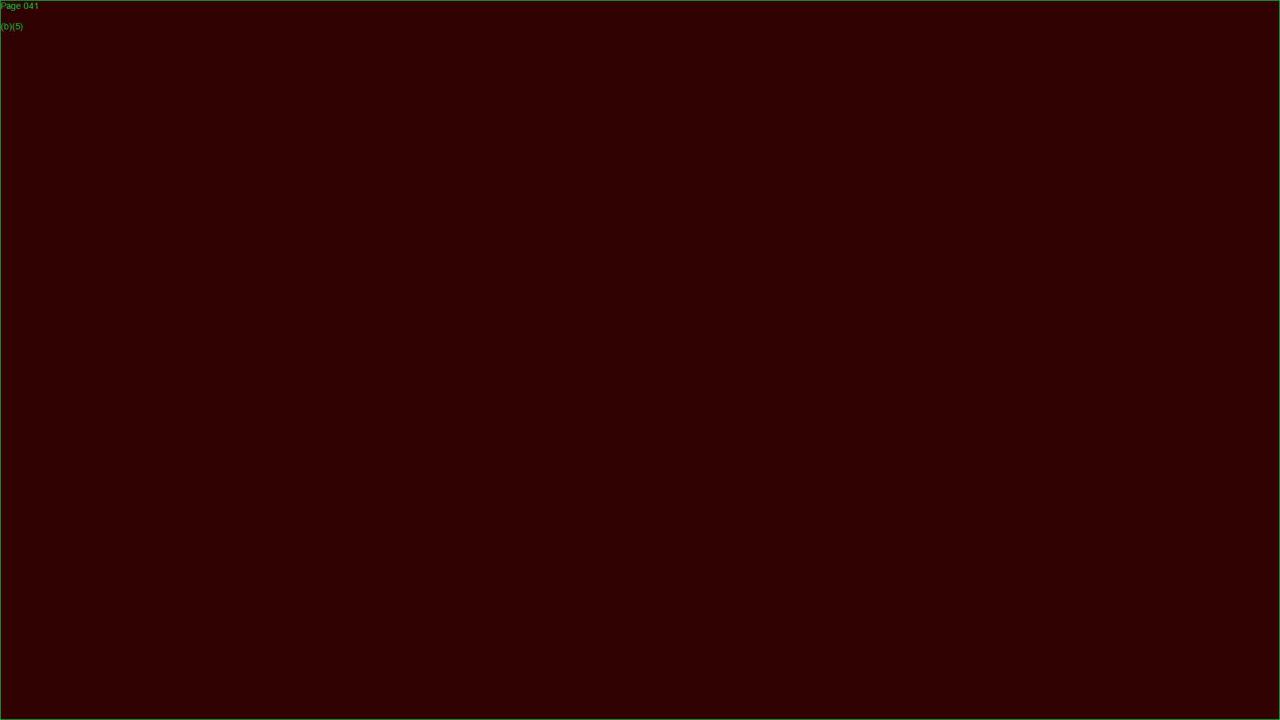


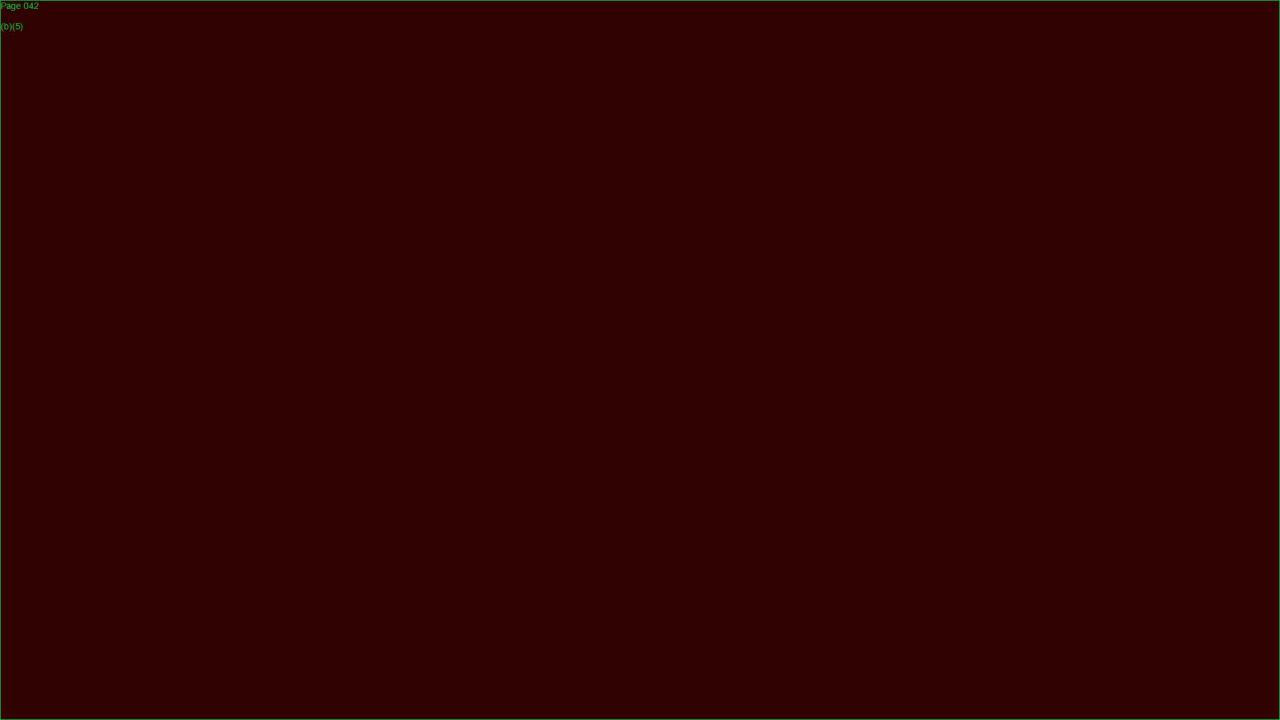


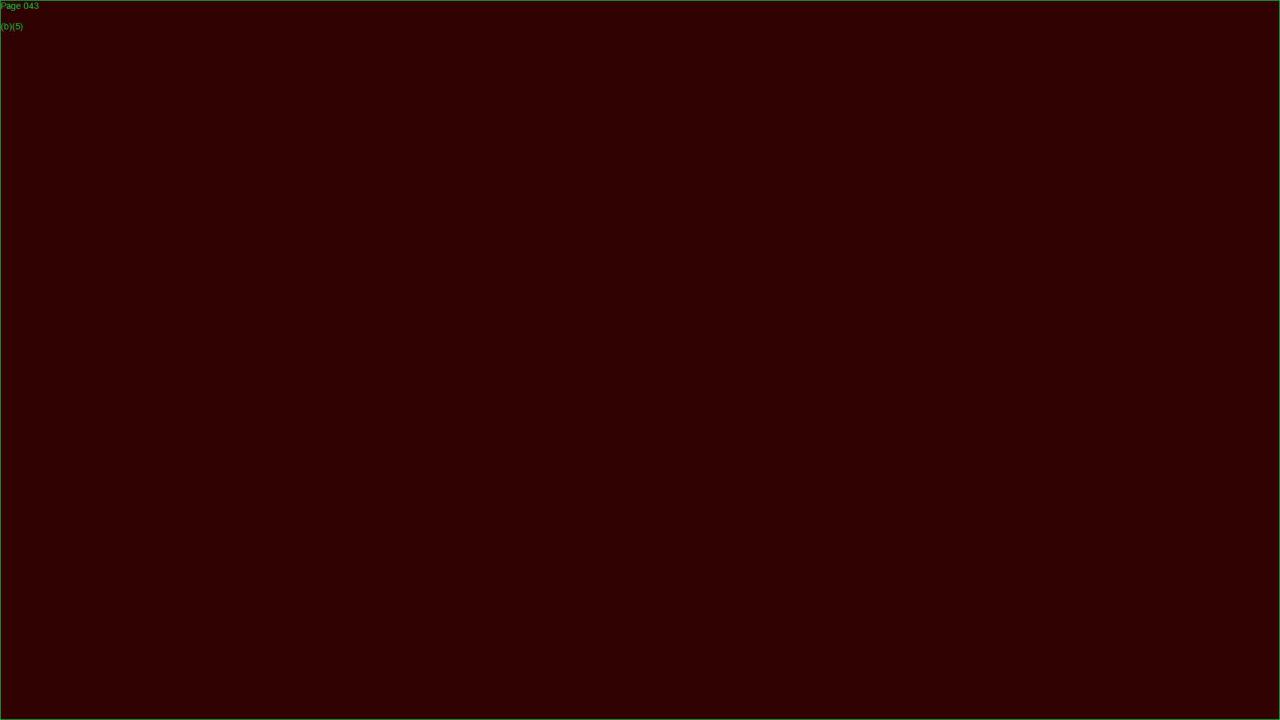


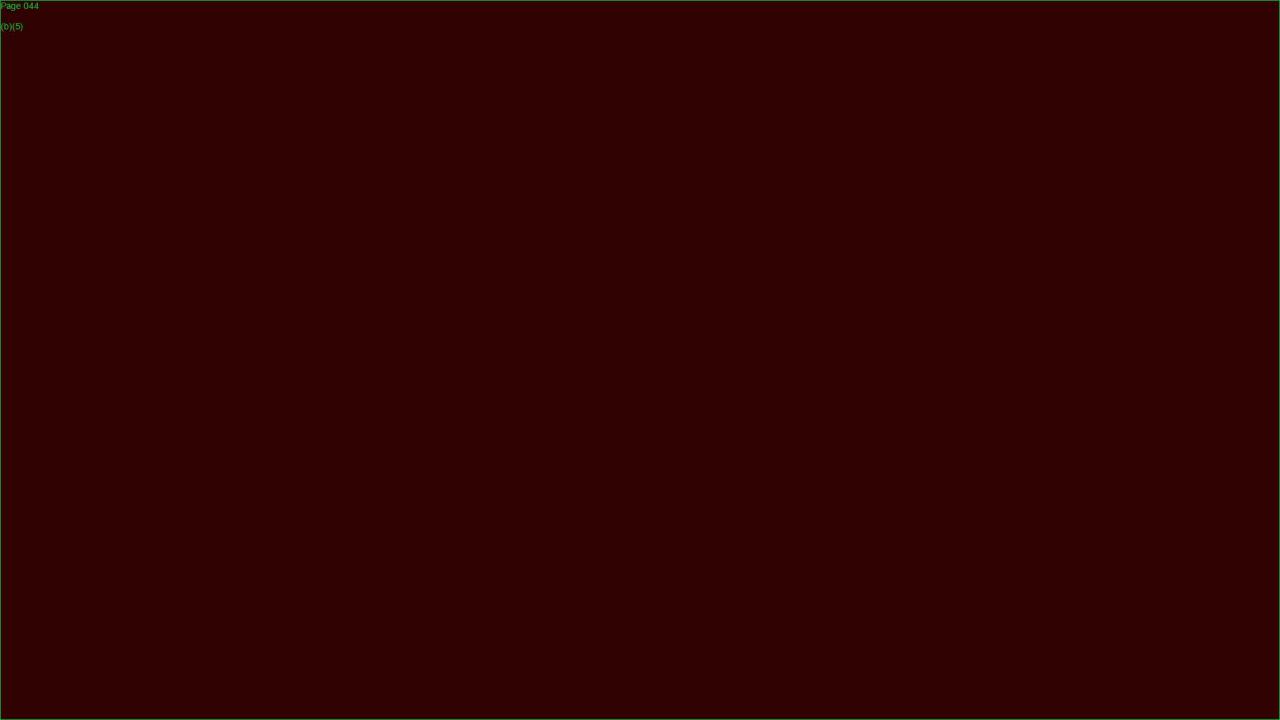












From: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Sent: Sun, 23 May 2021 14:41:02 +0000

To: Walensky, Rochelle (CDC/OD)

Cc: Berger, Sherri (CDC/OCOO/OD)

Subject: FW: Myocarditis\_update deck 5232021\_1033.pptx
Attachments: Myocarditis\_update deck 5232021\_1033.pptx

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>

Sent: Sunday, May 23, 2021 10:37 AM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

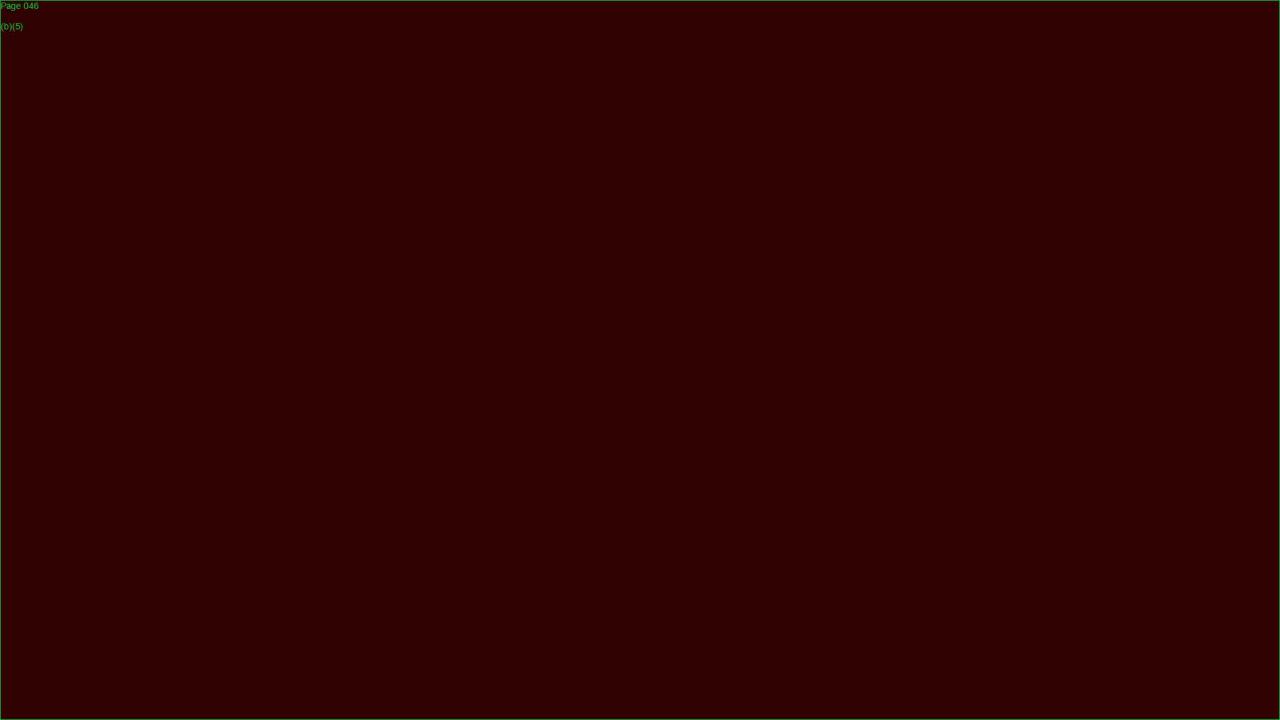
<kaf6@cdc.gov>

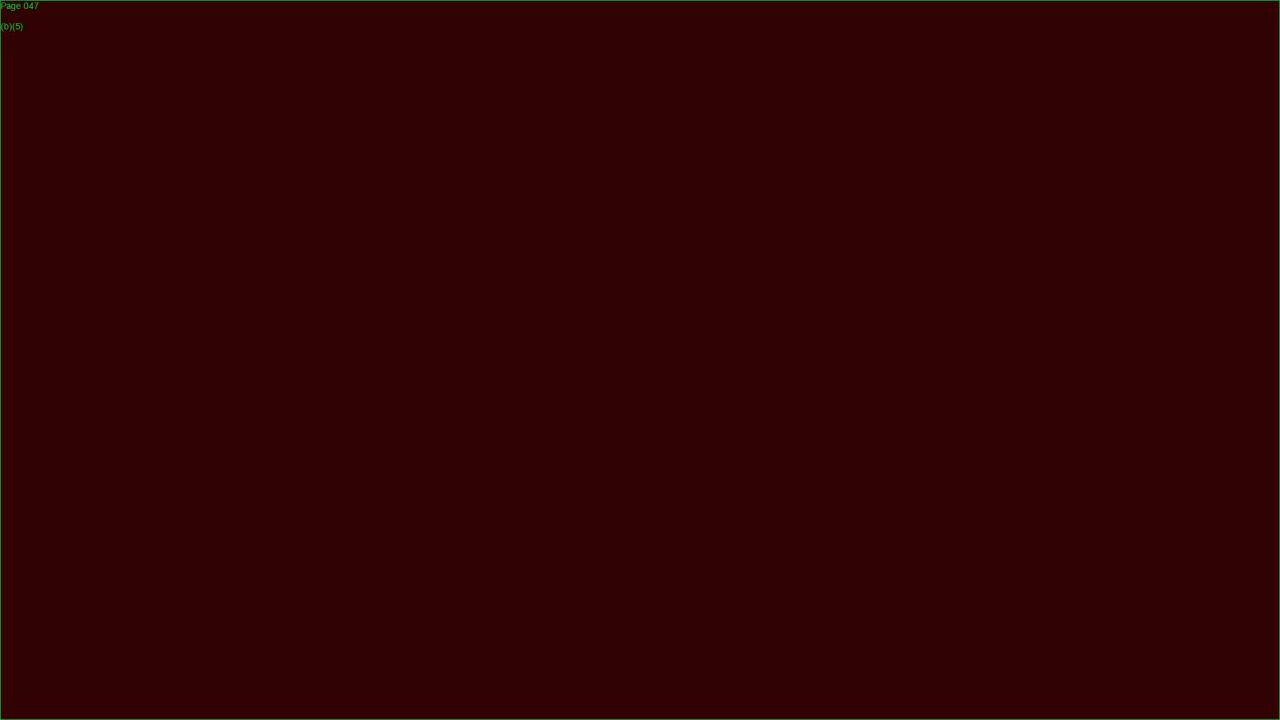
Subject: Myocarditis\_update deck 5232021\_1033.pptx

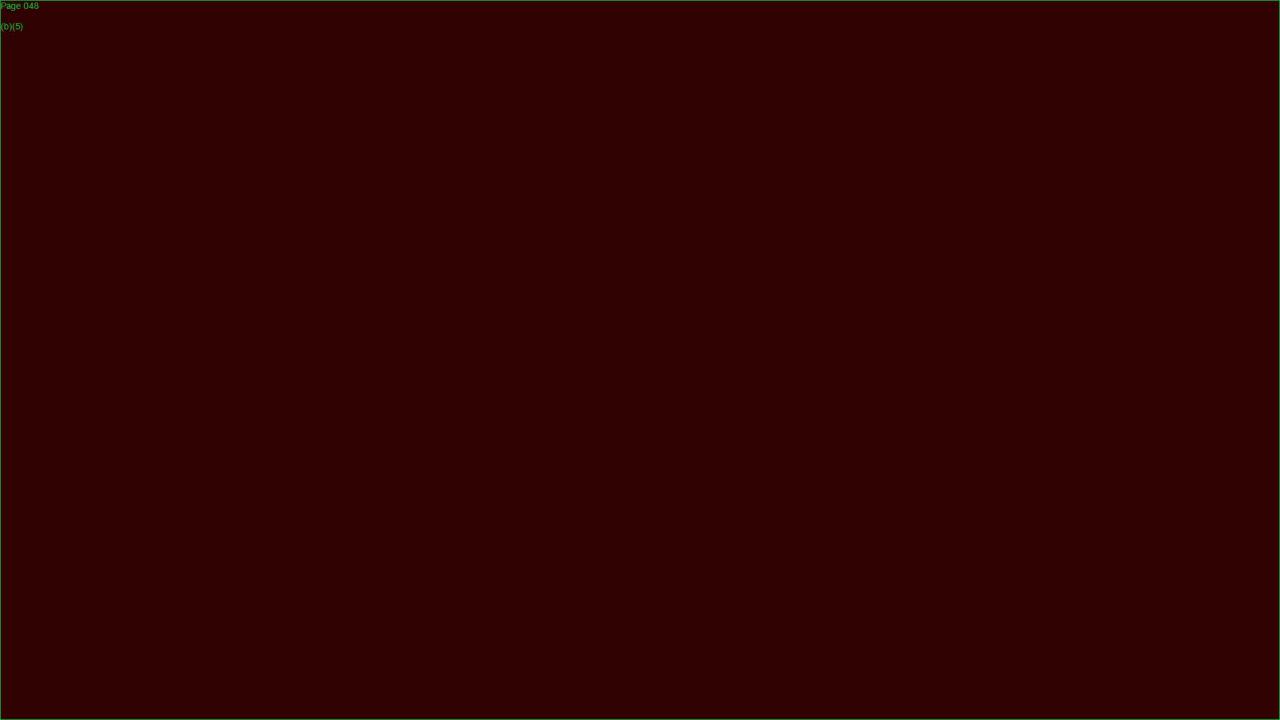
Henry-

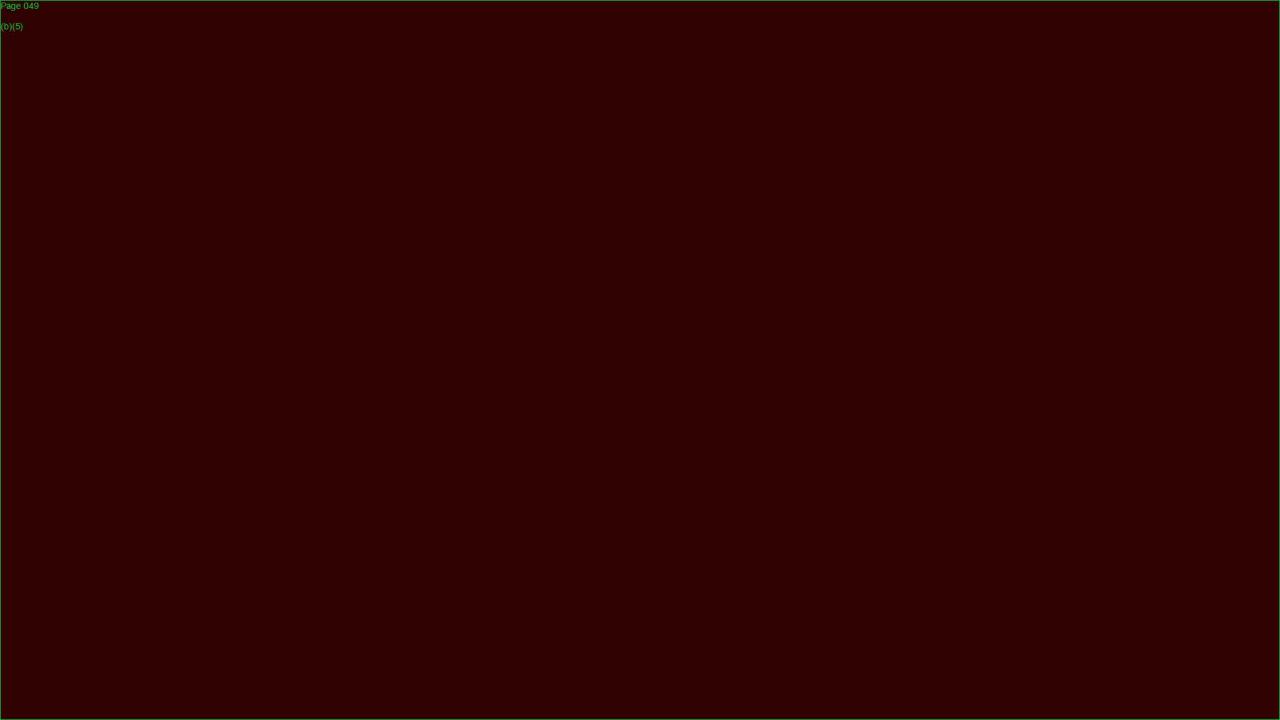
Am working on a couple of bullets but wanted to show you what we have. but have the raw VAERS in here. Will push to get my couple of unresolved issues fixed.

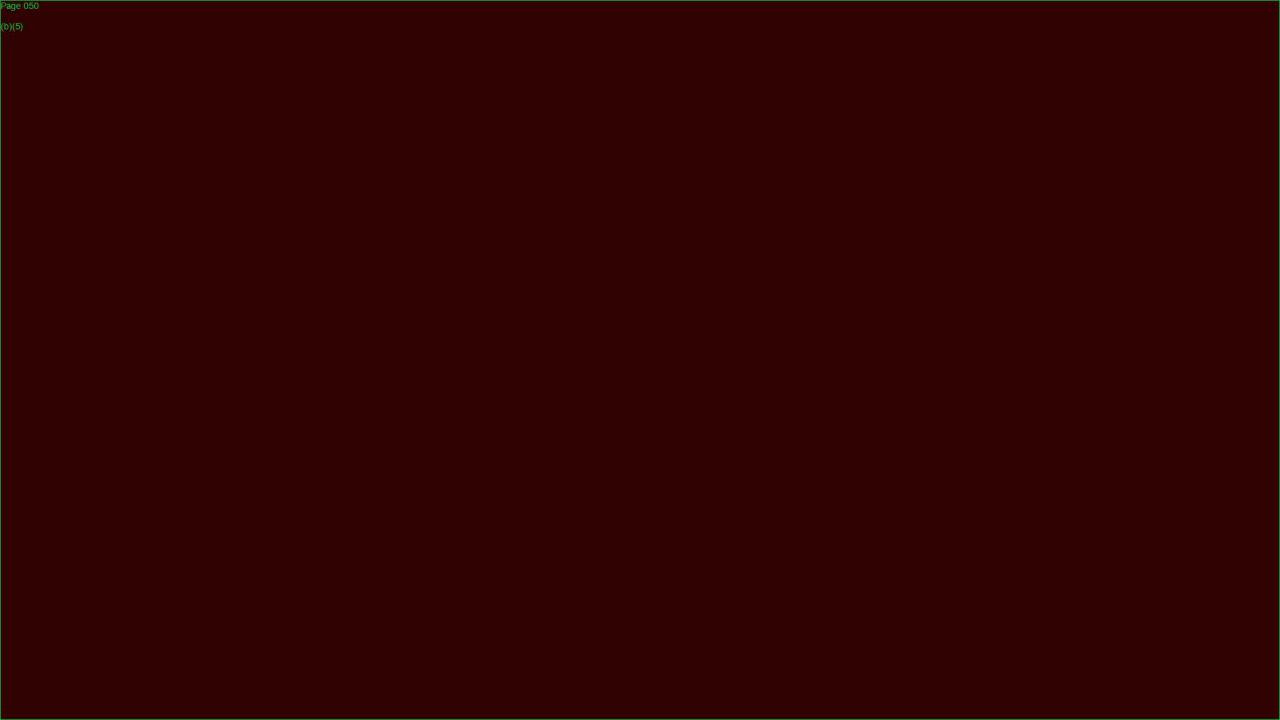
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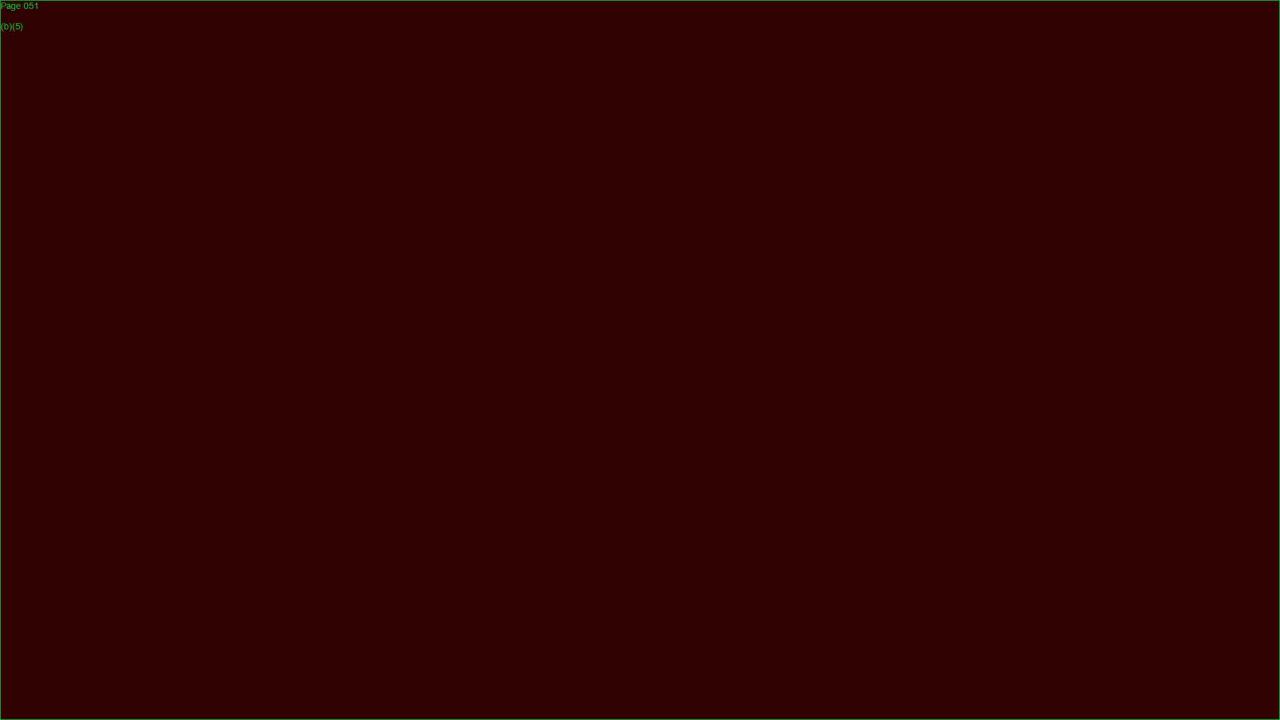


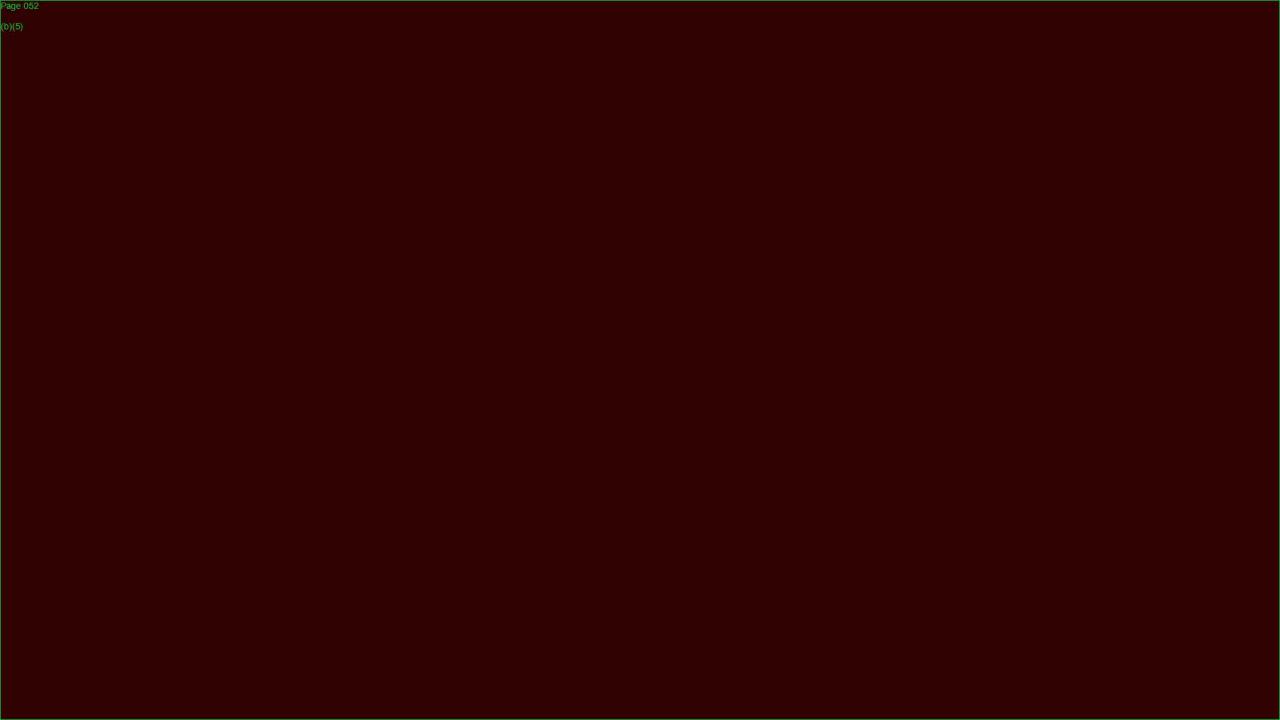


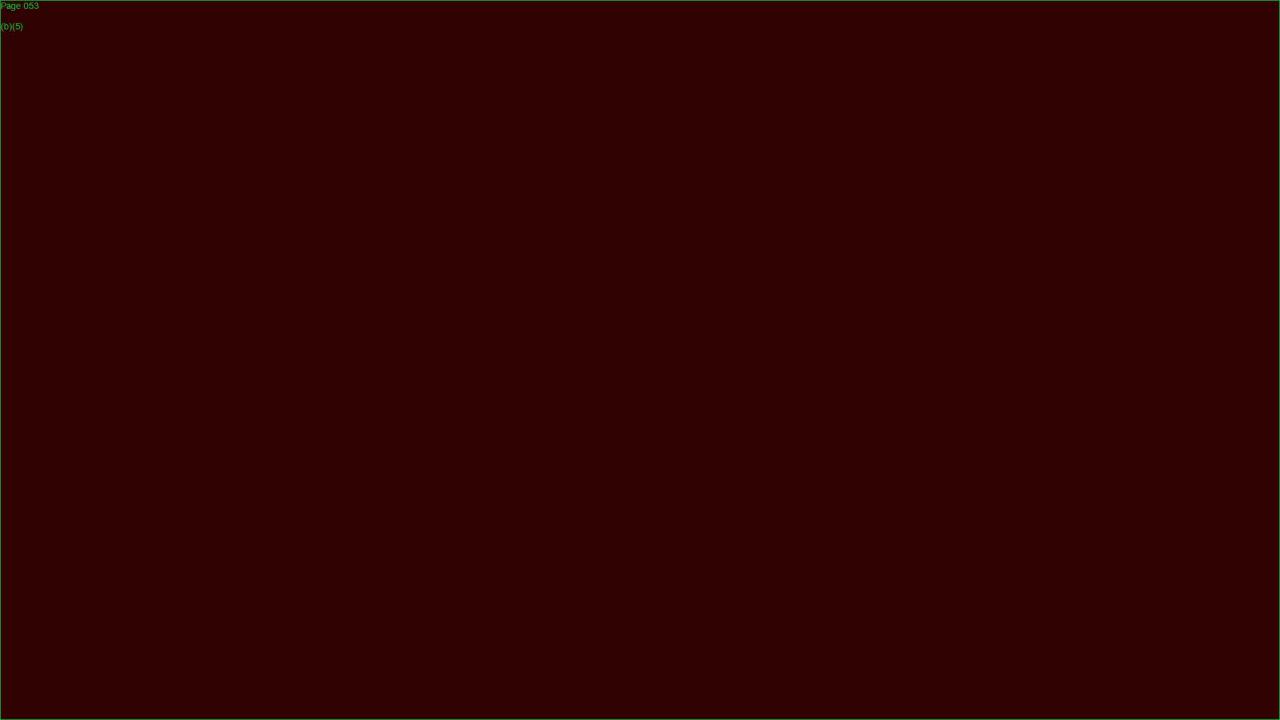


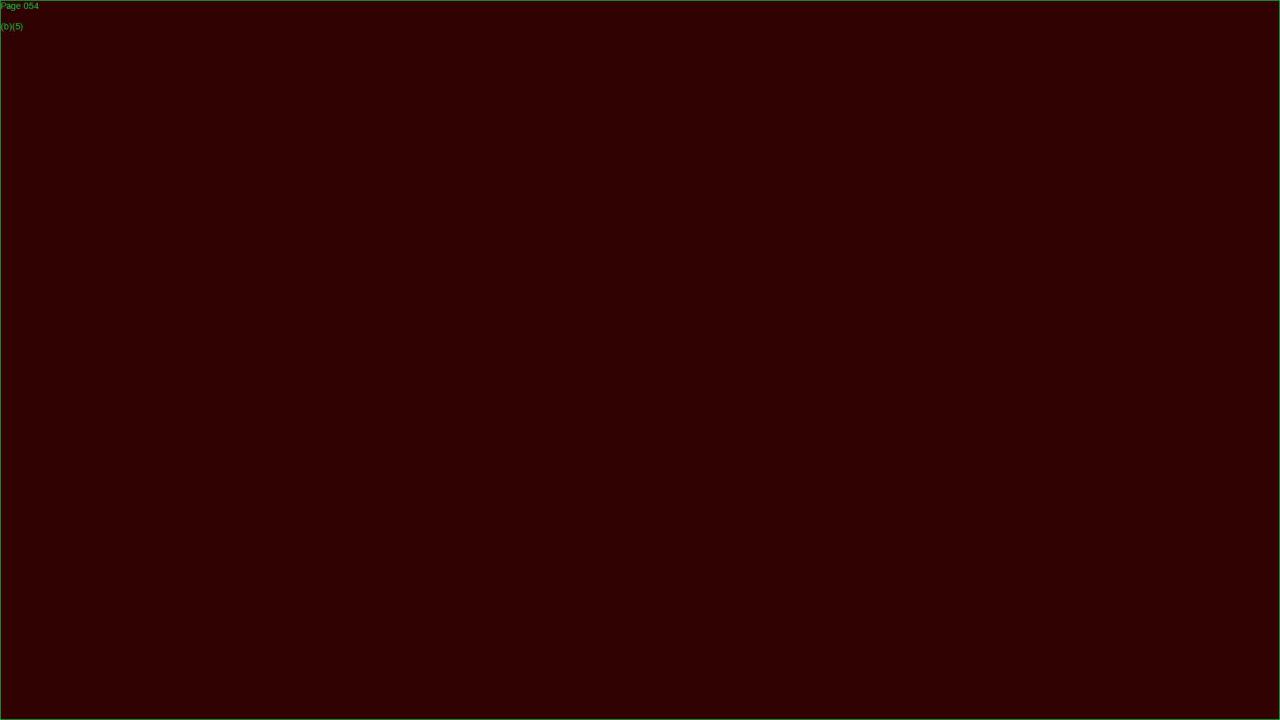


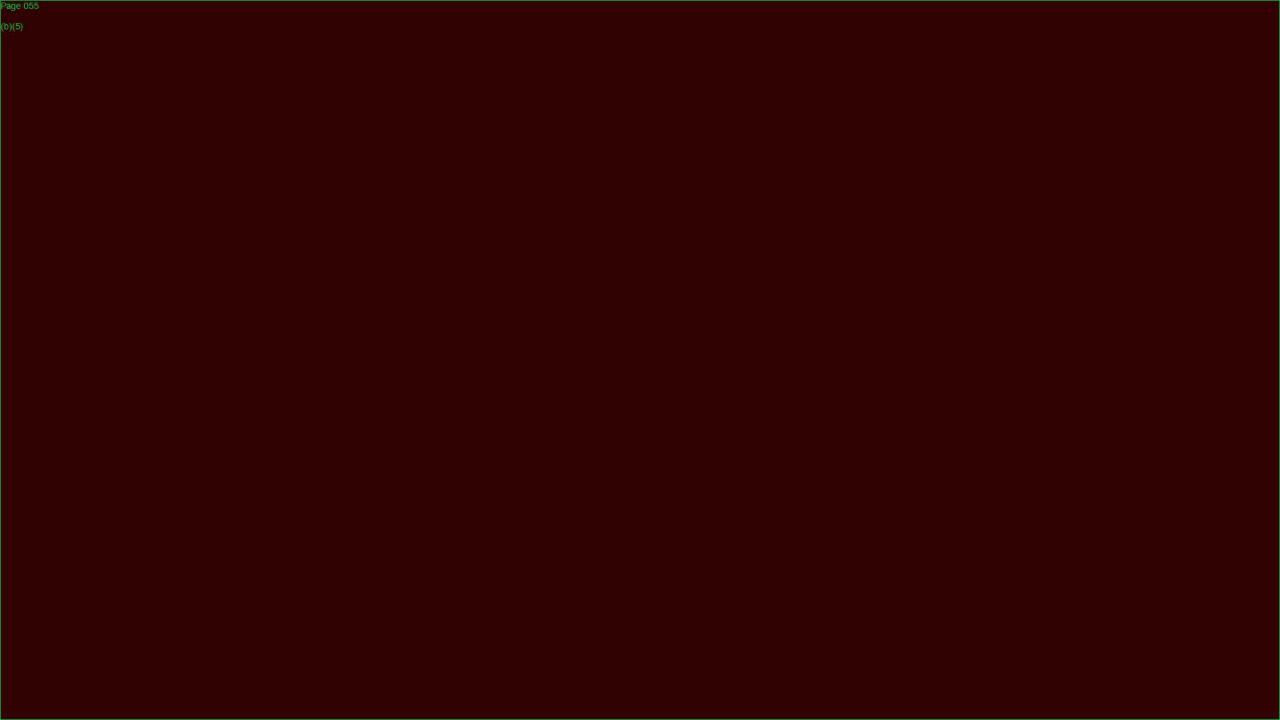


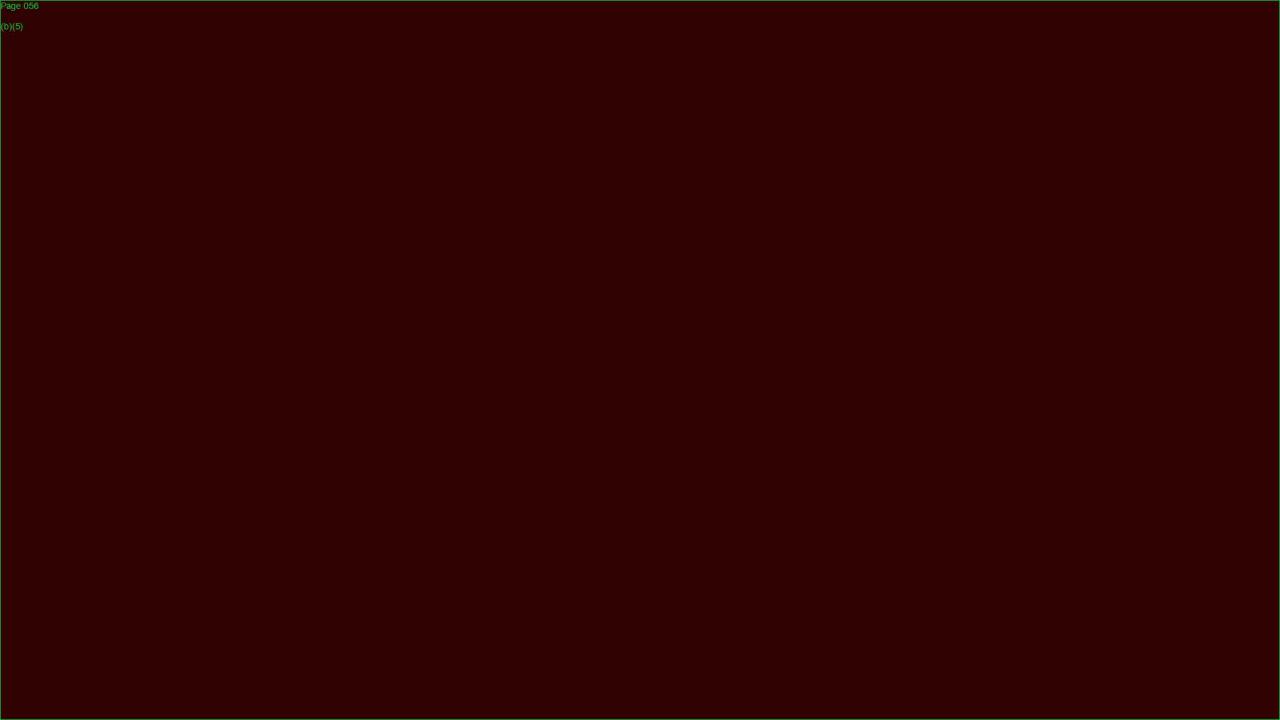


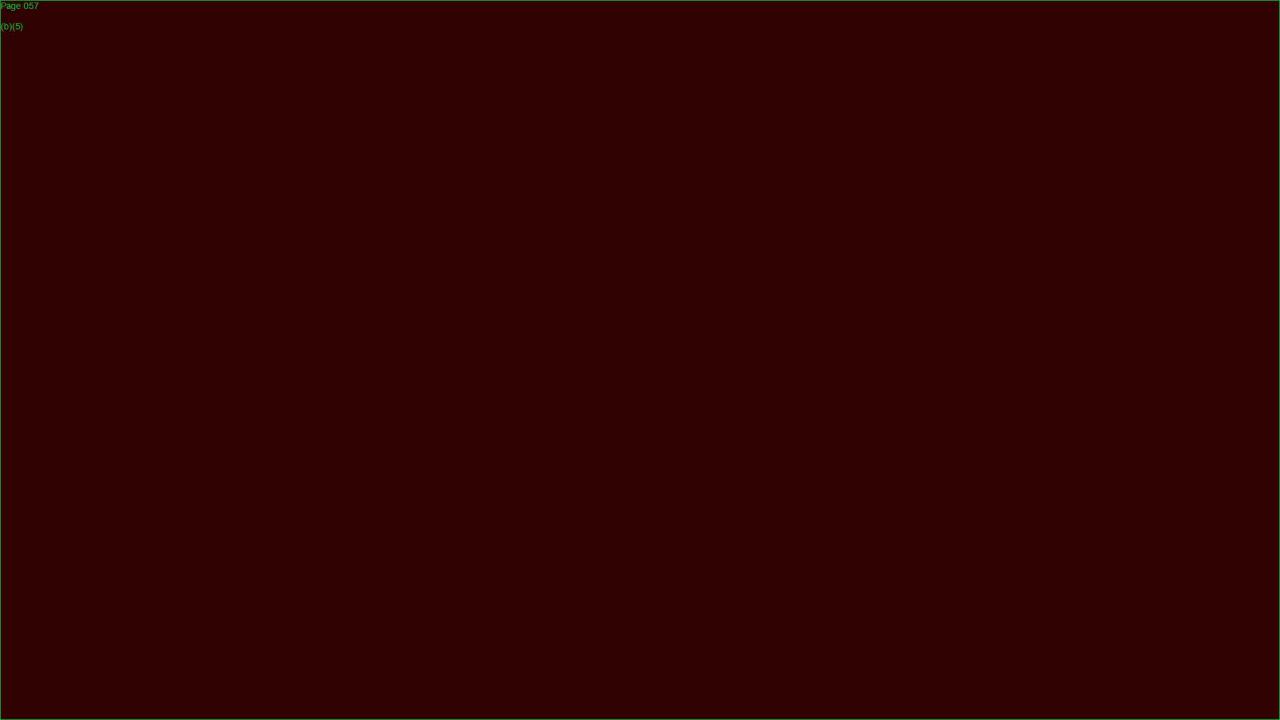












From: Ogden, Cynthia L. (CDC/DDPHSS/NCHS/DHNES)

**Sent:** Thu, 27 May 2021 22:56:45 +0000

To:

Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Berger, Sherri (CDC/OCOO/OD);

Bernstein, Kyle T. (CDC/DDID/NCHHSTP/DSTDP); Brooks, John T. (CDC/DDID/NCHHSTP/DHP); Butler, Jay C. (CDC/DDID/OD); Christie, Athalia (CDC/DDPHSIS/CGH/OD); Dowell, Deborah (Debbie) (CDC/DDNID/NCIPC/DOP); Goldstein, Robert (CDC/OD/OADPS); McDonald, Clifford

(CDC/DDID/NCEZID/DHQP); Murthy, Vivek (HHS/OASH); Schuchat, Anne MD (CDC/OD); Walensky,

Rochelle (CDC/OD); Walke, Henry (CDC/DDID/NCEZID/DPEI)

Cc: Rosenberg, Ronald (CDC/DDID/NCEZID/DVBD); Ogden, Cynthia L.

(CDC/DDPHSS/NCHS/DHNES)

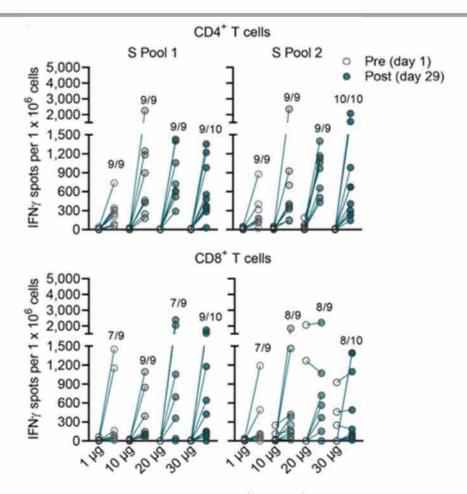
Subject: Director's Daily Update May 27, 2021

# CMOU Director's Daily Update COVID-19 SCIENCE

#### May 27, 2021, 4 Articles, 2 Items of Interest

All participants in a prime/boost, Phase 1/2 trial of BNT162b2 vaccine mounted de novo spike (S)-specific CD4 $^+$  T-cell responses; almost 90% mounted de novo CD8 $^+$  T-cell responses. 12 healthy volunteers (19-55 yr) were assigned to each dose: 1, 10, 20 or 30  $\mu$ g. T-cell response was dose independent above 1  $\mu$ g. BNT162b2 immune sera neutralized 22 synthesized virus epitopes representing B.1.351, B.1.1.7, P.1, and B1.1.298.

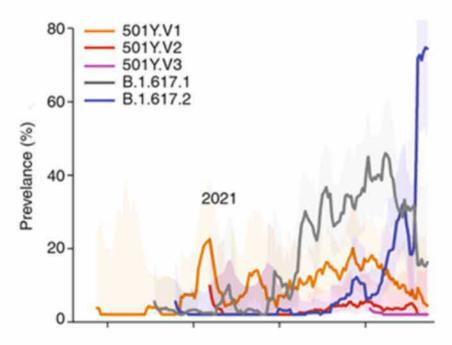
BNT162b2 vaccine induces neutralizing antibodies and poly-specific T cells in humans. Sahin et al. Nature (May 27, 2021)



Note: Magnitude and durability of BNT162b2-induced CD4<sup>+</sup> and CD8<sup>+</sup> T-cell responses. Changes from pre-inoculation (open circles) to 29 d after initial dose (filled circles) are shown. Magnitude of response, as interferon gamma activity, is plotted on y-axes; doses, on x-axes. Numbers above datapoints are positive participants/number tested. S pools 1 and 2 are sets of overlapping peptides that cover the whole sequence of the wild-type spike protein.

The surge of COVID-19 cases in India since March 2021 (from 53 to >200 per million population) has been driven by a succession of variant strains, including B.1.1.7, B.1.351, and B.1.1.28.1. There is now a steep rise in cases caused by B.1.617.2. Surveillance is being hindered by slow sequencing: only ~2,700 samples collected from 8 states were sequenced during January - April 2021.

SARS-CoV-2 variants of concern are emerging in India. Singh et al. Nature Medicine (May 27, 2021).



*Note:* Apparent cumulative prevalence of variants of concern 501Y.V1, 501Y.V2, 501Y.V3, B.1.617.1, and B.1.617.2 in India, presented as a 7-day rolling average of the percentage of total sequences. Shading shows 95% confidence intervals; X-axis represents January through April 2021.

In a convenience sample of 1,835 adults in Michigan, Black adults reported greater medical mistrust than other groups. 79% of the sample were women and 21% identified as Black; mean age was 49.4 yr. Black adults were least willing to participate in COVID-19 vaccine trials and to be vaccinated. Experiences of racism were cited as a leading reason for medical mistrust.

Factors associated with racial/ethnic group—based medical mistrust and perspectives on COVID-19 vaccine trial participation and vaccine uptake in the US. Thompson *et al.* JAMA Network Open (May 27, 2021).

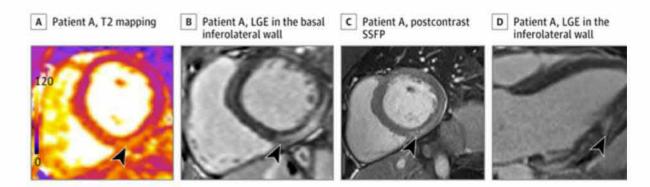
Table 3. COVID-19 Vaccine Trial and Uptake Willingness by Race/Ethnicity

Response	Participants, No. (%)						
	All	White	Black	MENA	Hispanic	Asian	Multiracial or other
Would participate in a vaccine trial							
Definitely no, probably no, or unsure	1376 (75)	669 (70)	345(88)	76 (82)	57 (68)	67 (70)	162 (80)
Definitely yes or probably yes	451 (25)	290 (30)	45 (12)	17 (18)	27 (32)	29 (30)	43 (21)
Would receive a vaccine							
Definitely no, probably no, or unsure	945 (52)	410 (43)	279 (72)	57 (62)	49 (58)	34 (36)	116 (57)
Definitely yes or probably yes	870 (48)	545 (57)	108 (28)	35 (38)	35 (42)	61 (64)	86 (43)

Note: MENA: Arab, Chaldean, Middle Eastern, or North African.

Among 1,597 college athletes from 13 universities who had cardiac magnetic resonance (CMR) imaging after COVID-19 infection, 37 (2.3%) were diagnosed with clinical (9) or subclinical (28) myocarditis. CMR imaging provides more complete prevalence of clinical and subclinical myocarditis in college athletes after COVID-19.

Prevalence of clinical and subclinical myocarditis in competitive athletes with recent SARS-CoV-2 infection: Results from the Big Ten COVID-19 Cardiac Registry. Daniels, et al. JAMA Cardiology (May 27, 2021). See Editorial in *Items of Interest* below.



Note: CMR Imaging for an athlete (Patient A) with subclinical possible myocarditis who was asymptomatic with normal electrocardiogram, echocardiogram, and high-sensitivity troponin findings. Panel A) T2 mapping showing elevated T2 in basal-mid inferolateral wall in short axis view. Panel B) late gadolinium enhancement (LGE) in the basal inferolateral wall in short axis view. Panel C) Postcontrast steady state-free precession (SSFP) images showing contrast uptake in the basal-mid inferolateral wall in short axis view. Panel D) LGE in the inferolateral wall in 3-chamber view.

#### Items of Interest:

Return to Play for Athletes After COVID-19 Infection: The Fog Begins to Clear. Udelson et al. JAMA Cardiology (May 27, 2021).

<u>Incentives for Immunity — Strategies for Increasing Covid-19 Vaccine Uptake</u>. Volpp *et al.* NEJM (May 26, 2021).

Disclaimer: For internal HHS communication only. Do not distribute.

From: (b)(6)

Sent: Sun, 23 May 2021 11:54:43 -0700
To: Walensky, Rochelle (CDC/OD)
Subject: Fwd: Myocarditis / age groups

Latest Pfizer data

Sent from my iPhone

Begin forwarded message:

From: "Caubel, Patrick" <Patrick.Caubel@pfizer.com>

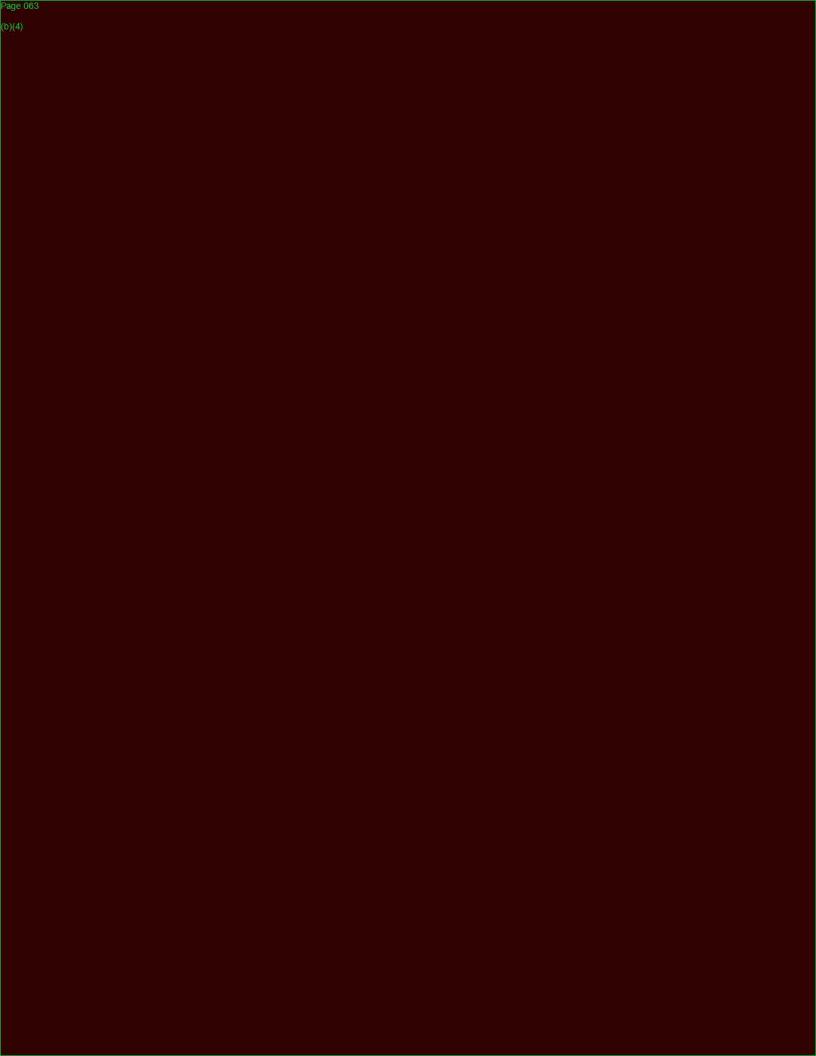
Date: May 23, 2021 at 11:44:29 AM PDT

To: (b)(6)

Subject: Myocarditis / age groups

Top graph is Myocarditis US ONLY, bottom is Myocarditis cumulative (all countries of occurrence).





From: Ohannessian, Dana (DPH)

**Sent:** Thu, 27 May 2021 15:41:56 +0000 **To:** Walensky, Rochelle (CDC/OD)

Subject: MA Department of Public Health - Weekly COVID-19 Vaccine Provider Bulletin

Attachments: Weekly COVID-19 vaccine provider bulletin\_5.27.21\_final.docx

Please find attached the Weekly COVID-19 Vaccine Provider Bulletin.

Information from attachment copied below.

# BULLETIN

# What Massachusetts COVID-19 Vaccine Providers Need to Know

### Week of 5/27/21

#### **Latest Numbers**

 As of 5/27, 3,558,197 people in Massachusetts have been fully vaccinated and 4,133,946 have received at least one dose of the Moderna or Pfizer vaccine.

#### Who to Vaccinate this Week

Anyone age 12 and older who lives, works, or studies in Massachusetts is eligible for a vaccine.
 Health care providers can also vaccinate their patient panels regardless of place of residency.

#### What to Know this Week

- New Changes to Pfizer COVID-19 Vaccine Storage: Undiluted, thawed Pfizer COVID-19 Vaccine vials can be stored in the refrigerator at 2°C 8°C for up to 1 month.
  - The vials must be undiluted to remain at 2°C 8°C for 1 month.
  - Step down storage & handling for Pfizer COVID vaccines is now as follows:
    - All Pfizer configurations are shipped ultra-cold.
    - **Ultra-cold (-70<sup>0</sup>C):** May be stored in ULT freezer until the expiration date, or temporarily in the shipper with regular dry ice replenishment.
    - Frozen (-20<sup>o</sup>C): Undiluted vials may remain frozen at -20<sup>o</sup>C for up to 2 weeks.
    - Refrigerated (2-8<sup>0</sup>C): Undiluted vials may remain at 2°C 8°C for 1 month.
  - Total storage time for Pfizer in freezer and refrigerator combined should not exceed 45 days.
- New *Pfizer vaccine will be available in a new 450-dose configuration:* As of May 28, providers will be able to order the 1,170-dose and 450-dose product configurations.

Pfizer 450 (New)	NDC 59267-1000-03	75 Multidose vials (3 trays of 25 vials		
		each)		

Pfizer 1,170	NDC 59267-1000-02	195. Itidose vials	
Pfizer 1,170	NDC 59267-1000-02	195. Itidose vials	

- Vials will be shipped in the same container as the 1,170-dose orders and will include the same Controlant temperature monitor.
- The newly extended refrigerator storage temperatures will decrease the need for dry ice. There will be no dry ice replenishment for the 450-dose pack.
- · Return shippers and Controlant monitors within 10 days.
- New ancillary kits have been created to support the 450-dose minimum order size. The
  adult ancillary kits contain the same ratio of 1" to 1.5" needles as the 1,170 kit. The
  pediatric ancillary kit contains only 1" needles. Other supplies in the kit remain the
  same.
- Reminder Moderna vials: Moderna vaccine is now available in two different vials the maximum 11-dose vial and a new maximum 15-dose vial. The vial will remain the same size but will be filled to the higher volume. A new NDC has been issued for the larger volume Moderna vial, which has been authorized for a range of 13-15 doses in the updated Moderna EUA factsheet for healthcare providers. The smaller maximum 11-dose vials being phased out. It will not always be possible to extract the 15<sup>th</sup> dose; providers should expect to withdraw 13-15 doses from a vial.
  - Talking points about the Moderna COVID-19 Vaccine EUA Amendments
  - FAQ about the EUA Amendments
  - Images of the new Moderna cartons and vial labels
  - Wastage Reporting Table
- New Updated Inventory Requirements for Primary Care Providers and Community Health Centers: Primary Care Providers (internal medicine, family practice, pediatric, and multi-specialty) and Community Health Centers must use COVID-19 vaccines within 4 weeks of receipt and must deplete existing inventory before an additional order is approved. Previously, all providers needed to administer vaccines within 10 days of receipt. This requirement has changed due to the increased availability of vaccines and a better understanding of logistical issues. All other providers must administer vaccines within 10 days of receipt. Review the ordering guidance for more information.
- New Encouraging vaccination with all your patients: Healthcare providers are the most trusted resource for patients in making health decisions. Your strong recommendation to get a COVID-19 vaccine is one of the most important factors in your patients' decision to accept vaccination.
  - Use CDC's <u>sample letter to patients to encourage COVID-19 vaccination</u> to communicate with all your patients.
  - Strongly recommend COVID-19 vaccine at every patient visit.
  - See <u>COVID-19 Vaccination Tips for Providers: Talking to Patients | Mass.gov</u> for help talking with your patients about COVID-19 vaccines.
  - If COVID-19 vaccines are not available at your office, offer to help them make an
    appointment. Use <u>VaxFinder.mass.gov</u> with over 900 pharmacies, health care providers,
    and other community locations listed across the Commonwealth. Users can also find
    information about no wait, walk-up appointments at select locations, accessibility
    information, and can plan for their appointment using the MBTA trip planner tool.
- New MIIS reports to identify patient immunization status:
  - The MIIS Coverage Reports allow each provider site to evaluate the immunization coverage for its practice. Check the "Include patient listing tables" box to ensure the

- output includes patient information. We recommend using the Custom Coverage report to research COVID-19 coverage rates.
- The MIIS Reminder/Recall Reports provide a list of patients that are due or overdue for a recommended vaccine, based on criteria specified by the user. Reminders are created for patients that will soon be due for a particular immunization and Recalls are created for patients that are currently overdue for a particular immunization.
- New Monitor COVID-19 vaccine expiration and beyond use dates: As the pace of COVID-19 vaccination slows down, providers may have more vaccine in inventory.
  - Rotate stock so that the oldest vaccine is used first.
  - Use the <u>Vaccine Expiration Date Tracking Tool</u>.
  - Use Beyond-use Date in Vial or Syringe for COVID-19 Vaccines.
  - Arrange to transfer vaccine that you will not be able to use before the expiration date. Use these resources to manage COVID-19 vaccine transfers:
    - MDPH Redistribution Guidance for COVID-19 Vaccines
    - USP Transporting COVID-19 Vaccines Off-Site
    - MIIS Transferring Vaccine through MIIS Video
    - MIIS How to Use the Inventory Decrementing Tool Video
- New Updated CDC materials: The following materials have been updated to reflect the latest ACIP recommendation to administer COVID-19 vaccine to adolescents aged 12 to 15 years.
  - Preparation and Administration Summary: <u>Pfizer-BioNTech</u> and <u>Moderna</u>
  - Standing Orders: <u>Pfizer-BioNTech</u> and <u>Moderna</u>
  - Interim Clinical Considerations
  - COVID-19 Vaccine Quick Reference Guide
  - Prevaccination Checklist
- Reminder COVID-19 vaccines and other vaccines may be administered without regard to timing: This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as co-administration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with co-administration. When deciding whether to co-administer other vaccines with COVID-19 vaccine, consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.
- New Encourage parents and guardians to enroll their adolescents in v-safe: V-safe after vaccination health checker is a smartphone-based tool that uses text messaging and web surveys to provide personalized health check-ins after COVID-19 vaccination. Through v-safe, participants can quickly tell CDC if they have any side effects after getting the COVID-19 vaccine.
- New Preregistration system closing: The Commonwealth's <u>vaccine preregistration system</u> is closing at the end of May. All remaining people who preregistered will be given an opportunity to book before the system closes. <u>Vaxfinder.mass.gov</u> will remain available.
- ACIP Interim Recommendations for Use of Pfizer COVID-19 Vaccine in Adolescents Ages 12–15:
   According to data published in the CDC Morbidity and Mortality Weekly Report (MMWR), the estimated efficacy of Pfizer COVID-19 vaccine was 100% in preventing symptomatic, laboratory-confirmed COVID-19 in adolescents ages 12–15. The local and systemic reactions were similar to those reported in persons aged ≥16 years. No specific safety concerns were identified. See the updated EUA fact sheets for providers and recipient and caregivers.
- AAP Recommendations for COVID-19 Vaccination for Children ages 12 and Older and Coadministration with Routine Immunizations: The American Academy of Pediatrics policy

statement recommends the following: 1) COVID-19 vaccination for all children and adolescents 12 years of age and older who do not have contraindications, 2) any COVID-19 vaccine authorized by the FDA, recommended by the CDC, and appropriate by age and health status can be used, and 3) supports co-administration of COVID-19 vaccine with routine immunizations in order to catch children up on any missed vaccines.

- Consent for Vaccination for People 12-17 Years of Age: For minors younger than 18 years of
  age, consent is obtained from a legally authorized representative on behalf of the child (usually a
  parent or guardian) by completing a written consent form that the minor can bring to their
  vaccination appointment. The parent or guardian does not need to go with the minor to their
  vaccination appointment to give consent.
  - For more information, including the consent form in multiple languages, see <u>COVID-19</u> vaccinations for people under age 18. Please note that health care providers can establish their own consent policies in consultation with their legal counsel.
- Reports of Myocarditis Occurring After COVID-19 Vaccination: CDC has been closely monitoring
  myocarditis/pericarditis in multiple safety systems. To date, there has not been a safety signal
  identified. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after
  COVID-19 vaccination. Healthcare providers should consider myocarditis in an evaluation of chest
  pain after vaccination and report all cases to VAERS. CDC continues to recommend COVID-19
  vaccination for people 12 years and older.

#### **Resources & Learning Opportunities**

- Download DPH <u>youth-related graphics</u> for your messaging on topics such as: how teens can get the COVID-19 vaccine; ingredients in the vaccine; how teens can protect themselves during COVID-19, and how to cope with COVID-19 stress.
- CDC COVID-19 Vaccines for Children and Teens
  - Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit
  - FAQs for providers
  - Vaccine Recipient Education
  - Recorded webinar: What Clinicians Need to Know About Pfizer-BioNTech COVID-19
     Vaccination of Adolescents.
  - Immunization Action Coalition (IAC), <u>Medical Management of Vaccine Reactions in</u>
     Children and Teens. Includes standing orders.
- · Visit the MIIS Resource Center for more training videos, guides and more
  - MIIS & Vaccine Accountability
  - Using the HL7 Admin Console Video



# **MASSACHUSETTS COVID-19 VACCINE PROGRAM**

# BULLETIN

# What Massachusetts COVID-19 Vaccine Providers Need to Know Week of 5/27/21

#### **Latest Numbers**

 As of 5/27, 3,558,197 people in Massachusetts have been fully vaccinated and 4,133,946 have received at least one dose of the Moderna or Pfizer vaccine.

#### Who to Vaccinate this Week

• Anyone age 12 and older who lives, works, or studies in Massachusetts is eligible for a vaccine. Health care providers can also vaccinate their patient panels regardless of place of residency.

#### What to Know this Week

- New Changes to Pfizer COVID-19 Vaccine Storage: Undiluted, thawed Pfizer COVID-19 Vaccine vials can be stored in the refrigerator at 2°C 8°C for up to 1 month.
  - The vials must be undiluted to remain at 2°C 8°C for 1 month.
  - Step down storage & handling for Pfizer COVID vaccines is now as follows:
    - All Pfizer configurations are shipped ultra-cold.
    - **Ultra-cold (-70°C):** May be stored in ULT freezer until the expiration date, or temporarily in the shipper with regular dry ice replenishment.
    - Frozen (-20°C): Undiluted vials may remain frozen at -20°C for up to 2 weeks.
    - Refrigerated (2-8°C): Undiluted vials may remain at 2°C 8°C for 1 month.
  - Total storage time for Pfizer in freezer and refrigerator combined should not exceed 45 days.
- New Pfizer vaccine will be available in a new 450-dose configuration: As of May 28, providers will be able to order the 1,170-dose and 450-dose product configurations.

Pfizer 450 (New)	NDC 59267-1000-03	75 Multidose vials (3 trays of 25 vials each)
Pfizer 1,170	NDC 59267-1000-02	195 Itidose vials

- Vials will be shipped in the same container as the 1,170-dose orders and will include the same Controlant temperature monitor.
- The newly extended refrigerator storage temperatures will decrease the need for dry ice. There will be no dry ice replenishment for the 450-dose pack.
- Return shippers and Controlant monitors within 10 days.
- New ancillary kits have been created to support the 450-dose minimum order size. The
  adult ancillary kits contain the same ratio of 1" to 1.5" needles as the 1,170 kit. The
  pediatric ancillary kit contains only 1" needles. Other supplies in the kit remain the
  same.

- Reminder Moderna vials: Moderna vaccine is now available in two different vials the maximum 11-dose vial and a new maximum 15-dose vial. The vial will remain the same size but will be filled to the higher volume. A new NDC has been issued for the larger volume Moderna vial, which has been authorized for a range of 13-15 doses in the updated Moderna EUA factsheet for healthcare providers. The smaller maximum 11-dose vials being phased out. It will not always be possible to extract the 15<sup>th</sup> dose; providers should expect to withdraw 13-15 doses from a vial.
  - Talking points about the Moderna COVID-19 Vaccine EUA Amendments
  - FAQ about the EUA Amendments
  - Images of the new Moderna cartons and vial labels
  - Wastage Reporting Table
- New Updated Inventory Requirements for Primary Care Providers and Community Health Centers: Primary Care Providers (internal medicine, family practice, pediatric, and multi-specialty) and Community Health Centers must use COVID-19 vaccines within 4 weeks of receipt and must deplete existing inventory before an additional order is approved. Previously, all providers needed to administer vaccines within 10 days of receipt. This requirement has changed due to the increased availability of vaccines and a better understanding of logistical issues. All other providers must administer vaccines within 10 days of receipt. Review the ordering guidance for more information.
- New Encouraging vaccination with all your patients: Healthcare providers are the most trusted resource for patients in making health decisions. Your strong recommendation to get a COVID-19 vaccine is one of the most important factors in your patients' decision to accept vaccination.
  - Use CDC's <u>sample letter to patients to encourage COVID-19 vaccination</u> to communicate with all your patients.
  - Strongly recommend COVID-19 vaccine at every patient visit.
  - See <u>COVID-19 Vaccination Tips for Providers: Talking to Patients | Mass.gov</u> for help talking with your patients about COVID-19 vaccines.
  - If COVID-19 vaccines are not available at your office, offer to help them make an appointment. Use <a href="VaxFinder.mass.gov">VaxFinder.mass.gov</a> with over 900 pharmacies, health care providers, and other community locations listed across the Commonwealth. Users can also find information about no wait, walk-up appointments at select locations, accessibility information, and can plan for their appointment using the MBTA trip planner tool.
- New MIIS reports to identify patient immunization status:
  - The MIIS Coverage Reports allow each provider site to evaluate the immunization coverage for its practice. Check the "Include patient listing tables" box to ensure the output includes patient information. We recommend using the Custom Coverage report to research COVID-19 coverage rates.
  - The <u>MIIS Reminder/Recall Reports</u> provide a list of patients that are due or overdue for a recommended vaccine, based on criteria specified by the user. **Reminders** are created for patients that will soon be due for a particular immunization and **Recalls** are created for patients that are currently overdue for a particular immunization.
- New Monitor COVID-19 vaccine expiration and beyond use dates: As the pace of COVID-19 vaccination slows down, providers may have more vaccine in inventory.
  - Rotate stock so that the oldest vaccine is used first.
  - Use the Vaccine Expiration Date Tracking Tool.
  - Use Beyond-use Date in Vial or Syringe for COVID-19 Vaccines.

- Arrange to transfer vaccine that you will not be able to use before the expiration date.
   Use these resources to manage COVID-19 vaccine transfers:
  - MDPH Redistribution Guidance for COVID-19 Vaccines
  - USP Transporting COVID-19 Vaccines Off-Site
  - MIIS Transferring Vaccine through MIIS Video
  - MIIS How to Use the Inventory Decrementing Tool Video
- New Updated CDC materials: The following materials have been updated to reflect the latest ACIP recommendation to administer COVID-19 vaccine to adolescents aged 12 to 15 years.
  - Preparation and Administration Summary: <u>Pfizer-BioNTech</u> and <u>Moderna</u>
  - Standing Orders: Pfizer-BioNTech and Moderna
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  - COVID-19 Vaccine Quick Reference Guide
  - Prevaccination Checklist
- Reminder COVID-19 vaccines and other vaccines may be administered without regard to timing:
   This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as co-administration within 14 days. It is unknown whether reactogenicity of COVID-19 vaccine is increased with co-administration. When deciding whether to co-administer other vaccines with COVID-19 vaccine, consider whether the patient is behind or at risk of becoming behind on recommended vaccines, their risk of vaccine-preventable disease (e.g., during an outbreak or occupational exposures), and the reactogenicity profile of the vaccines.
- New Encourage parents and guardians to enroll their adolescents in v-safe: V-safe after
   <u>vaccination health checker</u> is a smartphone-based tool that uses text messaging and web surveys
   to provide personalized health check-ins after COVID-19 vaccination. Through v-safe,
   participants can quickly tell CDC if they have any side effects after getting the COVID-19 vaccine.
- New Preregistration system closing: The Commonwealth's <u>vaccine preregistration system</u> is closing at the end of May. All remaining people who preregistered will be given an opportunity to book before the system closes. <u>Vaxfinder.mass.gov</u> will remain available.
- ACIP Interim Recommendations for Use of Pfizer COVID-19 Vaccine in Adolescents Ages 12–15:
   According to data published in the CDC Morbidity and Mortality Weekly Report (MMWR), the estimated efficacy of Pfizer COVID-19 vaccine was 100% in preventing symptomatic, laboratory-confirmed COVID-19 in adolescents ages 12–15. The local and systemic reactions were similar to those reported in persons aged ≥16 years. No specific safety concerns were identified. See the updated EUA fact sheets for providers and recipient and caregivers.
- AAP Recommendations for COVID-19 Vaccination for Children ages 12 and Older and Co-administration with Routine Immunizations: The American Academy of Pediatrics policy statement recommends the following: 1) COVID-19 vaccination for all children and adolescents 12 years of age and older who do not have contraindications, 2) any COVID-19 vaccine authorized by the FDA, recommended by the CDC, and appropriate by age and health status can be used, and 3) supports co-administration of COVID-19 vaccine with routine immunizations in order to catch children up on any missed vaccines.
- Consent for Vaccination for People 12-17 Years of Age: For minors younger than 18 years of
  age, consent is obtained from a legally authorized representative on behalf of the child (usually a
  parent or guardian) by completing a written consent form that the minor can bring to their
  vaccination appointment. The parent or guardian does not need to go with the minor to their
  vaccination appointment to give consent.

- For more information, including the consent form in multiple languages, see <u>COVID-19</u> vaccinations for people under age 18. Please note that health care providers can establish their own consent policies in consultation with their legal counsel.
- Reports of Myocarditis Occurring After COVID-19 Vaccination: CDC has been closely monitoring
  myocarditis/pericarditis in multiple safety systems. To date, there has not been a safety signal
  identified. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after
  COVID-19 vaccination. Healthcare providers should consider myocarditis in an evaluation of chest
  pain after vaccination and report all cases to VAERS. CDC continues to recommend COVID-19
  vaccination for people 12 years and older.

#### **Resources & Learning Opportunities**

- Download DPH <u>youth-related graphics</u> for your messaging on topics such as: how teens can get the COVID-19 vaccine; ingredients in the vaccine; how teens can protect themselves during COVID-19, and how to cope with COVID-19 stress.
- CDC COVID-19 Vaccines for Children and Teens
  - Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit
  - FAQs for providers
  - Vaccine Recipient Education
  - Recorded webinar: What Clinicians Need to Know About Pfizer-BioNTech COVID-19
     Vaccination of Adolescents.
  - Immunization Action Coalition (IAC), <u>Medical Management of Vaccine Reactions in Children and Teens</u>. Includes standing orders.
- Visit the MIIS Resource Center for more training videos, guides and more
  - MIIS & Vaccine Accountability
  - Using the HL7 Admin Console Video

From: Ohannessian, Dana (DPH)

**Sent:** Tue, 18 May 2021 18:31:04 +0000 **To:** Walensky, Rochelle (CDC/OD)

Subject: Weekly COVID-19 Vaccine Provider Bulletin

Attachments: Weekly COVID-19 vaccine provider bulletin\_5.18.21\_final.docx

Please find attached the Weekly COVID-19 Vaccine Provider Bulletin.



## **MASSACHUSETTS COVID-19 VACCINE PROGRAM**

## BULLETIN

# What Massachusetts COVID-19 Vaccine Providers Need to Know Week of 5/18/21

#### **Latest Numbers**

 As of 5/18, 3,243,160 people in Massachusetts have been fully vaccinated and 3,966,363 have received at least one dose of the Moderna or Pfizer vaccine.

#### Who to Vaccinate this Week

Anyone age 12 and older who lives, works, or studies in Massachusetts is eligible for a vaccine.
 Health care providers can also vaccinate their patient panels regardless of place of residency.

#### What to Know this Week

- New ACIP Interim Recommendations for Use of Pfizer-BioNTech COVID-19 Vaccine in Adolescents Ages 12–15 years: According to data provided to FDA and ACIP and published in the CDC Morbidity and Mortality Weekly Report (MMWR) on 5/14/21, the estimated efficacy of Pfizer COVID-19 vaccine was 100% in preventing symptomatic, laboratory-confirmed COVID-19 in adolescents ages 12–15. The immune response of adolescents in this age group was similar to that observed in people ages 16–25 years. Among vaccine recipients ages 12–15 years, reactogenicity symptoms during the 7 days after vaccination were frequent (90.9% of vaccine recipients reported any local reaction and 90.7% reported any systemic reaction) and mostly mild to moderate. Pain at the injection site was the most common local reaction. Systemic adverse reactions (e.g., fever, fatigue, headache, muscle pain) were more commonly reported after the second dose than after the first dose. The local and systemic reactions were similar to those reported in persons aged ≥16 years. No specific safety concerns were identified.
  - See the updated EUA fact sheets for providers and recipient and caregivers
- New AAP Recommendations for COVID-19 Vaccination for Children ages 12 and Older and Co-administration with Routine Immunizations: The American Academy of Pediatrics policy statement recommends the following: 1) COVID-19 vaccination for all children and adolescents 12 years of age and older who do not have contraindications, 2) any COVID-19 vaccine authorized by the FDA, recommended by the CDC, and appropriate by age and health status can be used, and 3) supports co-administration of COVID-19 vaccine with routine immunizations in order to catch children up on any missed vaccines. Co-administration is also supported in the CDC Clinical Considerations (see below).
- New CDC COVID-19 Vaccine Clinical Considerations: Key updates to the <u>Clinical Considerations</u> include:
  - Updated information for authorized age groups to include vaccination of adolescents ages 12–15 years with Pfizer-BioNTech COVID-19 vaccine.
  - Updated information on co-administration of COVID-19 vaccines with other vaccines.
     COVID-19 vaccines and other vaccines may now be administered without regard to

- **timing**. This includes simultaneous administration of COVID-19 vaccines and other vaccines on the same day, as well as co-administration within 14 days.
- A new section on persons with a history of multisystem inflammatory syndrome added to considerations for vaccination of people with certain underlying medical conditions.
- Updated recommendation for timing of COVID-19 vaccine administration in persons with a history of heparin-induced thrombocytopenia.
- Updated information on vaccination of children and adolescents.
- Reminder Consent for Vaccination for People 12-17 Years of Age: For minors younger than 18 years of age, consent is obtained from a legally authorized representative on behalf of the child (usually a parent or guardian) by completing a written consent form that the minor can bring to their vaccination appointment. The parent or guardian does not need to go with the minor to their vaccination appointment to give consent.
  - For more information, including copies of the consent form in multiple languages, see
     <u>COVID-19 vaccinations for people under age 18</u>. Please note that health care providers
     can establish their own consent policies in consultation with their legal counsel.
  - Individuals 12-15 years old can register for an appointment at VaccineSignUp.mass.gov
- New CDC Adolescent COVID-19 Vaccination Information & Resources for Healthcare and Vaccine Providers (HCP):
  - <u>Pediatric Healthcare Professionals COVID-19 Vaccination Toolkit</u> provides materials to help healthcare providers give parents clear and accurate information about COVID-19 vaccines. The toolkit includes answers to common questions, an explanation of how mRNA vaccines work, and printable materials to give to parents.
  - FAQs have been posted on the Pfizer product page for HCP with information about consent, prescreening questions, and other issues related to the vaccination of minors.
  - HCP can customize and send <u>this sample letter</u> to encourage their patients to get a COVID-19 vaccine. It includes the new recommendation that everyone aged 12 and up get a COVID-19 vaccination.
  - The <u>Vaccine Recipient Education</u> page has been updated to include resources about COVID-19 vaccination for adolescents.
  - View the recorded webinar: What Clinicians Need to Know About Pfizer-BioNTech COVID-19 Vaccination of Adolescents.
  - Immunization Action Coalition (IAC), <u>Medical Management of Vaccine Reactions in</u>
    Children and Teens. Includes standing orders.
  - See additional information for parents and adolescents in the Resources & Learning
     Opportunities section below.
- New Reports of Myocarditis Occurring After COVID-19 Vaccination: The European Medicines Agency recently requested data on reports of myocarditis and pericarditis after vaccination. CDC is aware of these reports, which are rare, and has been closely monitoring myocarditis/pericarditis in multiple safety systems, including the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD). To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and report all cases to VAERS. CDC continues to recommend COVID-19 vaccination for people 12 years and older.

- Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation
  of the lining outside the heart. In both cases, the body's immune system is causing
  inflammation in response to an infection or some other trigger. While myocarditis can
  be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart
  rhythms, shortness of breath, or chest pain.
- Ordering COVID-19 Vaccine Through the MIIS: Providers will be able to order COVID-19 vaccine directly from the MIIS as needed, within certain limits. Providers must use requested vaccine within 10 days and must deplete existing inventory before an additional order will be approved. Providers whose inventory on-hand exceeds 50% of their weekly allocation amount will not be able to order additional vaccine. This direct ordering process will allow providers more flexibility in identifying their vaccine needs and in planning their order timing. Existing providers will be transitioned to this new process within the next couple weeks. Review the ordering guidance for more information.

#### **Resources & Learning Opportunities**

- New COVID-19 Vaccine Information for Parents and Adolescents
  - <u>COVID-19 Vaccines for Children and Teens</u> provides information about the benefits of COVID-19 vaccines for adolescents aged 12 and older and what to expect during and after vaccination.
  - COVID-19 Vaccines for Preteens and Teens is a printable fact sheet for parents that
    explains the benefits of a COVID-19 vaccine for their children, safety information, and
    what to expect during and after vaccination.
  - Two <u>new FAQs</u> have been posted to address questions about the safety and benefits of COVID-19 vaccination for adolescents aged 12 and older.
  - A woman's menstrual cycle cannot be affected by being near someone who received a COVID-19 vaccine. This <u>question and answer</u> explains why.
  - It is safe for people who would like to have a baby one day to get a COVID-19 vaccine.
     This <u>question and answer</u> explains why.
  - Key Things to Know about COVID-19 Vaccines and About COVID-19 Vaccines now include the recommendation that adolescents aged 12 and older get vaccinated.
  - The web page <u>COVID-19 Vaccine Information for Specific Groups</u> has been updated to help the public find information about vaccination for adolescents.
  - This checklist can help parents as they prepare for their child's COVID-19 vaccination.
- New MIIS Resources Available
  - MIIS & Vaccine Accountability: outlines the importance of accounting for your vaccine through the MIIS and provides tools to assist you in managing your inventory.
  - <u>Transferring Vaccine through MIIS Video</u>: walks through how to transfer and accept transfers through the MIIS.
  - How to Use the Inventory Decrementing Tool Video: explains what the tool does and how to use it. It also describes the importance of reconciliation of your inventory.
  - <u>Using the HL7 Admin Console Video</u>: learn how to use the HL7 Admin Console to monitor your organizations HL7 messages to ensure your data is transmitting successfully and it has high data quality.
  - Visit the MIIS Resource Center for more training videos, guides and more.
- Reminder MDPH COVID 19 Vaccination Live Q&A Webinar: May 24, 2021 1:00 PM Register here.

From: (b)(4); (b)(6)

**Sent:** Tue, 25 May 2021 20:31:07 +0000

To: Berger, Sherri (CDC/OCOO/OD); Capozzola, Christa (CDC/OCOO/OFR)

(b)(4); (b)(6)

Subject: RE: EOC All Hands

Attachments: Response AHM Key Takeaways - Leadership Brief.docx, IMS All Hands Summary

to Staff\_052521.docx

Sherri and Christa,

Draft IMS staff email and SL email are attached; if possible it would be good to send today to keep information flowing in a timely way. We wrote these with that timeframe in mind (e.g., "today's All Hands Meeting..."), but we can re-work if they will not go out today. Also, the SL email includes excerpts from the Q&A, which adds length but will help with transparency.

Please let us know what changes you need.

#### (b)(4); (b)(6)

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov> Sent: Tuesday, May 25, 2021 3:53 PM To: (b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR) <KQR5@cdc.gov>; (b)(4); (b)(6) b)(4); (b)(6) (b)(4): (b)(6) Subject: [EXT] RE: EOC All Hands awesome From: (b)(4); (b)(6) Sent: Tuesday, May 25, 2021 3:52 PM To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>; (b)(4): (b)(6) Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; (b)(4); (b)(6) b)(4); (b)(6) b)(4); (b)(6) Subject: RE: EOC All Hands That's great. I will send draft of key points for senior leaders shortly.

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 3:50 PM

**To:** (b)(4); (b)(6) ; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; (b)(4); (b)(6)

Cc: (b)(4); (b)(6)

Subject: [EXT] EOC All Hands

Hi – sharing some data I got today – over 2000 people were in the All Hands (the largest prior was 1500'ish).

PDIMs are receiving unsolicited and unexpected feedback that is very positive and encouraging them to do this more often.

From: (b)(4); (b)(6)

Sent: Monday, May 17, 2021 8:31 AM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov> (b)(4); (b)(6) (b)(4); (b)(6)

Cc: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov >; (b)(4); (b)(6)

(b)(4): (b)(6)

Subject: RE: Weekly IMS update meeting

We can do as a call as we do not need to project slides. Angela will update the appointment with the slides so you have those in advance. Thanks.

#### (b)(4); (b)(6)

Deloitte Services LP

Tel/Direct: (b)(4); (b)(6)

Mobile: (b)(4); (b)(6)
www.deloitte.com

On May 17, 2021, at 7:37 AM, Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov > wrote:

Thanks all. I may have to join via telephone (v video).

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Monday, May 17, 2021 7:18:13 AM

**To**:(b)(4); (b)(6) Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: Weekly IMS update meeting

Hi – thanks - beyond updates, one issue I'd like to get everyone's input on is (b)(5)

(b)(5)

Christa

From:(b)(4); (b)(6)

Sent: Sunday, May 16, 2021 9:09 PM

To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: Weekly IMS update meeting

Sherri and Christa,

Please let us know if there are topics you would like to cover at the IMS weekly update meeting tomorrow at 11:30am.

From our end, we want to touch on 1) communication items, 2) three deliverables we are working on for the end of the month, and 3) support, if any, needed at the end of this four-week transition period.

Angela will send slides in advance, and we will add anything you want to cover.

Thank you,

### (b)(4); (b)(6)

#### (b)(4); (b)(6)

Deloitte Services LP

Tel/Direct: (b)(4); (b)(6)

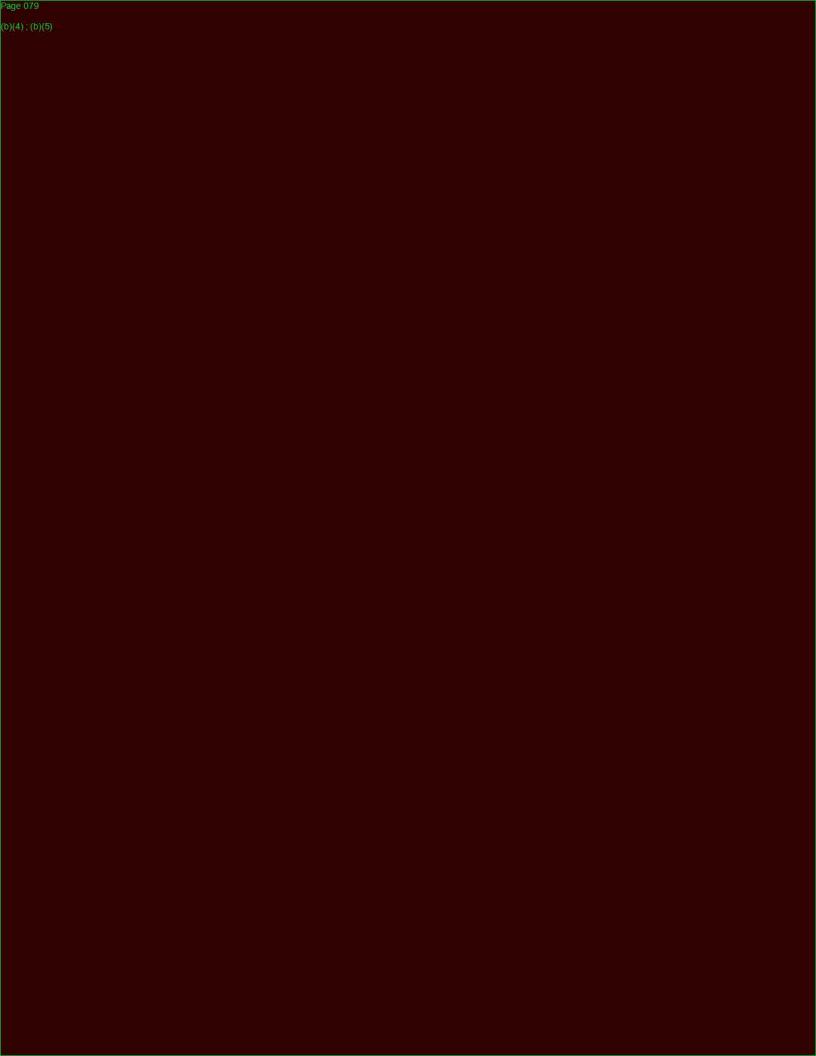
Mobile: (b)(4); (b)(6)

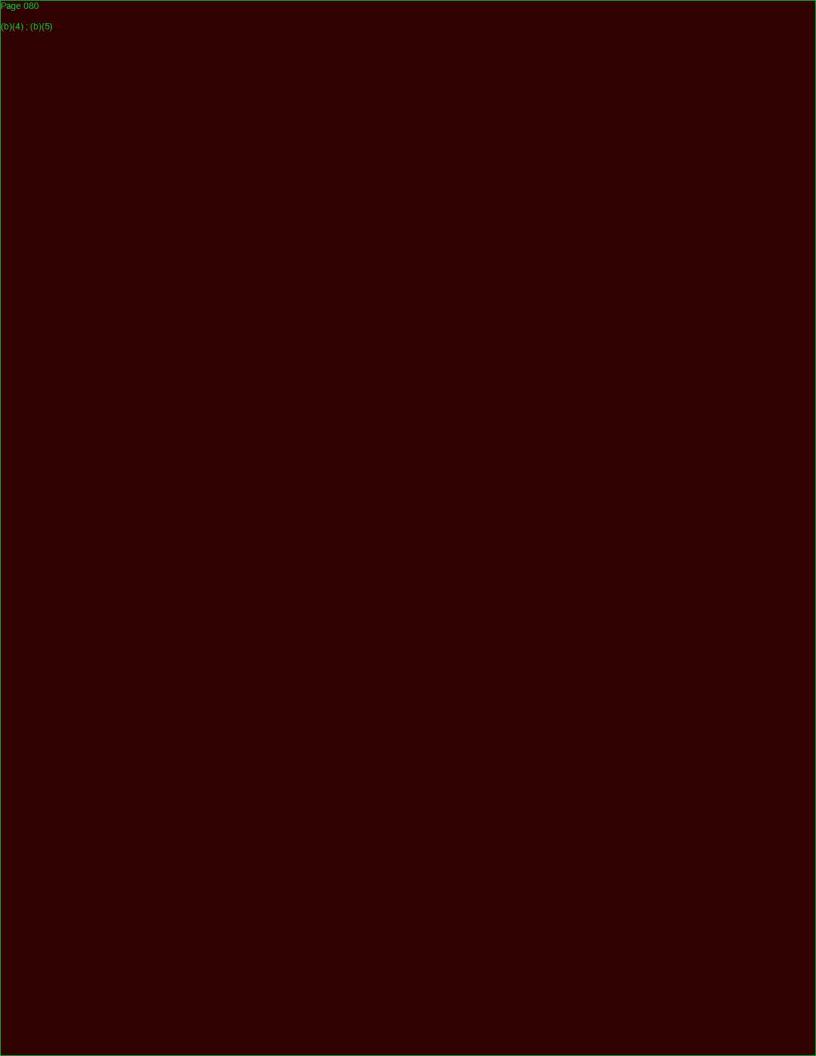
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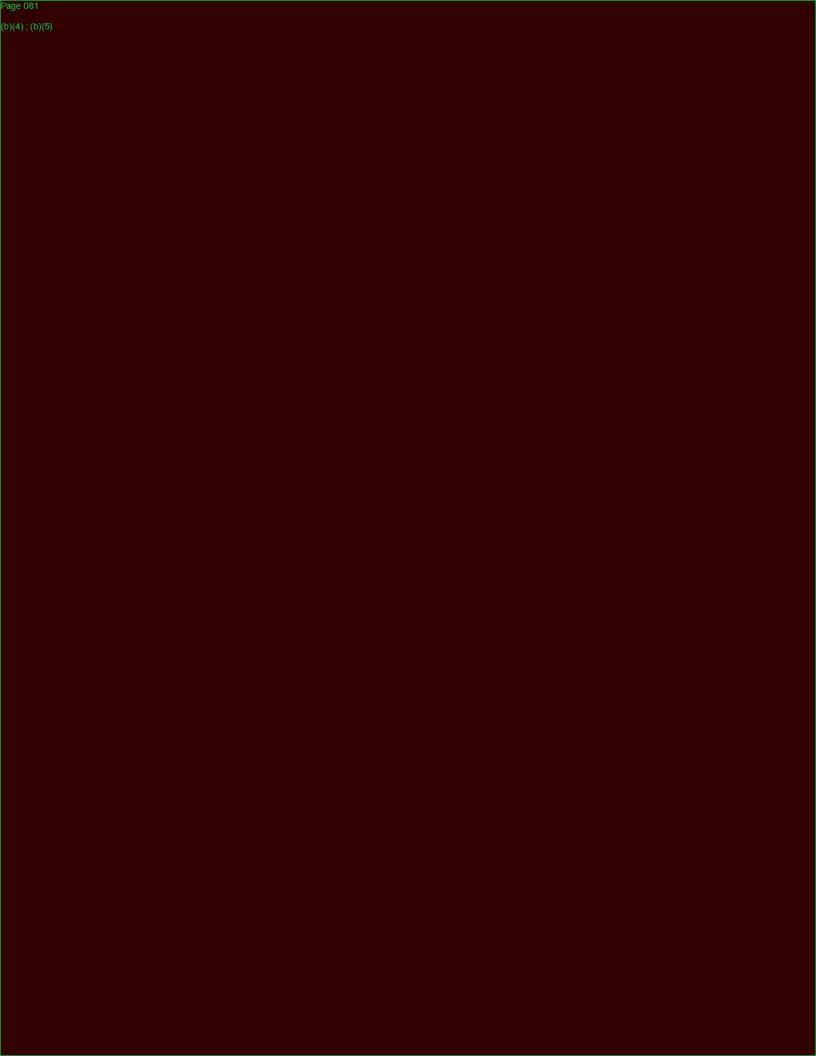
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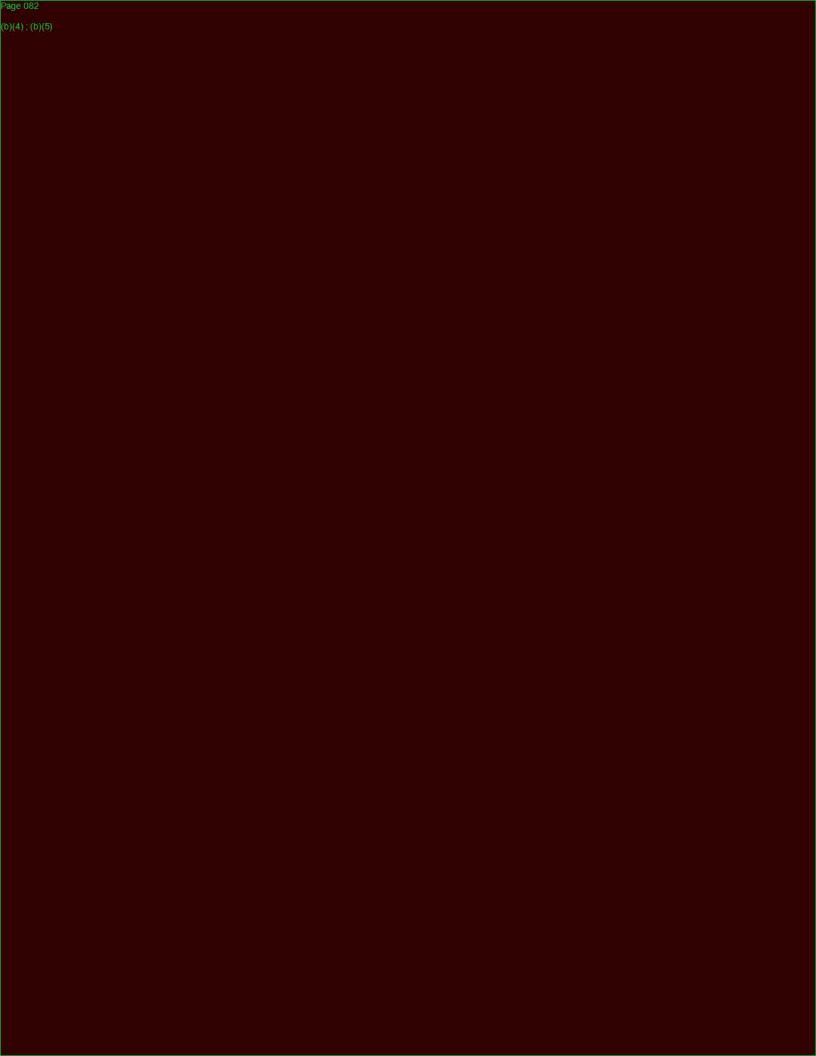
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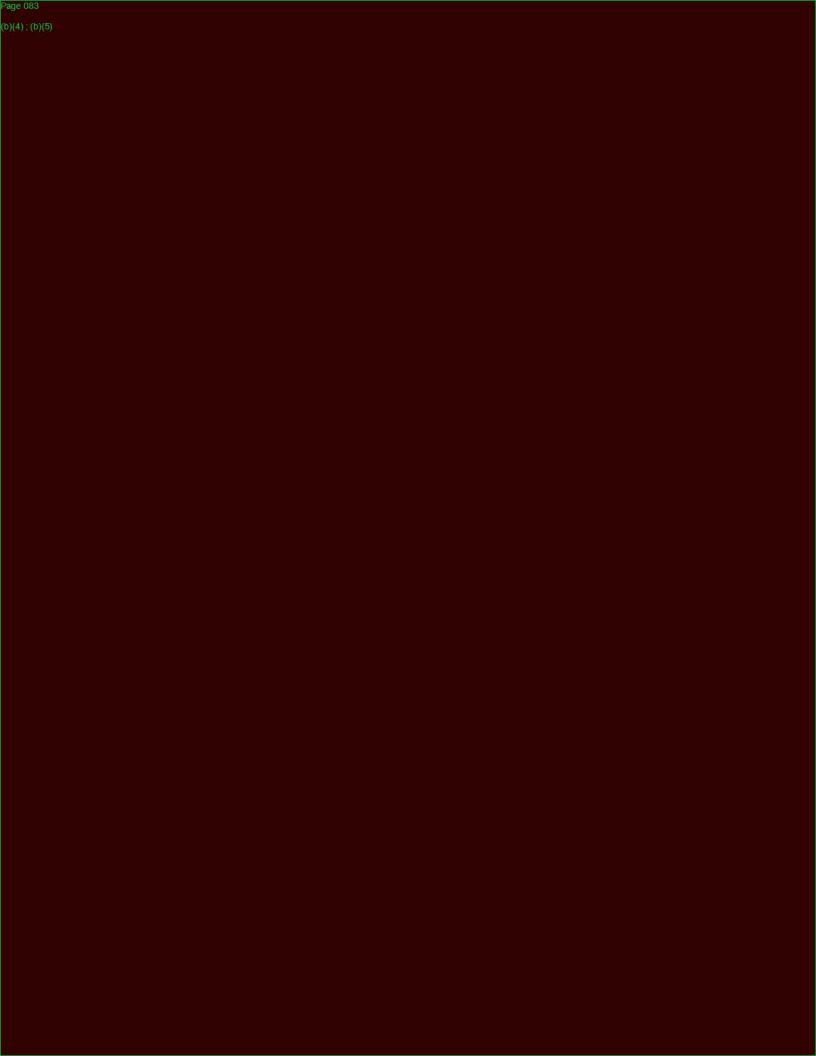
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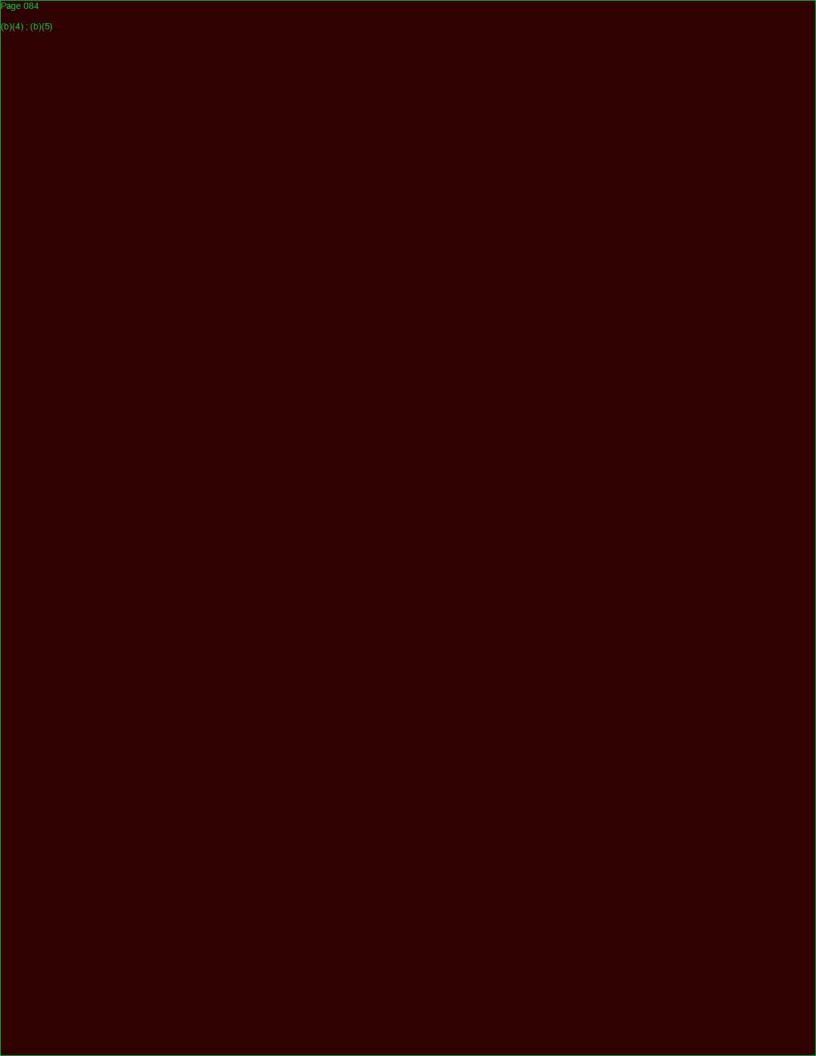


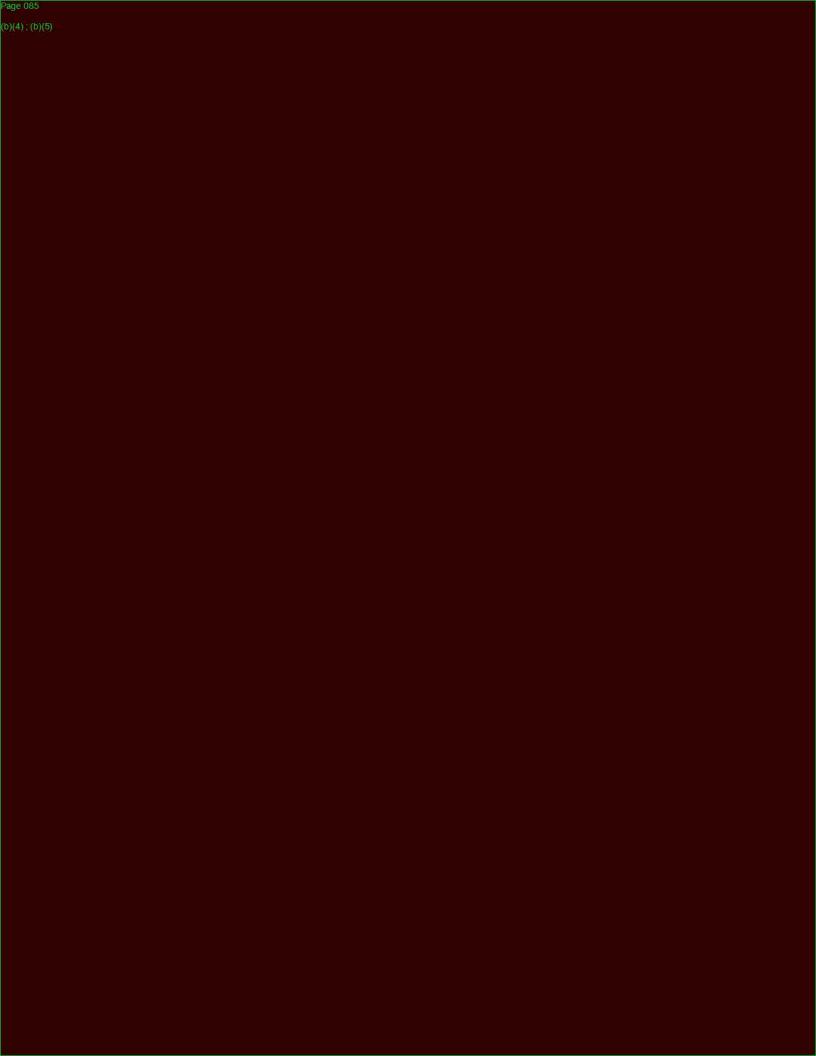


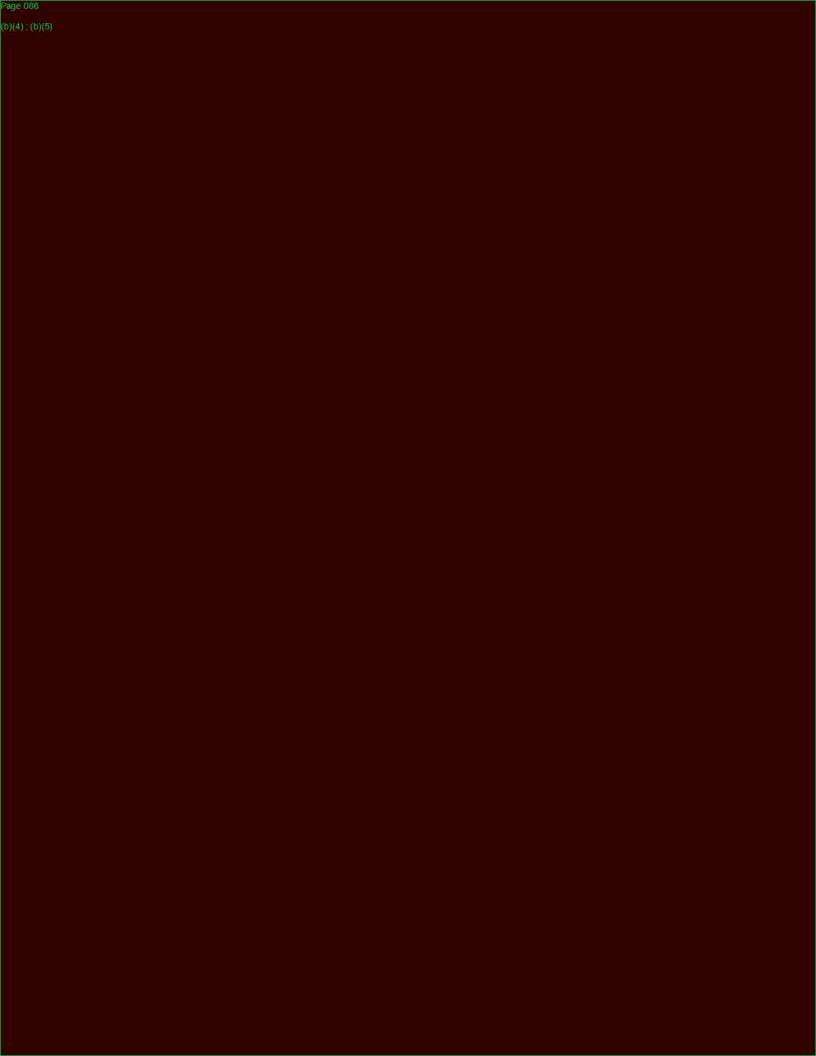












 From:
 Berger, Sherri (CDC/OCOO/OD)

 Sent:
 Thu, 27 May 2021 16:28:08 +0000

To: O'Connell, Dawn (HHS/IOS)

Subject: FW: HHS/CDC COVID Communication Strategy Look Ahead Attachments: HHS Product Awareness Table Week 5\_31\_2021.docx

From: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <mjb3@cdc.gov>

Sent: Thursday, May 27, 2021 11:30 AM

To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Pearlman, Aj (HHS/IOS) <Aj.Pearlman@hhs.gov>;

Sams, Ian (HHS/ASPA) <Ian.Sams@hhs.gov>; Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>; Despres, Sarah (HHS/IOS) <Sarah.Despres@hhs.gov>; Christie, Athalia (CDC/DDPHSIS/CGH/OD) <akc9@cdc.gov>

Cc: Holton, Kelly (CDC/DDNID/NCIPC/OD) <nfh5@cdc.gov>; Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <mrh7@cdc.gov>; Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <mib3@cdc.gov>

Subject: RE: HHS/CDC COVID Communication Strategy Look Ahead

For discussion today Thanks Michael

Michael J. Beach, PhD
Principal Deputy Incident Manager
CDC COVID-19 Emergency Response
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4018
404-667-0718

----Original Appointment----

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

**Sent:** Friday, April 30, 2021 11:04 AM

**To:** Berger, Sherri (CDC/OCOO/OD); Pearlman, Aj (HHS/IOS); Sams, Ian (HHS/ASPA); Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD); Despres, Sarah (HHS/IOS);

Christie, Athalia (CDC/DDPHSIS/CGH/OD)

Cc: Holton, Kelly (CDC/DDNID/NCIPC/OD); Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI)

Subject: HHS/CDC COVID Communication Strategy Look Ahead

When: Thursday, May 27, 2021 12:30 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Microsoft Teams Meeting

\_\_\_\_\_\_

## Microsoft Teams meeting

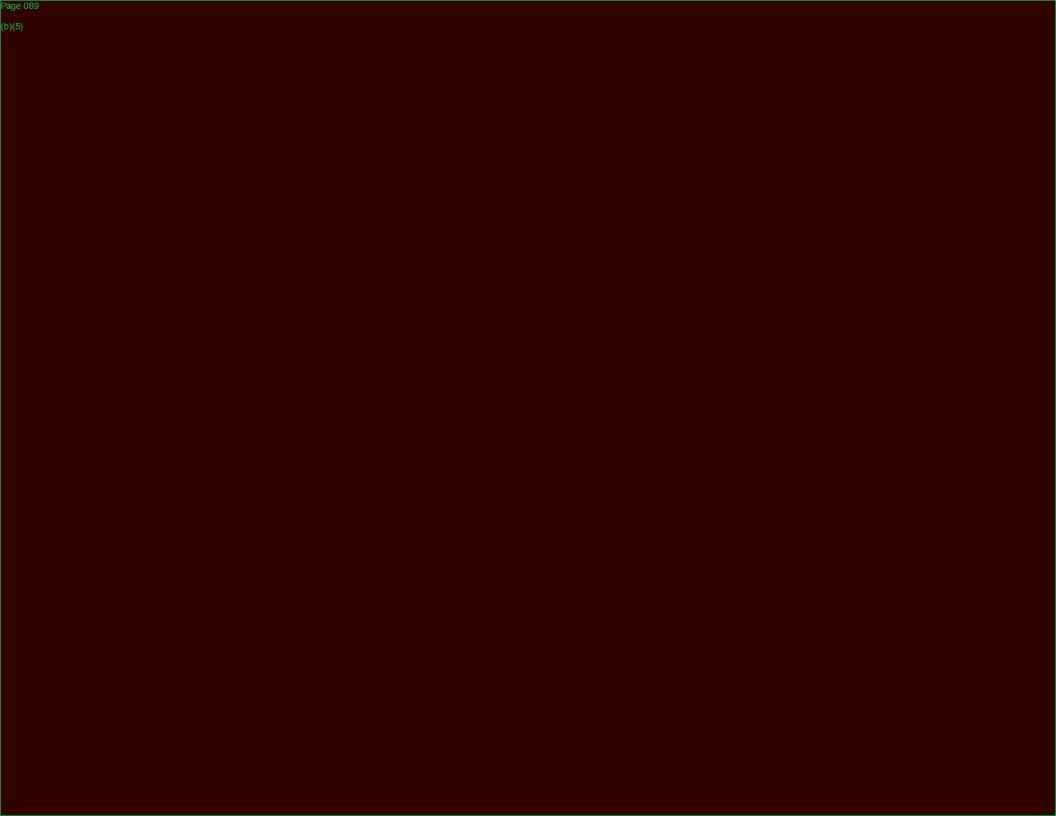
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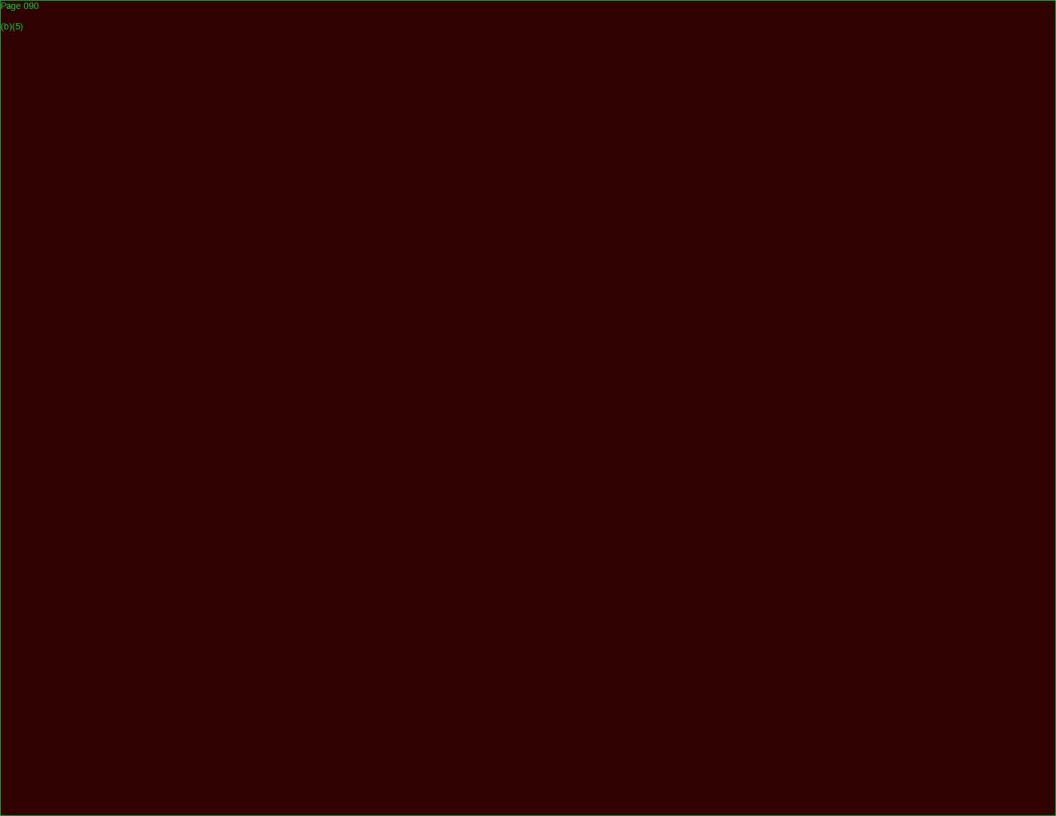
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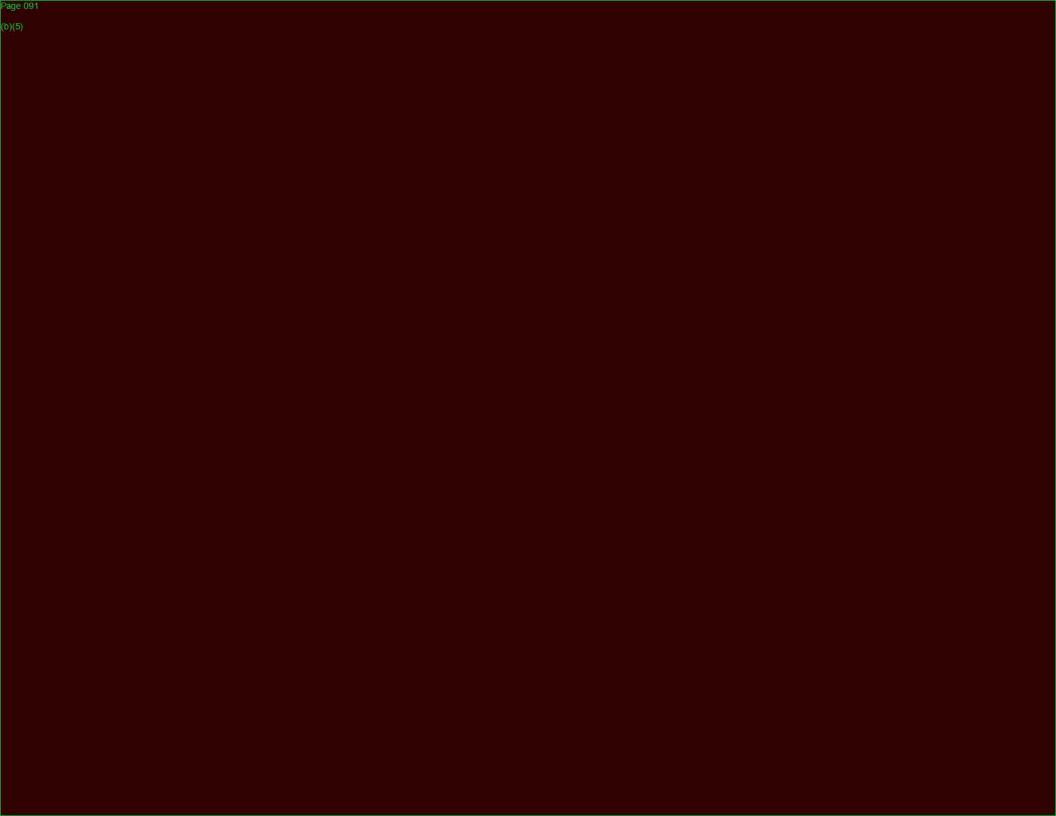
Or call in (audio only)

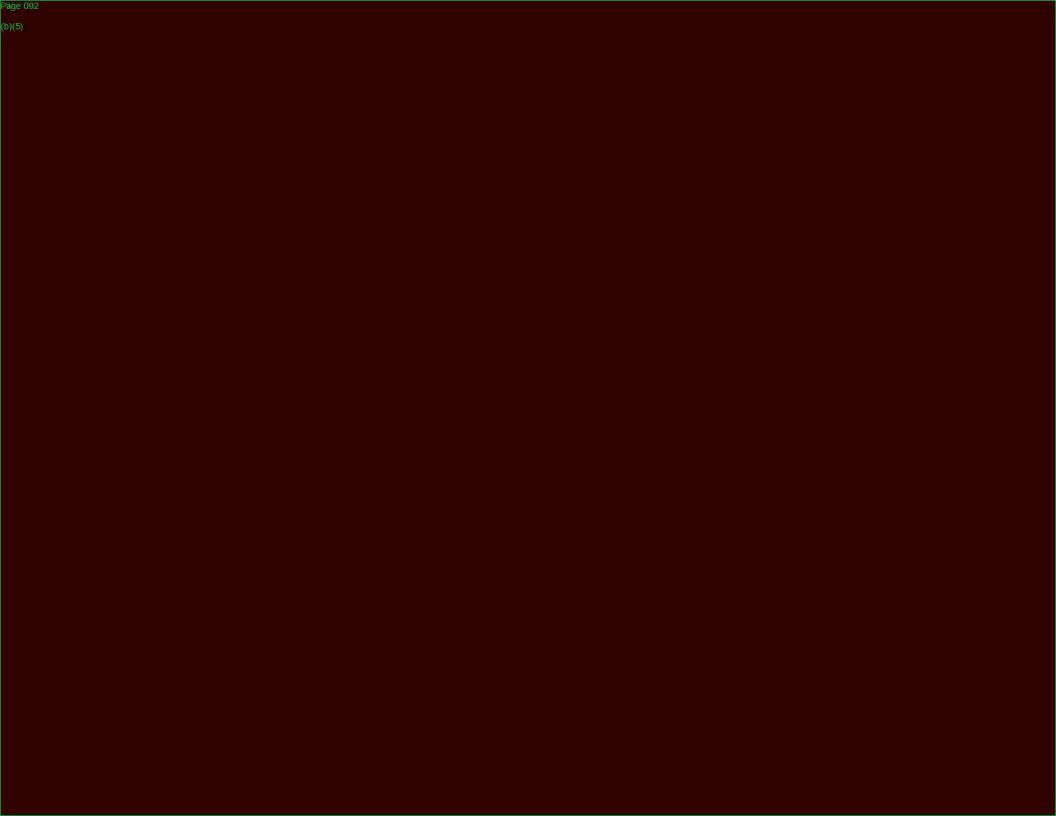


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From: Walensky, Rochelle (CDC/OD)

Sent: Fri, 21 May 2021 02:26:07 +0000

To: Berger, Sherri (CDC/OCOO/OD)

Subject: Fwd: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Attachments: memo to Brooks.docx

To discuss in am

#### Get Outlook for iOS

From: Celine Gounder, MD, ScM (b)(6)
Sent: Thursday, May 20, 2021 9:58 PM

**To:** Walensky, Rochelle (CDC/OD); Brooks, John T. (CDC/DDID/NCHHSTP/DHP) **Subject:** Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Dear Rochelle and John,

Jeremy Faust and I are working on an op-ed for the NYT (already green lit) about the risks-benefits of COVID and COVID vaccination, including the risk of long-term side effects of COVID vaccination (low) versus the long-term risks of COVID (high).

As you know, one of the reasons many people give for not getting vaccinated is that there isn't enough long-term safety data on COVID vaccines. Another reason given for not vaccinating kids is that COVID is no worse than influenza in children.

- We're hearing more and more reports of post-vaccination myocarditis from MA and NY
  where Jeremy and I are based, as well as elsewhere across the country. Is there anything
  you can share about post-vaccination myocarditis cases (demographics? fatal / non-fatal?)
  Or other serious post-vaccination events?
- I previously shared a memo from Jeremy to John re: Qs on influenza and COVID morbidity/mortality among children. I'm attaching that memo again here. John, have you gotten any feedback on the Qs Jeremy outlined in his memo?

These data could just be shared with us on background. We just want to make sure that in framing our argument, we're not misrepresenting the facts.

Warmly, Céline

\_\_

Céline Gounder, MD, ScM, FIDSA she / her / hers

CEO/Founder, JUST HUMAN PRODUCTIONS

Host/Producer, AMERICAN DIAGNOSIS & EPIDEMIC podcasts

Medical Analyst, CNN

Clinical Assistant Professor of Medicine & Infectious Diseases, <u>NYU School of Medicine</u> & Bellevue Hospital

Cell +1-917-275-2618 @celinegounder

#### Dear Dr. Brooks,

Twice now, *The New York Times* 'David Leonhardt has propagated a CDC statistic that is dubious and potentially harmful. I'd like to point out that two CDC Centers currently provide the public with contradicting information. I also would like to underscore why during the COVID-19 pandemic, this discrepancy is contributing to a problem relating to vaccine interest among children and parents. My aim here is to will draw your attention to the statistic in question, persuade you that it matters, and to demonstrate to you which of the two numbers is correct. Further, I hope to convince you that eliminating the inaccurate figure from public reporting immediately is important, as that number and others like it are now being used to downplay the severity of COVID-19 among children, and thereby undermining vaccine interest precisely when we need it to be bolstered.

Leonhardt and others have used this particular statistic to conclude that COVID-19 is no more harmful to children than seasonal influenza; specifically, the NCIRD states that in a recent flu season (2017-2018), 528 US children ages 5-17 (CDC link, NCIRD). Meanwhile, by April of this year, around 260 children in this age range had died of COVID-19 since the outbreak began (CDC link) in February 2020.

Relying on this, Leonhardt stated in his 4/22 Times column, that COVID-19 had killed fewer Americans under the age of 18 than seasonal flu routinely does. To correct this, I wrote to him to point out that according to CDC Wonder (direct link to query ICD J9-J11), in most years (or seasons) seasonal influenza does not kill *anywhere close* to 528 US children ages 5-17. The real number, per CDC/NCHS) is between 100-165 in most recent years, and often less. (At that point, Leonhardt no longer engaged though I did notice that the *Times* quietly *deleted* the offending sentence that previous stated that fewer American children had died of COVID-19 than typically die from seasonal influenza. Now the column says they are comparable. As I'll show later, they are not). He repeated the assertion again today.

#### CDC discrepancy (NCIRD and NCHS/CDC Wonder).

Sensing that this problem could occur again, I reached out to two analysts at CDC/NCIRD several weeks ago. They politely replied that the difference between the NCIRD figure and the NCHS/Wonder figure is that the former is an *estimate*, while the latter is a *counted figure*. That's true enough. However, in this case, if we wish to resolve the conflict (and I believe we must), the counted figure from the NCHS/Wonder, and not the estimated figure from NCIRD must be the correct one. This is for three distinct reasons.

- 1. Seasonal influenza is a reportable death for children 0-17. Therefore, unlike adult influenza, there is no need to estimate the number of underlying cause mortality from seasonal influenza.
- 2. Related to #1, if the NCIRD figure is correct, the CDC is currently implicitly accusing US states/Departments of Health of failing to report an incredible 70% of all pediatric flu deaths among children ages 5-17 (528-160=328; 328/528=69.7%). This simply lacks face validity, given the substantial state and local department of health resources that are devoted to investigating every single medical death of children.
- 3. The NCIRD estimate (528 influenza deaths among children 5-17 during the 2017-2018 season) cannot be correct because it happens to exceed the TOTAL number of

deaths from ALL Diseases of the Respiratory System (J00-J98, <u>CDC Wonder Query link</u>) during the 2017-2018 season (week 40 of 2017-week 39 2018). This renders the NCIRD estimate to have been an unintentional exercise in *reductio ad absurdum*. It would seem that, in the face of basic scrutiny, the estimate made by the NCIRD faces an insurmountable problem; it overshoots the total number of deaths in the entire category of all respiratory diseases for the year for the age group. The lack of attention to external validity here is alarming.

I politely pointed out this discrepancy to two staffers at NCIRD. Their response was to reiterate why they feel estimating influenza deaths is necessary. However, even if some estimation is needed (and I remain unconvinced to that), surely any estimate must not be allowed to overshoot *all* diseases of the respiratory system combined, of which influenza is but one subgroup. In fact, the only way that the NCIRD can even be *close to correct* is if several hundred deaths attributed to other underlying causes are in fact routinely and completely misfiled, year after year. This could be possible but unlikely. For example, perhaps some of the couple dozen cystic fibrosis patients ages 5-17 who are thought to have died due to CF maybe in reality died of seasonal influenza. In such a case, those deaths, per the NCIRD reasoning, should not reside in the Metabolic Disorders category (E70-E88), but rather in the Diseases of the Respiratory System (J00-J98). (I am sure this recategorizing would come to the surprise to workers in that CF silo, which I believe is Genomics and Precision Public Health).

The larger point is that there are only a certain number of deaths in any age group per year, and for the NCHS influenza data to be wrong (and for NCIRD to be correct), a great many number of pediatric deaths in CDC Wonder would therefore have to be incorrect at this time. And yet public health researchers rely on these data for a legion of projects and active research. When confronted with this, NCIRD had no response.

Today, David Leonhardt again wrote about pediatric flu and COVID-19 in the *Times*, saying, "Most reassuring is the fact that Covid is no more serious for children on average than the flu." I find that hard to believe, as per above.

But even more pointedly, the implications for which number is the correct one are non-trivial. Please inspect the following table, assembled from CDC data.

US population ages 5-17			
	CDC Wonder flu (counted). 2018.	NCIRD flu (estimate). 2017-2018.	CDC Covid-19 (counted). 2/1/2020-present.
Deaths	160	528	267
Symptomatic/documented cases	7,512,601	7,512,601	2,681,542
CFR (per 100k population)	2.1	7.0	10.0
Season-((influenza) or outbreak- (COVID-19) fatality rate (per 100k population)	0.30	0.99	0.50

As the table shows, if the NCHS/Wonder reported figure is correct, then the CFR of COVID-19 for US children 5-17 is around 4.8x that of seasonal flu (10.0/2.1=4.8). If NCIRD is correct than the CFR of COVID-19 is just 1.4x.

But denominators can be problematic. Therefore, the seasonal flu population fatality rate (influenza 2017-2018) can be compared to the total-US-COVID-19 outbreak population fatality rate (I used 2019 population figures, 53.4 million, for all groups, to keep it simple). As you can see, if CDC Wonder is correct, the population fatality rate for COVID-19 since the outbreak began for US children 5-17 is 1.6x that of seasonal flu. But if NCIRD influenza estimates were to be correct, influenza would appear to be nearly twice as likely to cause death as COVID-19, *a qualitative reversal*.

Keep in mind that the COVID-19 data reflect the context of shelter-in-place and school closures of 2020-2021, while the influenza numbers from 2017-2018 reflect a normal year without masks or physical distancing. If schools had remained open all year the last 15 months, the pediatric COVID-19 fatality numbers would certainly be higher (by how much, we can't really know).

My concern is that advocates arguing against pediatric vaccinations are already weaponizing the NCIRD figure. I hope to have convinced you that the NCIRD estimate is both incorrect, and suddenly in the context of COVID-19, harmful in that it has already been co-opted to undermine vaccination efforts. Because seasonal influenza is a reportable death for children, there is simply no need to estimate pediatric flu deaths, as above, and certainly not one that appears to be as wildly inaccurate as the current one.

The CDC should resolve this issue by instructing the NCIRD to remove estimated influenza deaths for children from its reporting. Doing so will resolve a contradiction and increase accuracy in our ongoing assessments.

Best,

Jeremy Faust MD MS

Jeremy Samuel Faust, M.D., M.S., M.A., FACEP Brigham & Women's Hospital Department of Emergency Medicine Division of Health Policy and Public Health Instructor, Harvard Medical School From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

**Sent:** Mon, 8 Mar 2021 23:12:36 +0000

To: Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Berger, Sherri (CDC/OCOO/OD);

Brooks, John T. (CDC/DDID/NCHHSTP/DHP); Butler, Jay C. (CDC/DDID/OD); Christie, Athalia

(CDC/DDPHSIS/CGH/OD); Goldstein, Robert (CDC/OD/OADPS); McDonald, Clifford

(CDC/DDID/NCEZID/DHQP); Ogden, Cynthia L. (CDC/DDPHSS/NCHS/DHNES); Schuchat, Anne MD

(CDC/OD); Walensky, Rochelle (CDC/OD); Walke, Henry (CDC/DDID/NCEZID/DPEI)

**Subject:** FW: Director's Daily Update March 8, 2021

Happy Monday!

## CMOU Director's Daily Update

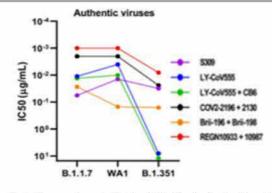


COVID-19 SCIENCE

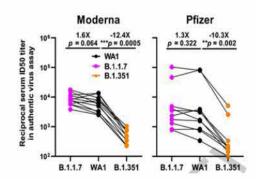
#### March 8, 2021, 5 Articles

B.1.351, which has the E484K mutation, is resistant to multiple monoclonal antibodies and threatens the protection of current mRNA vaccines.

Antibody Resistance of SARS-CoV-2 Variants
B.1.351 and B.1.1.7. Nature Wang et al. (March 8, 2021)



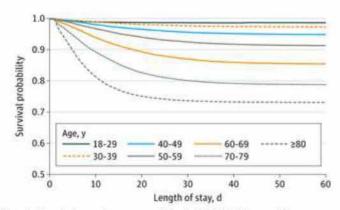
*Note:* Changes in neutralization IC50 of authorized or investigational therapeutic monoclonal antibodies against B.1.1.7, WT (WA1), B.1.351 viruses.



 $\it Note:$  Changes in neutralization IC50 of sera from vaccinees against B.1.1.7, WT (WA1), B.1.351 viruses.

Among 192,550 adults hospitalized with COVID-19 in 555 US medical centers from March-August 2020, in-hospital mortality was high (13.6%) and increased with increasing age; there was a significant reduction in mortality from March (22.1%) to August (6.5%).

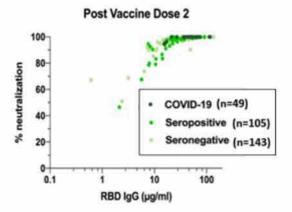
Outcomes and Mortality Among Adults
Hospitalized With COVID-19 at US Medical
Centers. JAMA Nguyen et al. (March 5, 2021)



Note: In-hospital mortality among adults with COVID-19 by age: US

Two doses of mRNA vaccine are needed to reach equivalently high levels of IgG and neutralization activity among seropositive, with and without history of prior COVID-19, and seronegative persons.

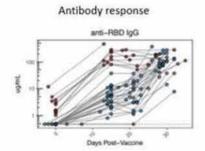
Comparison of IgG and neutralizing antibody responses after one or two doses of COVID-19 mRNA vaccine in previously infected and uninfected persons. medRxiv Demonbreun et al. (Preprint, March 8, 2021)

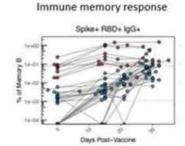


*Note:* Anti-RBD IgG concentration and % neutralization increased dramatically after two doses among seropositive and seronegative samples.

mRNA vaccine induced significant antibody immunological memory responses following two doses among seronegative persons and one dose among seropositive persons.

Longitudinal Analysis Reveals
Distinct Antibody and Memory B
Cell Responses in SARS-CoV2
Naïve and Recovered Individuals
Following mRNA
Vaccination. medRxiv Goel et al.
(Preprint, March 6, 2021)





Note: Concentration of anti-RBD IgG antibodies and immune response as frequency of antigen specific IgG+ memory B cells over time in SARS-CoV2 naïve and SARS-CoV2 recovered vaccinated individuals.

Dotted lines indicate the limit of detection for the assay.

Professional athletes with prior COVID-19 illness have low prevalence of inflammatory heart disease and can safely return to play with implementation of current cardiovascular risk stratification practices.

Cross-sectional study of 789 professional athletes who underwent return-to-play cardiac screening.

Prevalence of inflammatory heart disease among professional athletes with prior COVID-19 infection who received systematic return-to-play cardiac screening. JAMA Cardiology Martinez et al. (March 4, 2021)

30 (3.8%) athletes received additional testing after screening; of whom 5 (0.6%) has inflammatory heart disease: 3 with myocarditis and 2 with pericarditis.

All 5 athletes had preceding symptoms consistent with moderate COVID-19 illness (such as loss of taste and smell, nonspecific fatigue, and cough without dyspnea).

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From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

Sent: Fri, 14 May 2021 22:48:59 +0000

To: Walensky, Rochelle (CDC/OD)

Subject: FW: Vaccines and myocarditis

From: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Sent: Friday, May 14, 2021 6:43 PM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) < anc0@cdc.gov>; Posner, Sam (CDC/DDID/NCIRD/OD) < shp5@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Greco Kone, Rebecca (CDC/DDPHSIS/OD) < ftm1@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < kaf6@cdc.gov>; Patel, Manish (CDC/DDID/NCIRD/ID) < aul3@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < lem2@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) < mew2@cdc.gov>; Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) < vif6@cdc.gov>; Mahon, Barbara (CDC/DDID/NCIRD/OD) < bdm3@cdc.gov>

Cc: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) <IGP8@cdc.gov>

Subject: RE: Vaccines and myocarditis

Thanks, John. I'll just reinforce that initiating VAERS reports is the best way to get information to us—these cases are escalated and VAERS will reach out for more information and to collect medical records.

Also asking Tom the best approach to organizing a call—it might be to initiate a CISA consult and include involved providers, but he may wish to do something sooner and less formal for now since it sounds like several institutions are involved.

tom

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Friday, May 14, 2021 5:59 PM

To: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < \( \text{ymo0@cdc.gov} \); Cohn, Amanda (CDC/DDID/NCIRD/OD) < \( \text{shp5@cdc.gov} \); Walke, Henry (CDC/DDID/NCEZID/DPEI) < \( \text{hfw3@cdc.gov} \); Greco Kone, Rebecca (CDC/DDPHSIS/OD) < \( \text{ftm1@cdc.gov} \); Fox, Kimberley (CDC/DDID/NCIRD/DBD) < \( \text{kaf6@cdc.gov} \); Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < \( \text{tnc4@cdc.gov} \); Patel, Manish (CDC/DDID/NCIRD/ID) < \( \text{aul3@cdc.gov} \); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < \( \text{ayv6@cdc.gov} \); Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < \( \text{lem2@cdc.gov} \); Wharton, Melinda (CDC/DDID/NCIRD/ISD) < \( \text{mew2@cdc.gov} \); Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) < \( \text{vif6@cdc.gov} \); Mahon, Barbara (CDC/DDID/NCIRD/OD) < \( \text{bdm3@cdc.gov} \)

Cc: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) < IGP8@cdc.gov>

Subject: RE: Vaccines and myocarditis

Hi all,

Looping everyone in with Matt Oster, pediatric cardiologist at Emory and also with CDC (chronic disease).

He shared the following info below.

Very willing to work with whomever he might best connect in the vaccine safety group.

-john

From: Oster, Matt (CDC/DDNID/NCBDDD/DBDID) (CTR) < IGP8@cdc.gov>

Sent: Friday, May 14, 2021 5:53 PM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Subject: FW: Vaccines and myocarditis

#### **Updates:**



(b)(5)

- 6. For a call, I would personally like to request NOT to have one on Saturday between 12-3 (b)(6) or 5-10 (b)(6). Any other time I can make work.
- 7. Totally fine to loop in others.

--Matt

Matthew Oster, MD, MPH
CDC COVID-19 Response, Multisystem Inflammatory Syndrome Unit
CDC Center on Birth Defects and Developmental Disabilities
Pediatric Cardiologist, Sibley Heart Center, Children's Healthcare of Atlanta
Emory University School of Medicine | Emory University Rollins School of Public Health
Igp8@cdc.gov

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Sent: Friday, May 14, 2021 4:28 PM
To: Matt Oster < Oster M@kidsheart.com >
Subject: RE: Vaccines and myocarditis

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## Matt,

Yes, confirmed we would be very much like to talk to any group with data, have them share what they know (including ideally the ACIP expect group on vaccine adverse events – very sharp thinkers on this topic), offer feedback if they'd like it, and know their publication plan so we can prepare.

Ideally, not tonight because if we can agree to share data, we want to ensure we have time to get the key people on that call.

Perhaps tomorrow PM or Sunday PM?

ALSO: (b)(5

b)(5)

Cheers,

-john

PS: I'd like to loop others into this conversation. Saves a lot of emailing and people at our end are hyper-confidential!

From: Matt Oster < Oster M@kidsheart.com >

Sent: Friday, May 14, 2021 3:30 PM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Subject: RE: Vaccines and myocarditis

Need quick advice. Call if you have a second? (b)(6)

#### Matt Oster, MD, MPH

Director, Children's CORPS (Cardiac Outcomes Research Program at Sibley Heart Center) Sibley Heart Center Cardiology, Children's Healthcare of Atlanta Emory University School of Medicine | Emory University Rollins School of Public Health 2835 Brandywine Road, Suite 300 | Atlanta, GA | 30341 o: 404-256-2593 | f: 770-488-9477

osterm@kidsheart.com | www.choa.org/heart





From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Sent: Friday, May 14, 2021 1:14 PM
To: Matt Oster <OsterM@kidsheart.com>

Cc: Sperling, Laurence (CDC/DDNID/NCCDPHP/DHDSP) <pvl0@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>

Subject: RE: Vaccines and myocarditis

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THANSKS! Apologies if I was nudgy...

From: Matt Oster < OsterM@kidsheart.com >

Sent: Friday, May 14, 2021 1:13 PM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Cc: Sperling, Laurence (CDC/DDNID/NCCDPHP/DHDSP) <pvl0@cdc.gov>; Shimabukuro, Tom

Subject: RE: Vaccines and myocarditis

#### (b)(5)

I and others have been encouraging all

that we hear of to report.

#### Matt Oster, MD, MPH

Director, Children's CORPS (Cardiac Outcomes Research Program at Sibley Heart Center)

Sibley Heart Center Cardiology, Children's Healthcare of Atlanta

Emory University School of Medicine | Emory University Rollins School of Public Health

Medical Officer, CDC Center on Birth Defects and Developmental Disabilities | CDC COVID-19 Response

2835 Brandywine Road, Suite 300 | Atlanta, GA | 30341

o: 404-256-2593 | f: 770-488-9477

osterm@kidsheart.com | www.choa.org/heart





From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>

Sent: Friday, May 14, 2021 12:44 PM
To: Matt Oster < Oster M@kidsheart.com>

Cc: Sperling, Laurence (CDC/DDNID/NCCDPHP/DHDSP) <pvl0@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>

Subject: RE: Vaccines and myocarditis

CAUTION: \*\*\*\*This email originated from outside of Sibley. Do not click links or open attachments unless you recognize the sender and know the content is safe.\*\*\*\*

Matt,

Unfortunately that's not my call. (b)(5)

b)(5)

(b)(5)

(b)(5) to consider. That's
(b)(5)
(b)(5)

In terms of data:

(b)(5)

Thanks Matt!

-john

John T. Brooks, MD

Chief Medical Officer, CDC COVID-19 Response

Email: zud4@cdc.gov

Apologies for errors in my messages that may be due to my need to dictate.



http://intranet.cdc.gov/library/covid19/index.html



From: Matt Oster < Oster M@kidsheart.com >

Sent: Friday, May 14, 2021 11:52 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Subject: RE: Vaccines and myocarditis

Thanks. Would it be helpful for me to be on the ACIP call on Monday?

Re your questions:

(b)(5)



Finally, besides just me as an SME, it may be worth looping 6

(b)(5)

--Matt

#### Matt Oster, MD, MPH

Director, Children's CORPS (Cardiac Outcomes Research Program at Sibley Heart Center) Sibley Heart Center Cardiology, Children's Healthcare of Atlanta Emory University School of Medicine | Emory University Rollins School of Public Health 2835 Brandywine Road, Suite 300 | Atlanta, GA | 30341 o: 404-256-2593 | f: 770-488-9477 osterm@kidsheart.com | www.choa.org/heart





From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Sent: Friday, May 14, 2021 11:12 AM

To: Matt Oster < OsterM@kidsheart.com >
Subject: RE: Vaccines and myocarditis

CAUTION: \*\*\*\*This email originated from outside of Sibley. Do not click links or open attachments unless you recognize the sender and know the content is safe.\*\*\*\*

Hi Matt,

I wanted to get back to you and let you know myocarditis in young men after mRNA vaccination is a topic area of active investigation by CDC and FDA. Folks are reviewing VAERS and other data sources and collecting case reports.

Importantly, to the extent you are able, it is important to **remind** anyone who has a suspect case(s) to report them through VAERS (<a href="https://vaers.hhs.gov/">https://vaers.hhs.gov/</a>) so that FDA and CDC can be made aware. Follow-up is very fast (a day or two typically) for report of TTS and myocarditis.

Although Israel, the European Medicines Agency, and US DoD are all also investigating the issue at present, a clear association has not yet been established. As such, the topic was not included in discussions during the recent ACIP meeting. However, this Monday (May 17) the ACIP subgroup that routinely reviews data for safety signals is gong to be discussing this topic.

# On another note:



Hope all is well at your end. What a long year and a half it's been... If

(b)(6)

I would have lost my mind.

Miss seeing (b)(6) Please say hi.

-john

From: Matt Oster < Oster M@kidsheart.com > Sent: Wednesday, May 12, 2021 10:17 PM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Subject: RE: Vaccines and myocarditis

Don't think it came up with ACIP, but this topic (b)(

(b)(5)

b)(5)

(11)

I think CDC needs to get ahead of this.

### Matt Oster, MD, MPH

Director, Children's CORPS (Cardiac Outcomes Research Program at Sibley Heart Center) Sibley Heart Center Cardiology, Children's Healthcare of Atlanta Emory University School of Medicine | Emory University Rollins School of Public Health 2835 Brandywine Road, Suite 300 | Atlanta, GA | 30341 o: 404-256-2593 | f: 770-488-9477

osterm@kidsheart.com | www.choa.org/heart





From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Tuesday, May 11, 2021 10:59 AM
To: Matt Oster < Oster M@kidsheart.com >
Subject: RE: Vaccines and myocarditis

CAUTION: \*\*\*\*This email originated from outside of Sibley. Do not click links or open attachments unless you recognize the sender and know the content is safe.\*\*\*\*

Righto – I know the topic has been much discussed by the vaccine safety folks and I believe the ACIP safety group. Curious if it comones up at tomorrow's meeting. They certainly are *not* aware. ©

John T. Brooks, MD

Chief Medical Officer, CDC COVID-19 Response

Email: zud4@cdc.gov

Apologies for errors in my messages that may be due to my need to dictate.



http://intranet.cdc.gov/library/covid19/index.html



From: Matt Oster < Oster M@kidsheart.com > Sent: Tuesday, May 11, 2021 10:09 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Subject: RE: Vaccines and myocarditis

#### (b)(5)

## Matt Oster, MD, MPH

Director, Children's CORPS (Cardiac Outcomes Research Program at Sibley Heart Center) Sibley Heart Center Cardiology, Children's Healthcare of Atlanta Emory University School of Medicine | Emory University Rollins School of Public Health 2835 Brandywine Road, Suite 300 | Atlanta, GA | 30341

o: 404-256-2593 | f: 770-488-9477

osterm@kidsheart.com | www.choa.org/heart





From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Tuesday, May 11, 2021 9:54 AM

To: Matt Oster < Oster M@kidsheart.com >
Subject: RE: Vaccines and myocarditis

CAUTION: \*\*\*\*This email originated from outside of Sibley. Do not click links or open attachments unless you recognize the sender and know the content is safe.\*\*\*\*

# Tanks Matt,

Do you have data to share that could be shared with the folks reviewing COVID-19 vaccine adverse events?

# -john

John T. Brooks, MD

Chief Medical Officer, CDC COVID-19 Response

Email: zud4@cdc.gov

Apologies for errors in my messages that may be due to my need to dictate.



http://intranet.cdc.gov/library/covid19/index.html



From: Matt Oster < Oster M@kidsheart.com > Sent: Tuesday, May 11, 2021 9:19 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Subject: Vaccines and myocarditis

Just a heads up: (b)(5)

(b)(5)

--Matt

# Matt Oster, MD, MPH

Director, Children's CORPS (Cardiac Outcomes Research Program at Sibley Heart Center) Sibley Heart Center Cardiology, Children's Healthcare of Atlanta

Emory University School of Medicine | Emory University Rollins School of Public Health 2835 Brandywine Road, Suite 300 | Atlanta, GA | 30341 o: 404-256-2593 | f: 770-488-9477 osterm@kidsheart.com | www.choa.org/heart





 From:
 Capozzola, Christa (CDC/OCOO/OFR)

 Sent:
 Wed, 26 May 2021 21:54:36 +0000

To: (b)(4); (b)(6) (CDC/OCOO/OD) (CTR); (b)(4); (b)(6)

(CDC/OCOO/OD) (CTR); Berger, Sherri (CDC/OCOO/OD)

**Cc:** (b)(4); (b)(6) (CDC/DDID/NCIRD/OD) (CTR)

**Subject:** From SB To SL on Response All Hands - Final

Attachments: Response AHM Key Takeaways - Leadership Brief\_final clean 5262021.docx

Here's the latest and final for you to send later or tomorrow....thanks!

From: (b)(4); (b)(6) (CDC/OCOO/OD) (CTR) <xwx7@cdc.gov>

Sent: Wednesday, May 26, 2021 2:31 PM

To: Capozzola, Christa (CDC/OCOO/OFR) <KQR5@cdc.gov>;(b)(4); (b)(6) (CDC/OCOO/OD) (CTR)

<anj3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Cc: (b)(4); (b)(6) (CDC/DDID/NCIRD/OD) (CTR)

<avk0@cdc.gov>

Subject: Re: EOC All Hands

From: (b)(4); (b)(6)

Sorry if this is a duplication, email is not cooperating today.

(b)(4); (b)(6)

Sent: Wednesday, May 26, 2021 2:21 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; (b)(4); (b)(6)

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

If hasn't already gone out, see attached. I

(b)(5)

thnx

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Wednesday, May 26, 2021 12:27 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6)

Cc: (b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

Here you go!

We made a few minor adjustments.

Thanks, Christa From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Tuesday, May 25, 2021 5:36 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>; (b)(4); (b)(6)

(b)(4): (b)(6)

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

No problem, just let me know what is final please

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 5:35 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; (b)(4); (b)(6)

(b)(4): (b)(6)

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

I sent it to him and Melissa as soon as I got it – we just got off the long budget briefing call with IRD – so I will ping Melissa shortly.

Thanks.

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Tuesday, May 25, 2021 5:34 PM

To:(b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

Any edits to what I am sending?

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 5:31 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: EOC All Hands

Update attached. If it's too long, you could include the Q&A as an attachment.

# (b)(4); (b)(6)

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 5:20 PM

To: (b)(4); (b)(6)

Cc: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

I think it's actually more important – people are multi-tasking during an all hands, so they'll definitely want to catch what they missed!

I don't think we need much in the intro section – that's a way to shorten a bit.

Thanks!

From:(b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 5:07 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>; (b)(4); (b)(6)

b)(4); (b)(6)

Subject: RE: EOC All Hands

We can add if you want - did not include in All Staff mostly because of length.

(b)(4); (b)(6)

Deloitte Services LP

Tel/Direct: (b)(4); (b)(6)

Mobile: (b)(4); (b)(6) www.deloitte.com

On May 25, 2021, at 4:57 PM, Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov> wrote:

Yes.

I also would suggest that (b)(5)

(b)(5)

Thanks.

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Sent: Tuesday, May 25, 2021 4:56 PM

To:(b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<<u>KQR5@cdc.gov></u>
Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

Ok, Christa do you want to run by Henry please before I send?

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 4:55 PM

**To:** Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

The all staff one should, but I think the SL should come from you as it is written.

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<KQR5@cdc.gov>

Cc:(b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

Should they both come from Henry?

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Sent: Tuesday, May 25, 2021 4:31 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

Sherri and Christa,

Draft IMS staff email and SL email are attached; if possible it would be good to send today to keep information flowing in a timely way. We wrote these with that timeframe in mind (e.g., "today's All Hands Meeting..."), but we can re-work if they will not go out today. Also, the SL email includes excerpts from the Q&A, which adds length but will help with transparency.

Please let us know what changes you need.

# (b)(4); (b)(6)

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

**Sent:** Tuesday, May 25, 2021 3:53 PM

To: (b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<<u>KQR5@cdc.gov</u>>;(b)(4); (b)(6) (b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

awesome

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 3:52 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6) Berger, Sherri (CDC/OCOO/OD) <<u>sob8@cdc.gov</u>>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: EOC All Hands

That's great. I will send draft of key points for senior leaders shortly.

From: Capozzola, Christa (CDC/OCOO/OFR) <KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 3:50 PM

To: (b)(4); (b)(6) Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; (b)(4); (b)(6)

Cc: (b)(4); (b)(6)

Subject: [EXT] EOC All Hands

Hi – sharing some data I got today – over 2000 people were in the All Hands (the largest prior was 1500'ish).

PDIMs are receiving unsolicited and unexpected feedback that is very positive and encouraging them to do this more often.

From: (b)(4); (b)(6)

Sent: Monday, May 17, 2021 8:31 AM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; (b)(4); (b)(6)

Cc: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: Weekly IMS update meeting

We can do as a call as we do not need to project slides. Angela will update the appointment with the slides so you have those in advance. Thanks.

#### (b)(4); (b)(6)

Deloitte Services LP

Mobile: (b)(A)-(b)(6)
www.deloitte.com

On May 17, 2021, at 7:37 AM, Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov > wrote:

Thanks all. I may have to join via telephone (v video).

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Monday, May 17, 2021 7:18:13 AM

**To:** (b)(4); (b)(6) Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov> Cc: (b)(4); (b)(6)

Subject: RE: Weekly IMS update meeting

Hi – thanks - beyond updates, one issue I'd like to get everyone's input on is (b)(5)

(b)(5)

#### Christa

From: (b)(4); (b)(6)

Sent: Sunday, May 16, 2021 9:09 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: Weekly IMS update meeting

Sherri and Christa,

Please let us know if there are topics you would like to cover at the IMS weekly update meeting tomorrow at 11:30am.

From our end, we want to touch on 1) communication items, 2) three deliverables we are working on for the end of the month, and 3) support, if any, needed at the end of this four-week transition period.

Angela will send slides in advance, and we will add anything you want to cover.

Thank you, b)(4); (b)(6)

## (b)(4); (b)(6)

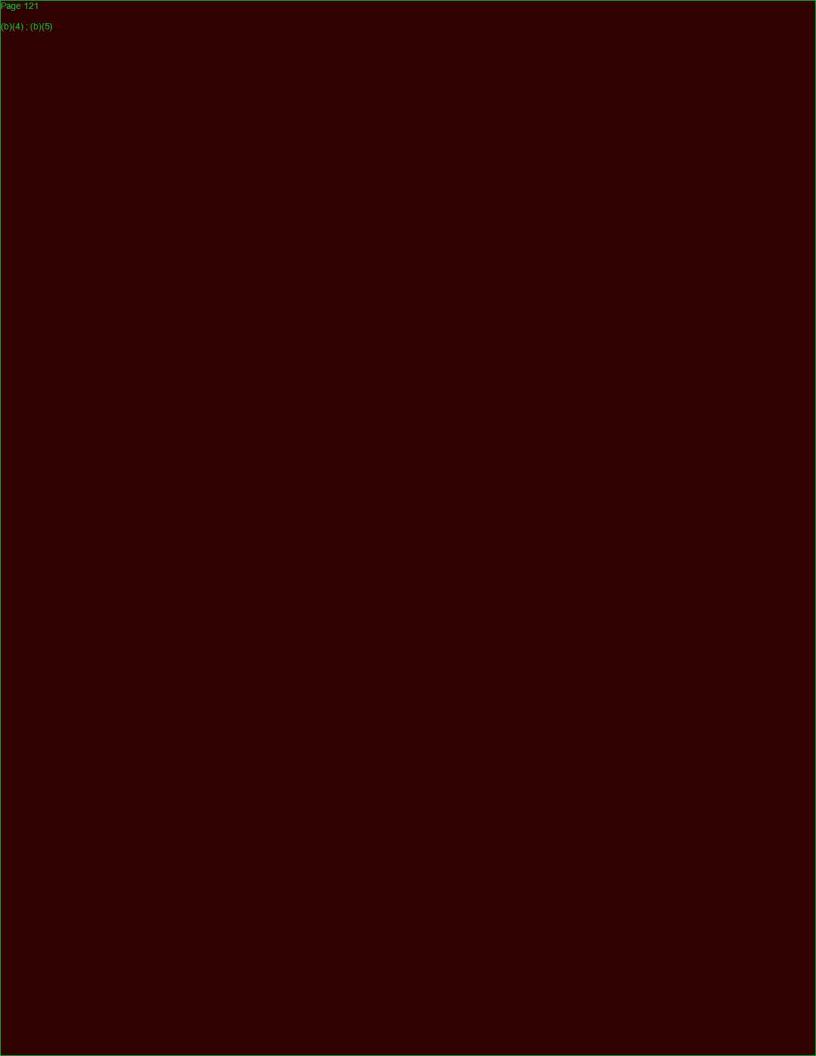
Deloitte Services LP

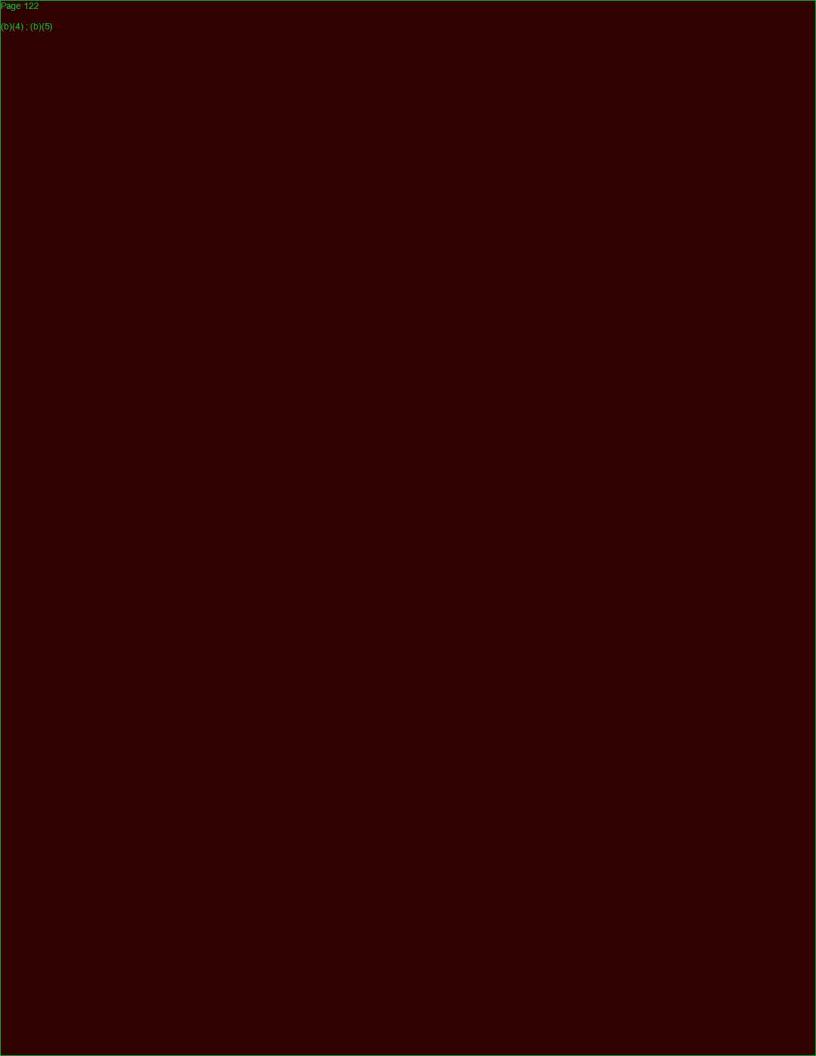
Mobile: (b)(A)-(b)(6)
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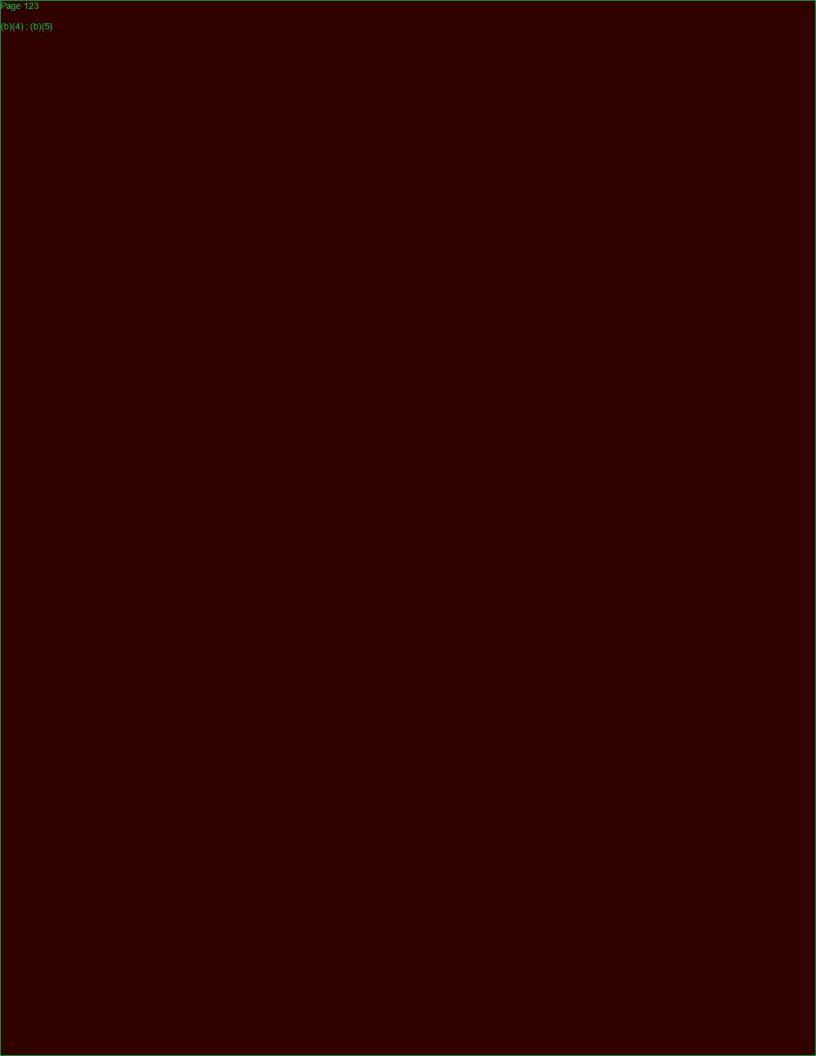
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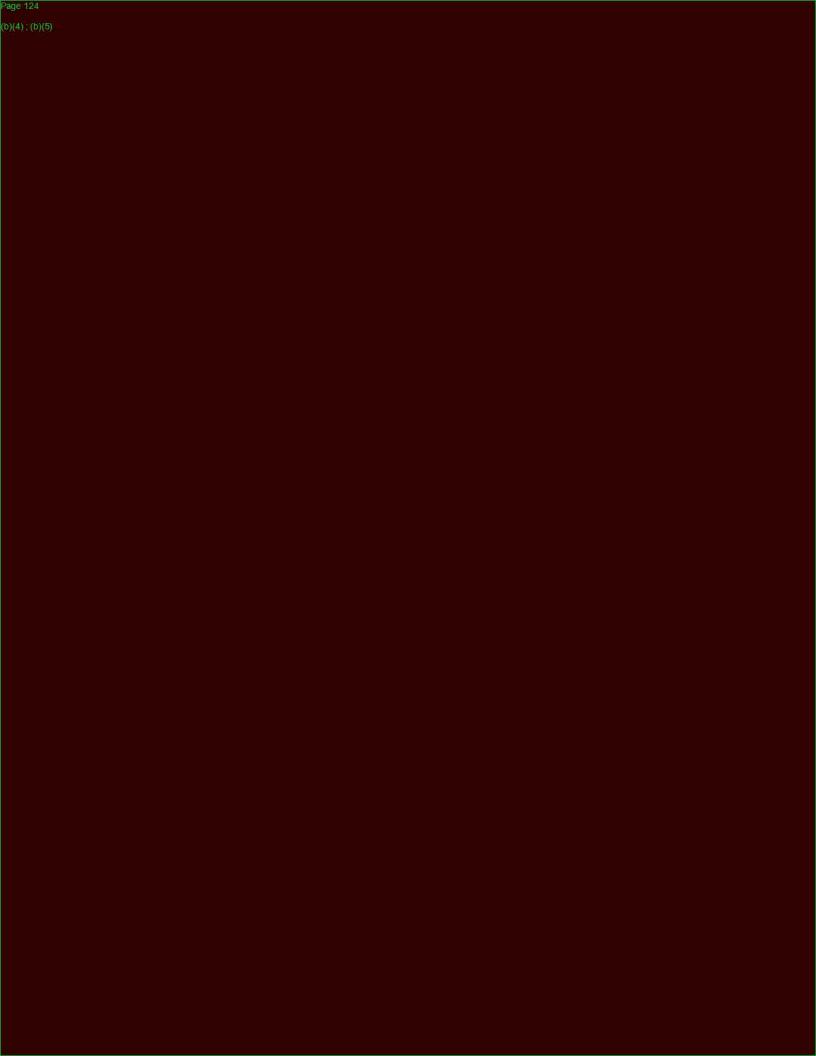
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v.E.1









From: (b)(4); (b)(6)

**Sent:** Tue, 25 May 2021 21:30:51 +0000 **To:** Capozzola, Christa (CDC/OCOO/OFR)

Cc: Berger, Sherri (CDC/OCOO/OD); (b)(4); (b)(6)

Subject: RE: EOC All Hands

Attachments: IMS All Hands Summary to Staff\_052521\_Updated.docx

Update attached. If it's too long, you could include the Q&A as an attachment.

(b)(a):

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 5:20 PM

To: (b)(4); (b)(6)

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

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(b)(4); (b)(6)

Subject: RE: EOC All Hands

We can add if you want - did not include in All Staff mostly because of length.

### (b)(4); (b)(6)

Deloitte Services LP

Mobile: (b)(A)-(b)(6)
www.deloitte.com

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Please let us know what changes you need.

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To: (b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov> (b)(4); (b)(6)

b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

awesome

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(b)(4); (b)(6) Berger, Sherri (CDC/OCOO/OD) <<u>sob8@cdc.gov</u>>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: EOC All Hands

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Sent: Tuesday, May 25, 2021 3:50 PM

**To:** (b)(4); (b)(6) Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>;(b)(4); (b)(6)

Cc:(b)(4);(b)(6)

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Cc: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>; (b)(4); (b)(6)

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Subject: RE: Weekly IMS update meeting

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<sob8@cdc.gov> Cc: (b)(4); (b)(6)

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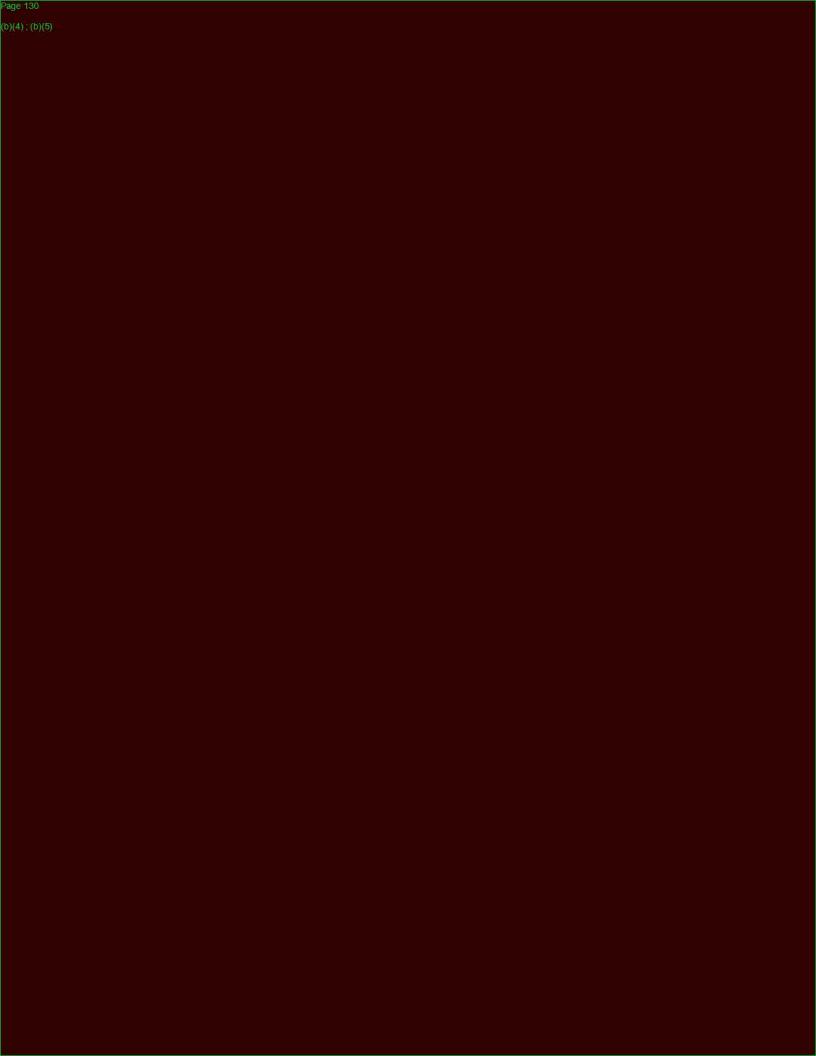
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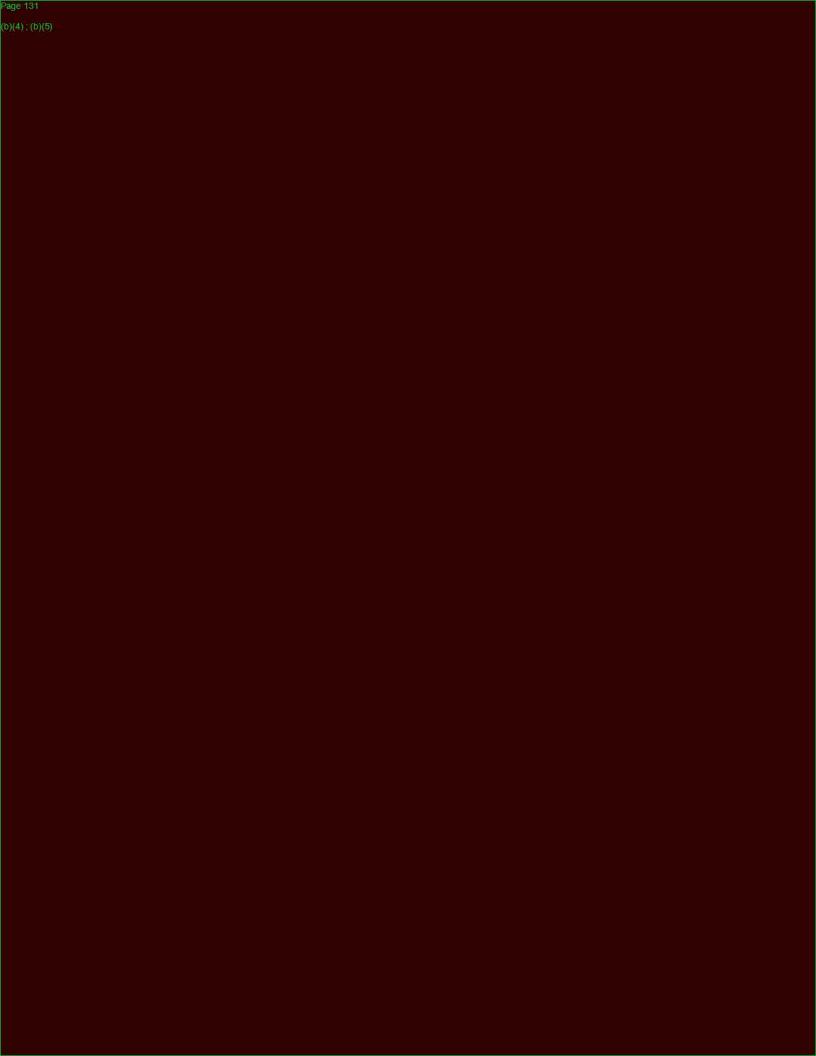
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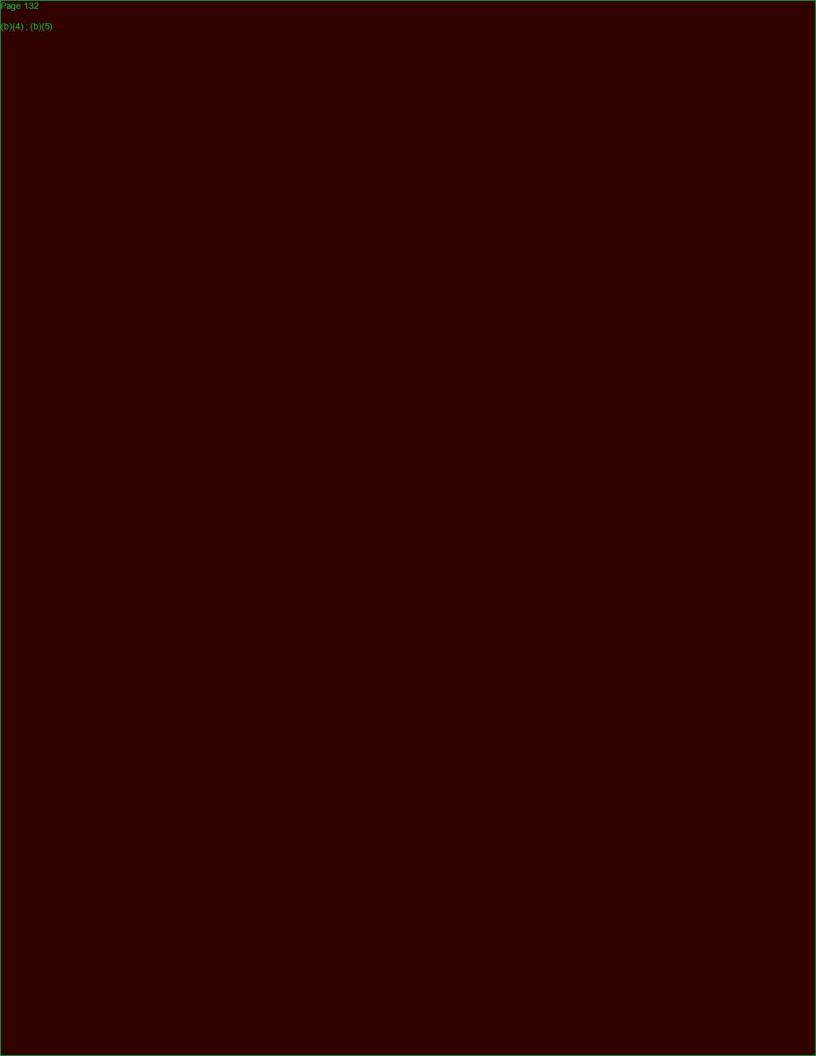
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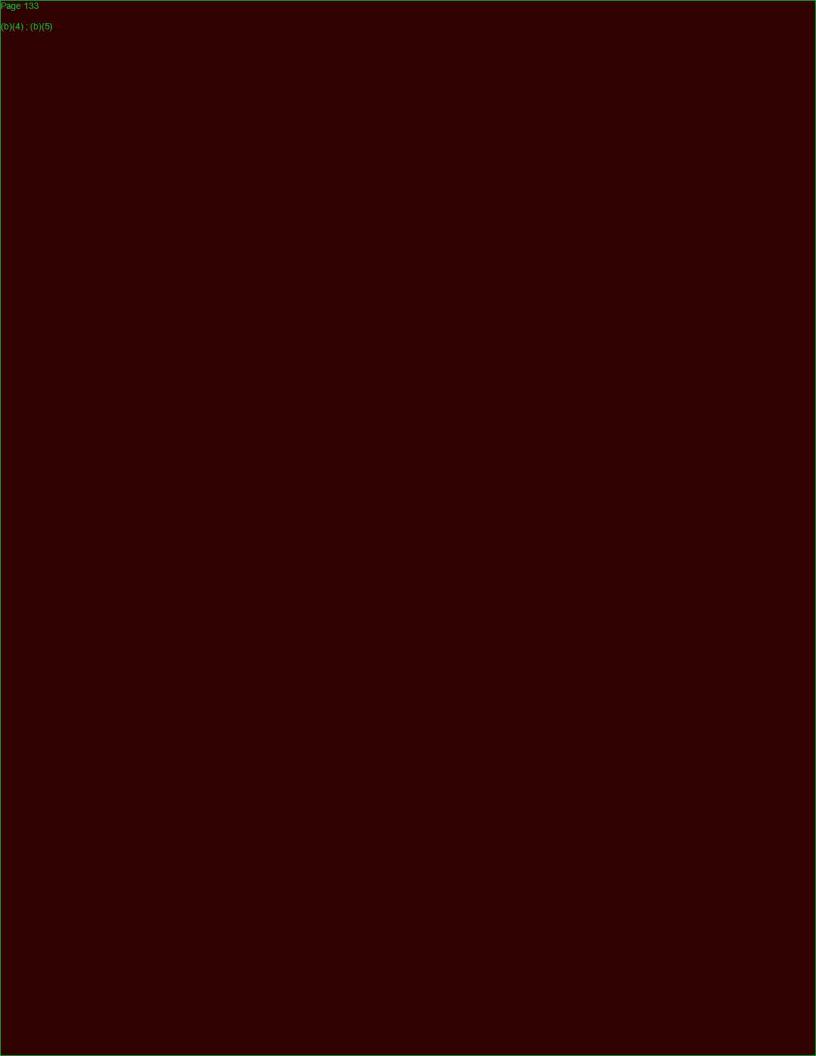
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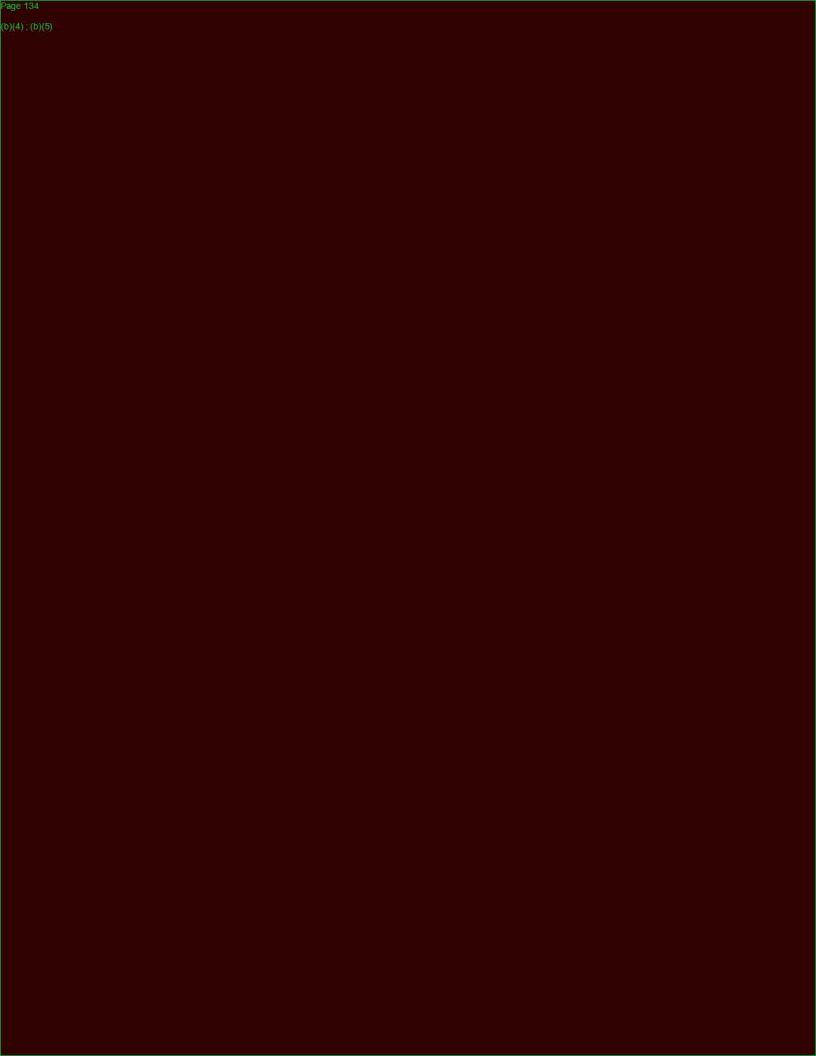
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From: (b)(4); (b)(6) (CDC/OCOO/OD) (CTR)

**Sent:** Wed, 26 May 2021 18:30:56 +0000

To: Capozzola, Christa (CDC/OCOO/OFR); (b)(4); (b)(6) (CDC/OCOO/OD)

(CTR); Berger, Sherri (CDC/OCOO/OD)

Cc: (b)(4); (b)(6) (CDC/DDID/NCIRD/OD) (CTR)

Subject: Re: EOC All Hands

Attachments: Response AHM Key Takeaways - Leadership Brief\_final clean 5262021.docx

From: (b)(4); (b)(6)

Sorry if this is a duplication, email is not cooperating today.

(b)(4): (b)(6)

Sent: Wednesday, May 26, 2021 2:21 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; (b)(4); (b)(6)

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

If hasn't already gone out, see attached. I

b)(5)

thnx

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Wednesday, May 26, 2021 12:27 PM

**To:** Berger, Sherri (CDC/OCOO/OD) < <u>sob8@cdc.gov</u>>;(b)(4);(b)(6)

(b)(4); (b)(6)

Cc: (b)(4); (b)(6)

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Cc: (b)(4); (b)(6)

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(b)(4); (b)(6)

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awesome

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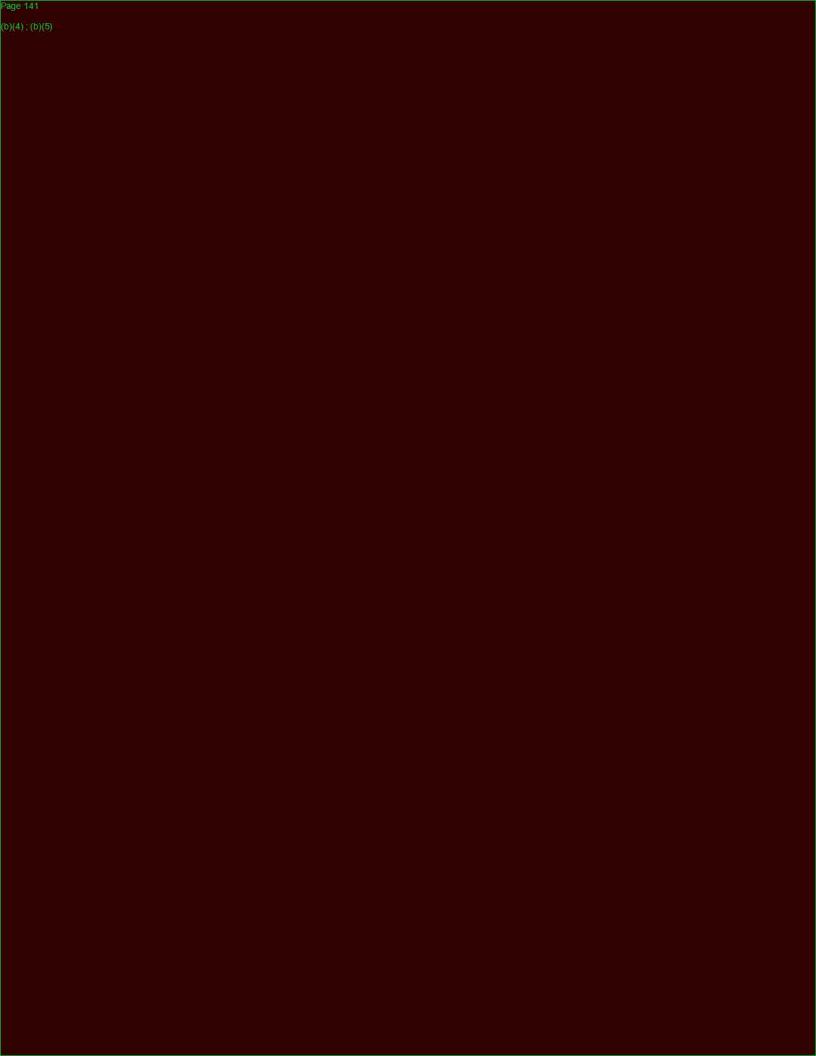
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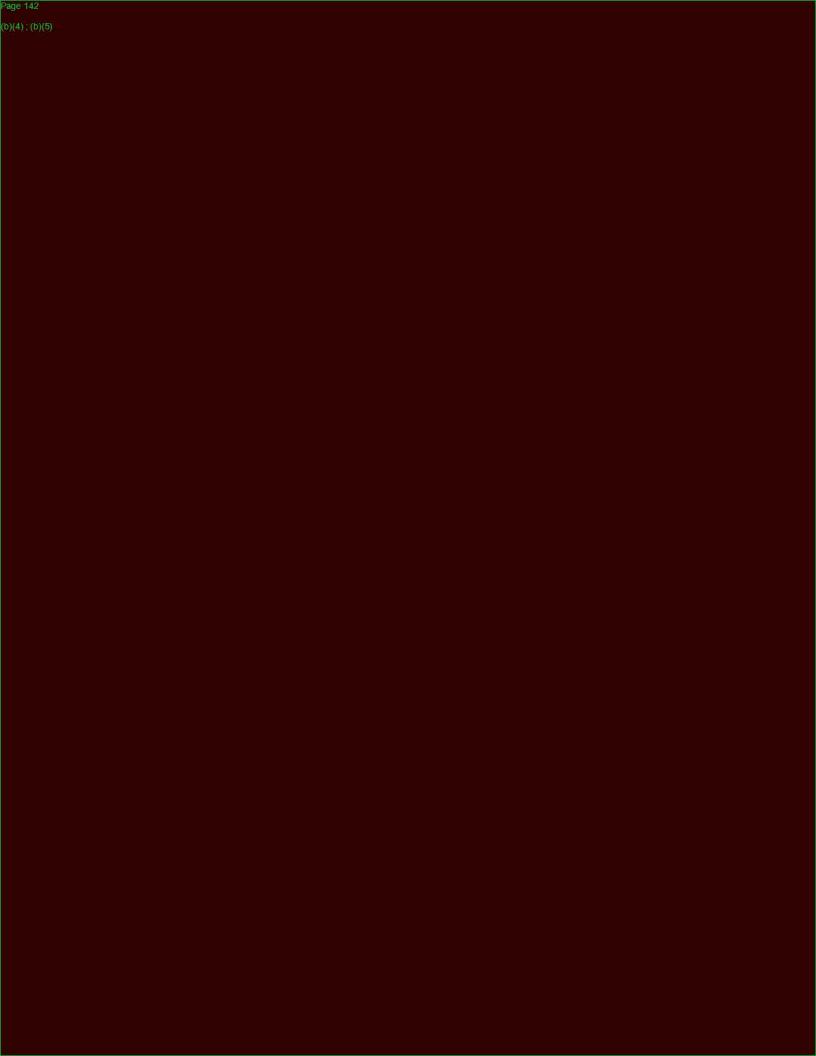
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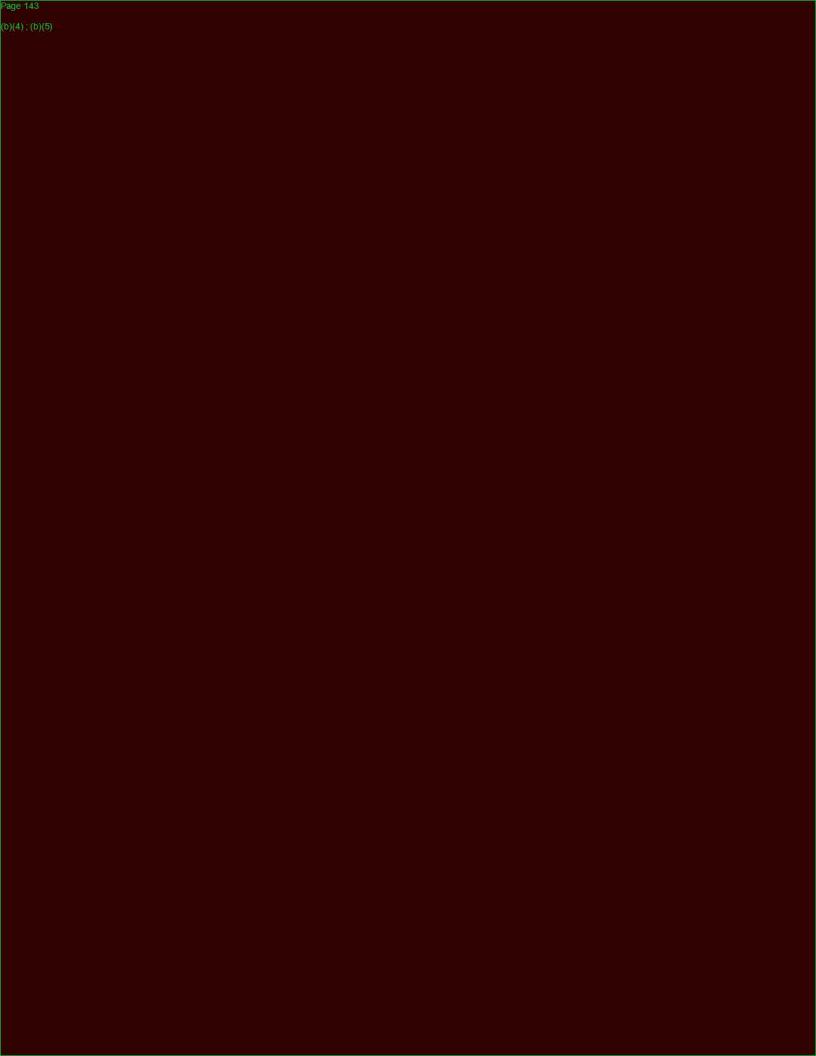
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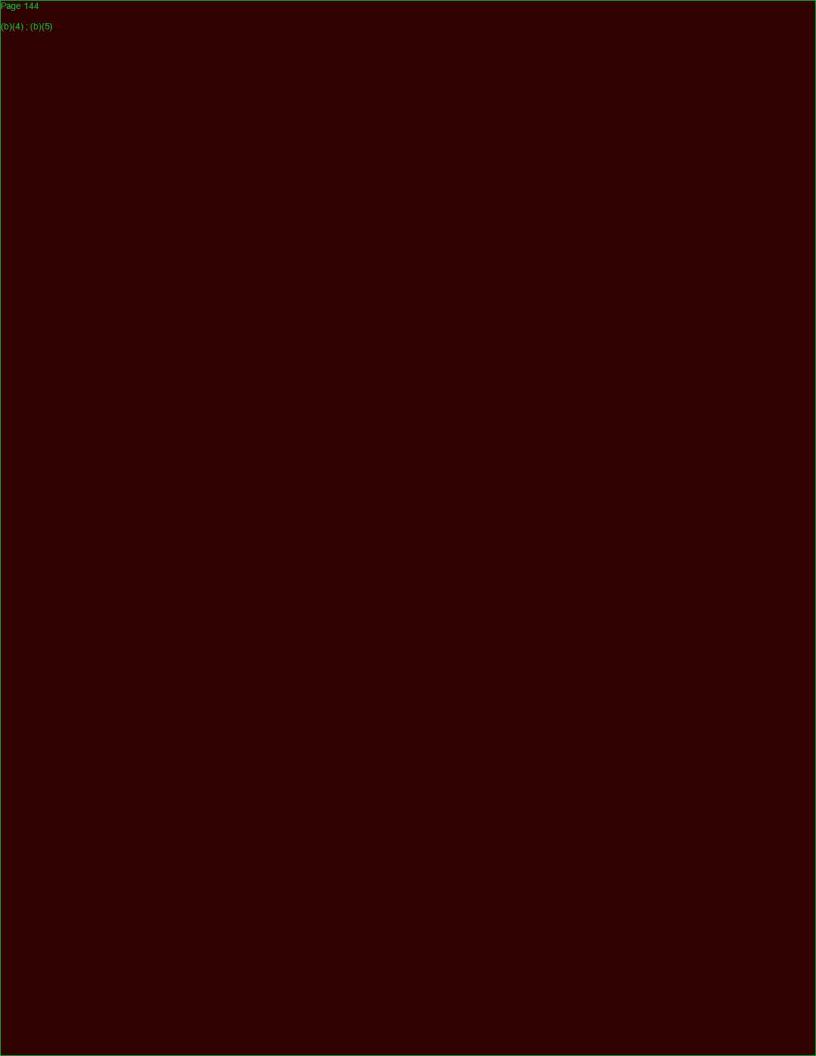
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Capozzola, Christa (CDC/OCOO/OFR) From: Sent: Wed, 26 May 2021 16:26:49 +0000

Berger, Sherri (CDC/OCOO/OD); (b)(4); (b)(6) To:

Cc:

RE: EOC All Hands Subject:

Attachments: Response AHM Key Takeaways - Leadership Brief\_final clean.docx

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Yes.

I also would suggest that Henry's message to staff include the Q/A and summary of remarks – as the headline – instead of just the summary of changes.

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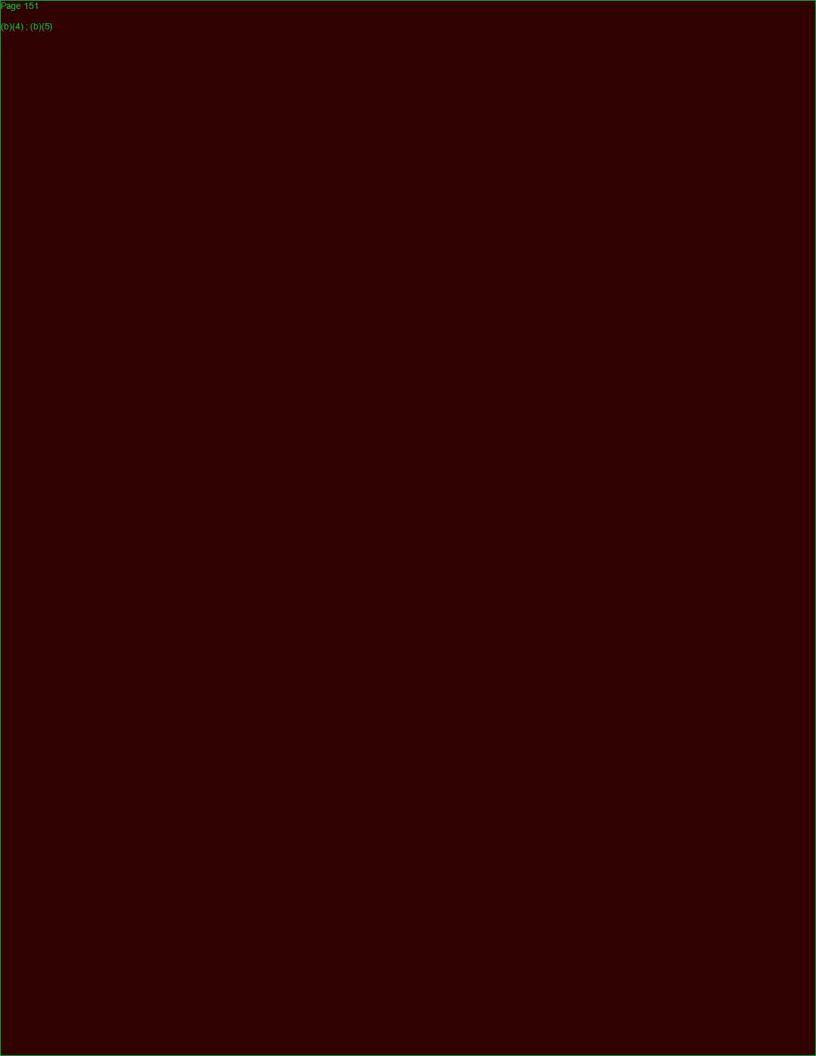
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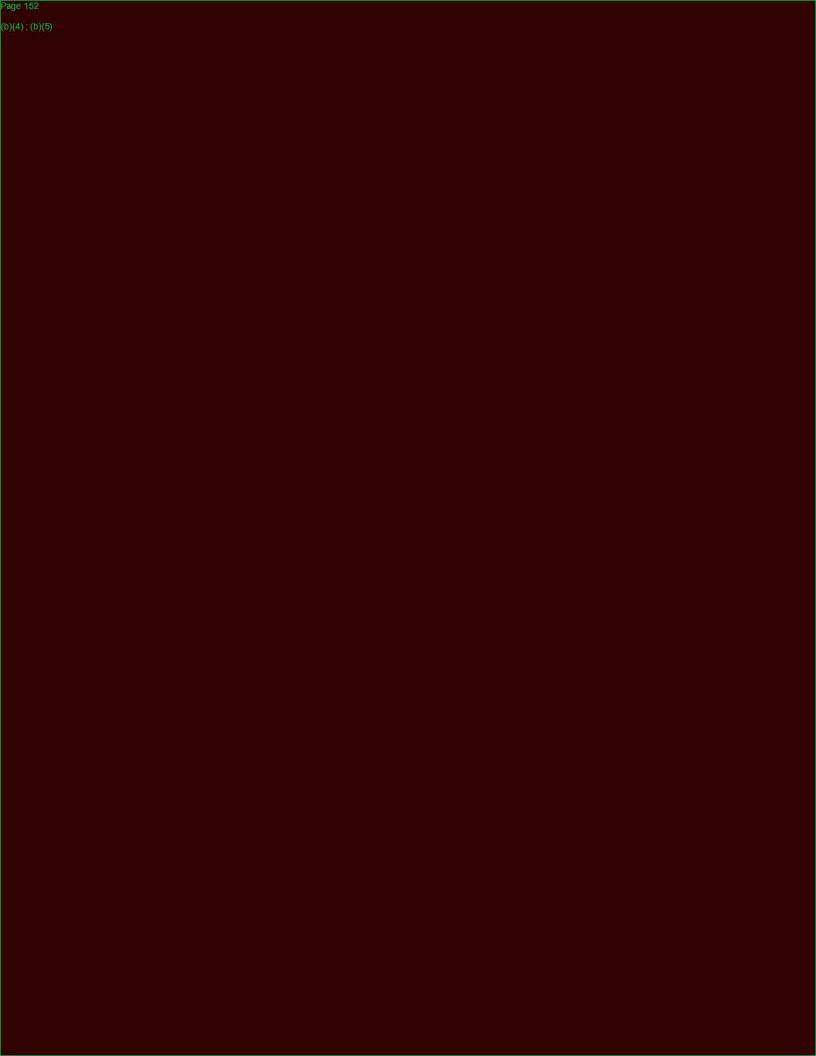
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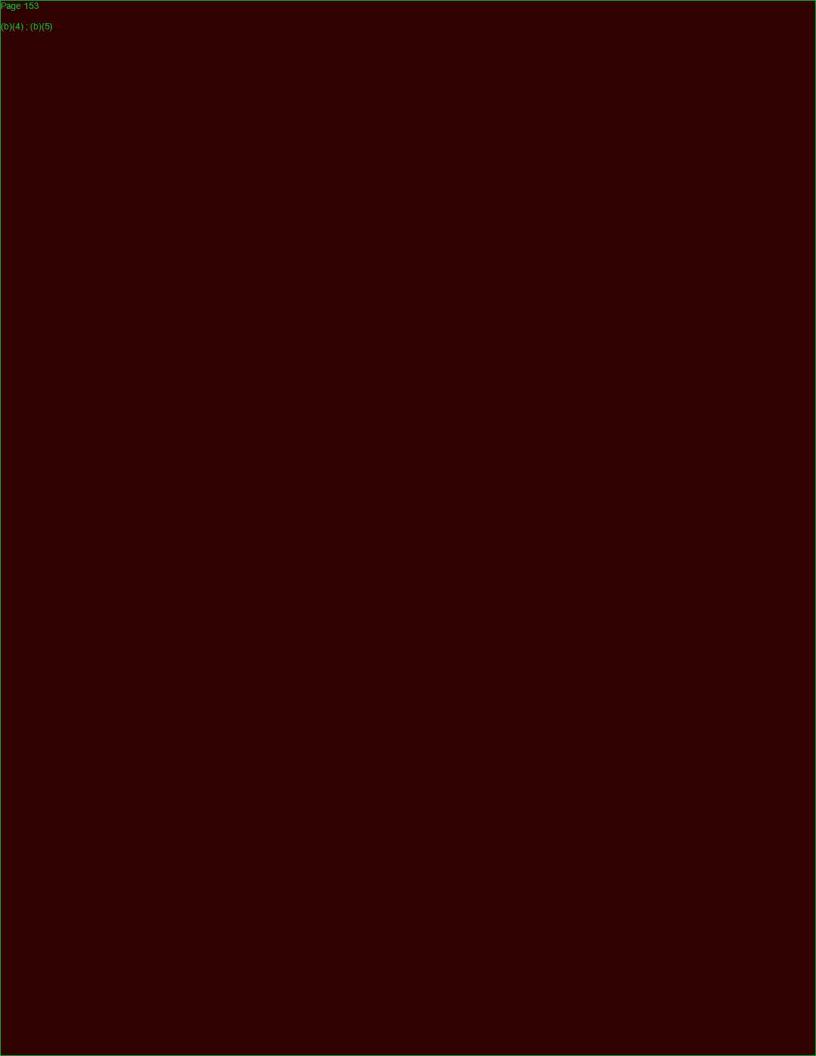
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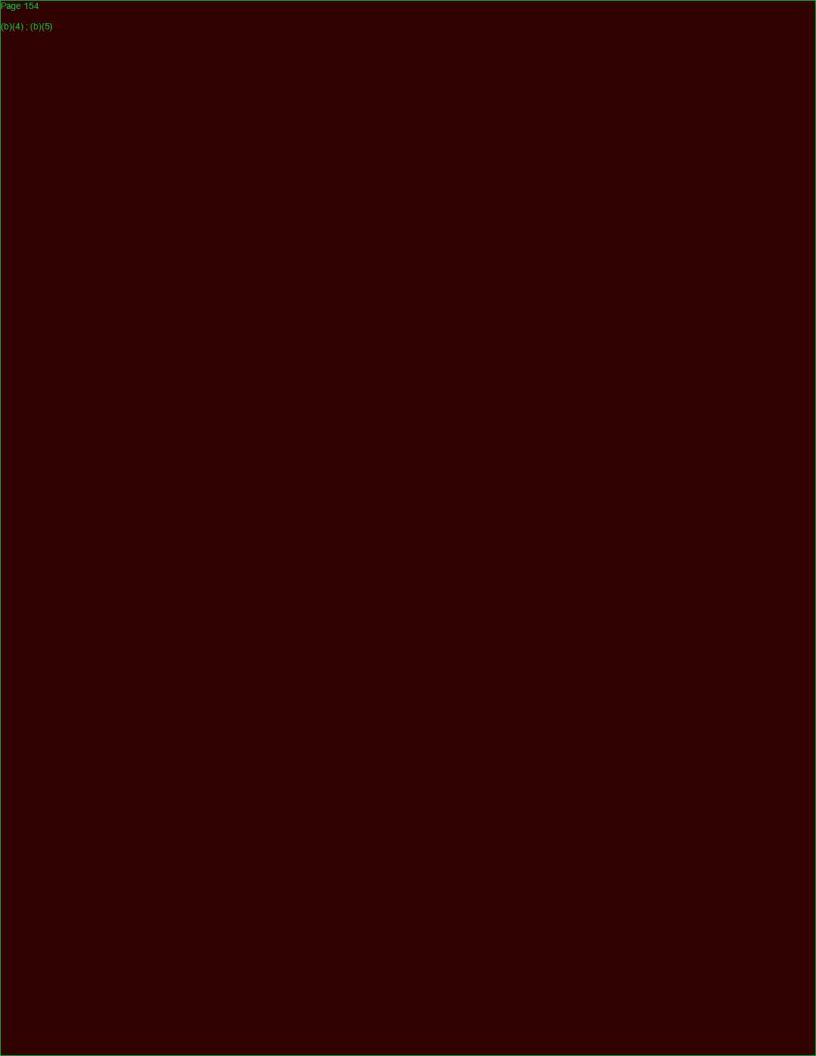
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v.E.1









From: Beach, Michael J. (CDC/DDID/NCEZID/DFWED)

**Sent:** Fri, 5 Mar 2021 14:20:09 +0000

To: Berger, Sherri (CDC/OCOO/OD); Despres, Sarah; Jones, Christopher M.

(CDC/DDNID/NCIPC/OD); Pearlman, Aj; Romanik, Nikki Jo (CDC/OD/OCS); ian.sams@hhs.gov; Marandet,

Angele G. (CDC/DDID/NCHHSTP/DHPIRS)

Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD); Beach, Michael J.

(CDC/DDID/NCEZID/DFWED)

Subject: RE: COVID-19: CDC/HHS Product Awareness (Not for S/R)
Attachments: HHS Awareness week listing 03-08-2021\_updated.docx

Please use this updated version

Michael J. Beach, PhD
Principal Deputy Incident Manager
CDC COVID-19 Emergency Response
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4018
404-667-0718

From: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <mjb3@cdc.gov>

Sent: Friday, March 5, 2021 9:15 AM

**To:** Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Despres, Sarah <sarah.despres@hhs.gov>; Jones, Christopher M. (CDC/DDNID/NCIPC/OD) <FJR0@cdc.gov>; Pearlman, Aj <Aj.Pearlman@hhs.gov>; Romanik, Nikki Jo (CDC/OD/OCS) <kon6@cdc.gov>; ian.sams@hhs.gov; Marandet, Angele G.

(CDC/DDID/NCHHSTP/DHPIRS) < jpx1@cdc.gov>

Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD) <akc9@cdc.gov>; Beach, Michael J.

(CDC/DDID/NCEZID/DFWED) <mjb3@cdc.gov>

Subject: RE: COVID-19: CDC/HHS Product Awareness (Not for S/R)

Document for today

Michael

Michael J. Beach, PhD
Principal Deputy Incident Manager
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Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4018
404-667-0718

----Original Appointment----

From: EOC Report (CDC) < eocreport@cdc.gov > Sent: Wednesday, January 27, 2021 5:41 PM

To: EOC Report (CDC); Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Berger, Sherri (CDC/OCOO/OD);

Despres, Sarah; Jones, Christopher M. (CDC/DDNID/NCIPC/OD); Pearlman, Aj; CDC IMS 2019 NCOV Response IM-PDIM Special Assts; Romanik, Nikki Jo (CDC/OD/OCS); <a href="mailto:ian.sams@hhs.gov">ian.sams@hhs.gov</a>; Marandet, Angele G. (CDC/DDID/NCHHSTP/DHPIRS)

**Cc:** CDC IMS Response Coordinator -2; CDC IMS AV/Communications; Christie, Athalia (CDC/DDPHSIS/CGH/OD)

Subject: COVID-19: CDC/HHS Product Awareness (Not for S/R)

When: Friday, March 5, 2021 9:30 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Bldg. 21, 3025B and Zoom (b)(6)

\*\*\* Meeting Start Time Indicates Eastern Time \*\*\*

\*\*\* Response Options has been disabled\*\*\*

POC: CDC IMS 2019 NCOV Response IM-PDIM Special Assts <eocevent446@cdc.gov>

Join ZoomGov Meeting
(b)(6)

Meeting ID: (b)(6)

Passcode: (b)(6)

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(b)(6)

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(b)(6)

US (San Jose)

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US (New York)

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US (San Jose)

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US (San Jose)

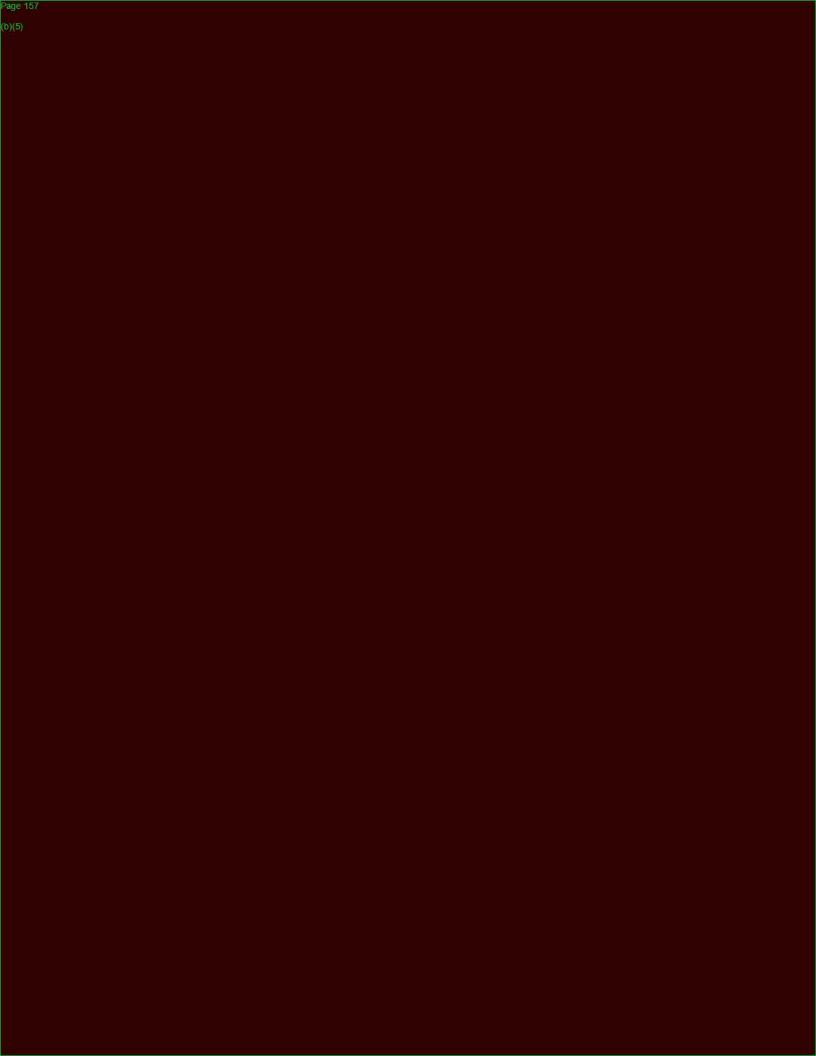
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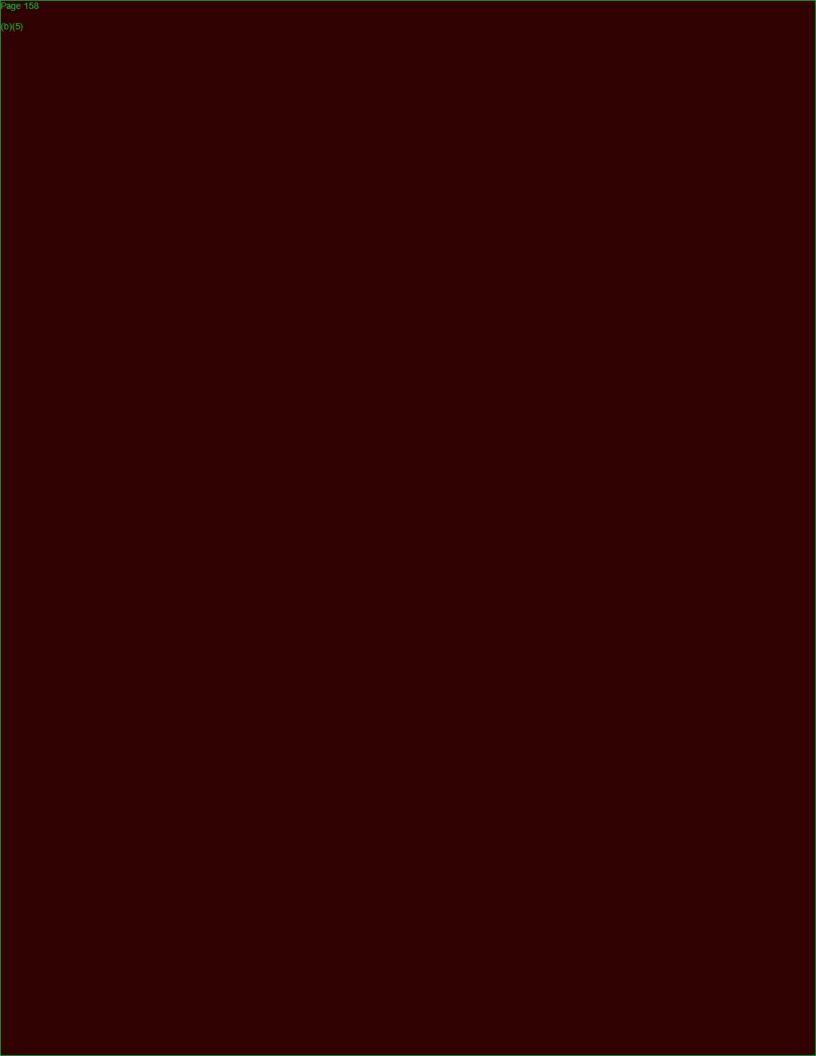
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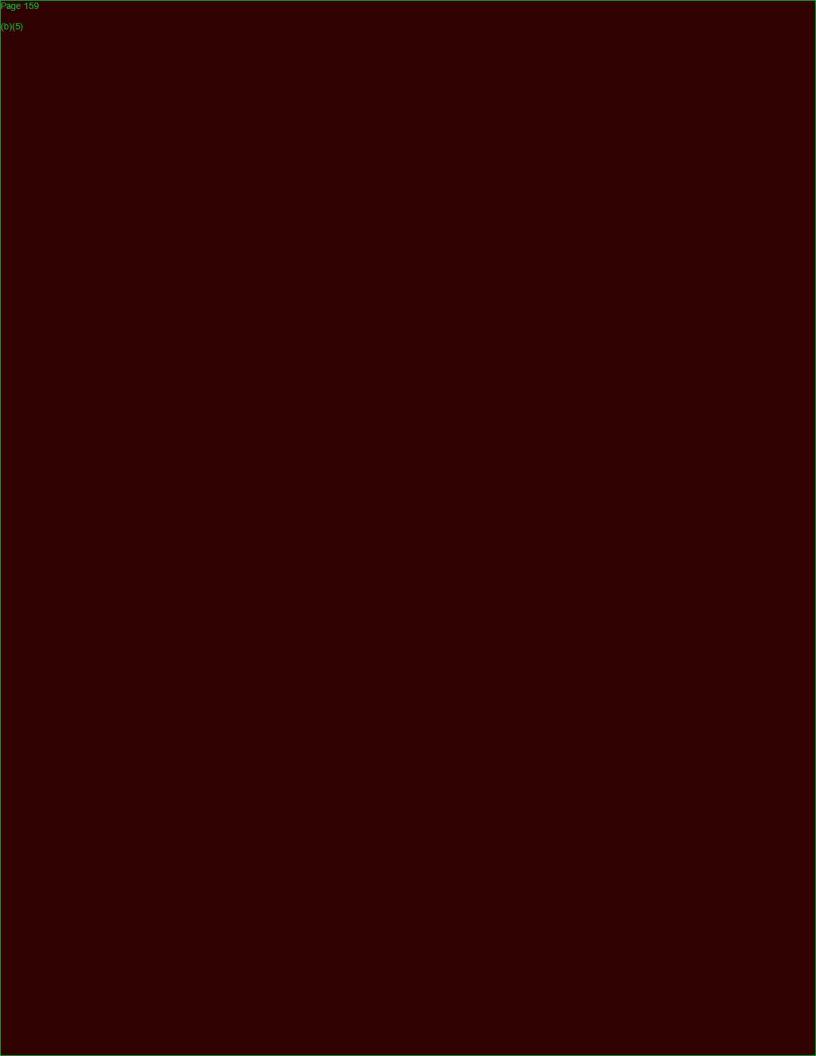
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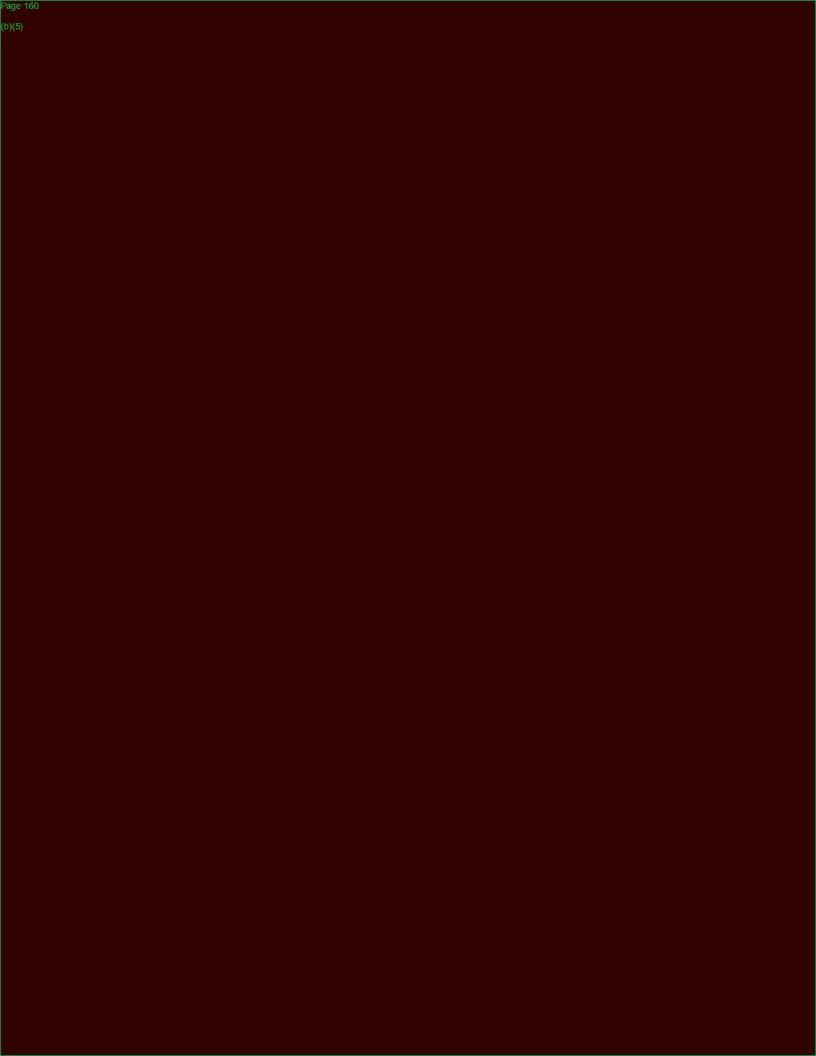
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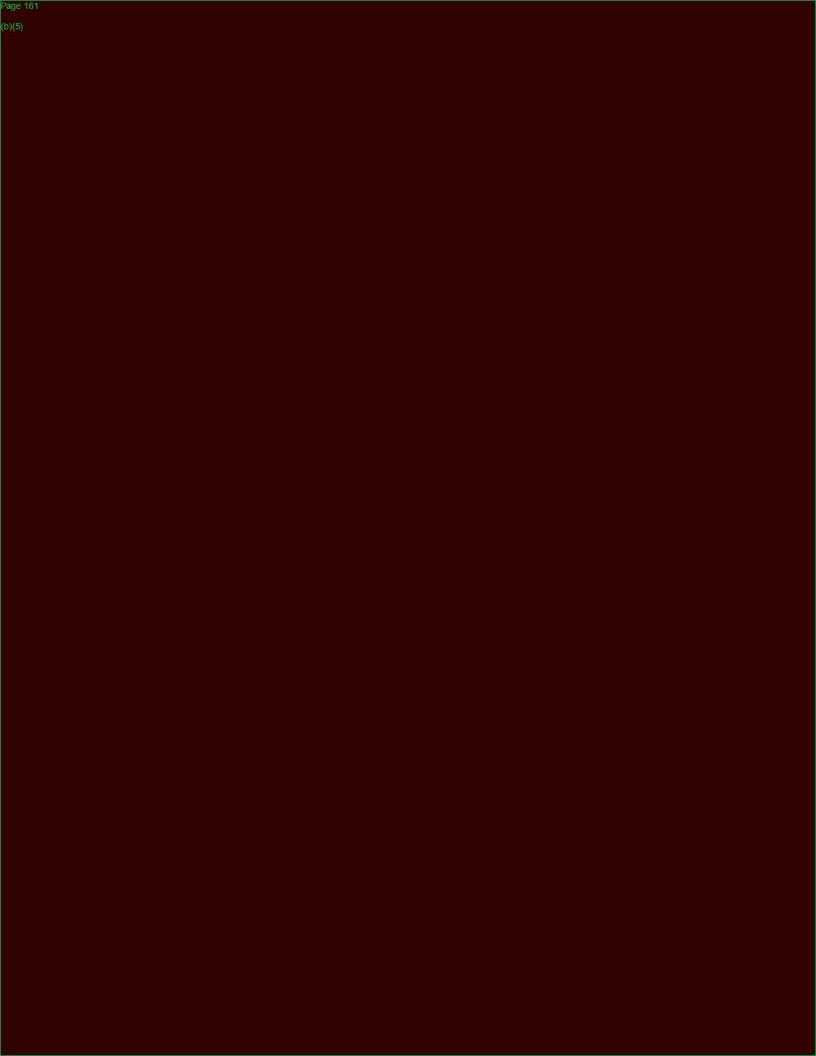
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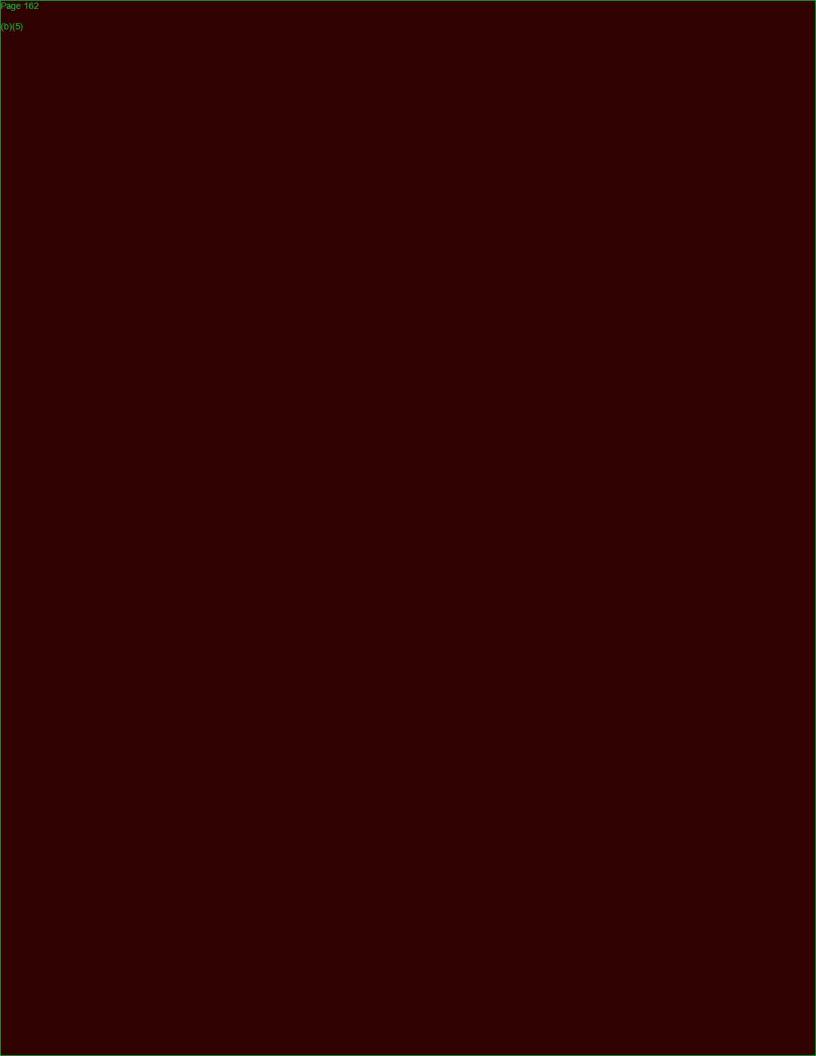












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(CDC/DDNID/NCIPC/OD); Pearlman, Aj; Romanik, Nikki Jo (CDC/OD/OCS); ian.sams@hhs.gov; Marandet,

Angele G. (CDC/DDID/NCHHSTP/DHPIRS)

Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD); Beach, Michael J.

(CDC/DDID/NCEZID/DFWED)

Subject: RE: COVID-19: CDC/HHS Product Awareness (Not for S/R)

Attachments: HHS Awareness week listing 03-08-2021.docx

Document for today Michael

Michael J. Beach, PhD
Principal Deputy Incident Manager
CDC COVID-19 Emergency Response
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4018
404-667-0718

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Sent: Wednesday, January 27, 2021 5:41 PM

**To:** EOC Report (CDC); Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Berger, Sherri (CDC/OCOO/OD); Despres, Sarah; Jones, Christopher M. (CDC/DDNID/NCIPC/OD); Pearlman, Aj; CDC IMS 2019 NCOV Response IM-PDIM Special Assts; Romanik, Nikki Jo (CDC/OD/OCS); ian.sams@hhs.gov; Marandet, Angele G. (CDC/DDID/NCHHSTP/DHPIRS)

Cc: CDC IMS Response Coordinator -2; CDC IMS AV/Communications; Christie, Athalia (CDC/DDPHSIS/CGH/OD)

Subject: COVID-19: CDC/HHS Product Awareness (Not for S/R)

When: Friday, March 5, 2021 9:30 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

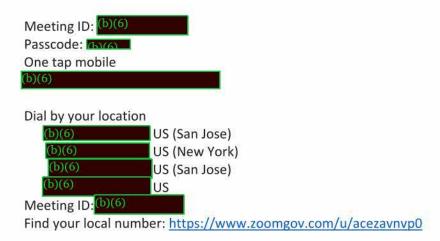
Where: Bldg. 21, 3025B and Zoom +(b)(6)

\*\*\* Meeting Start Time Indicates Eastern Time \*\*\*

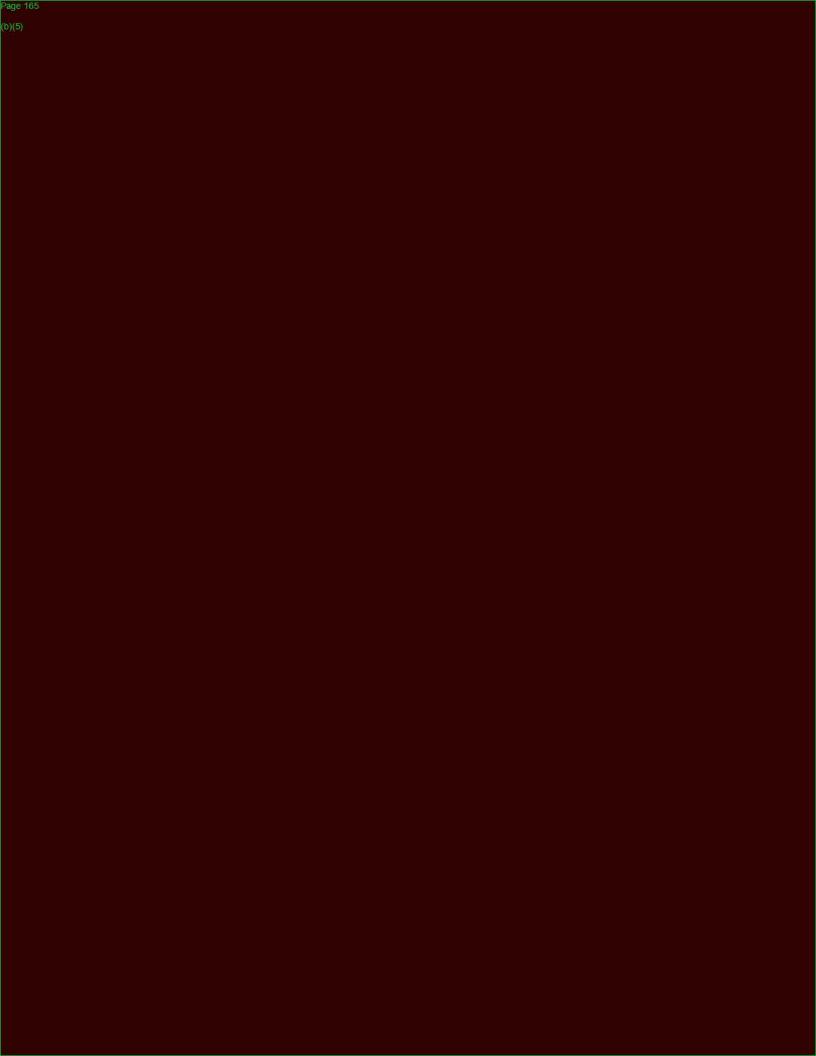
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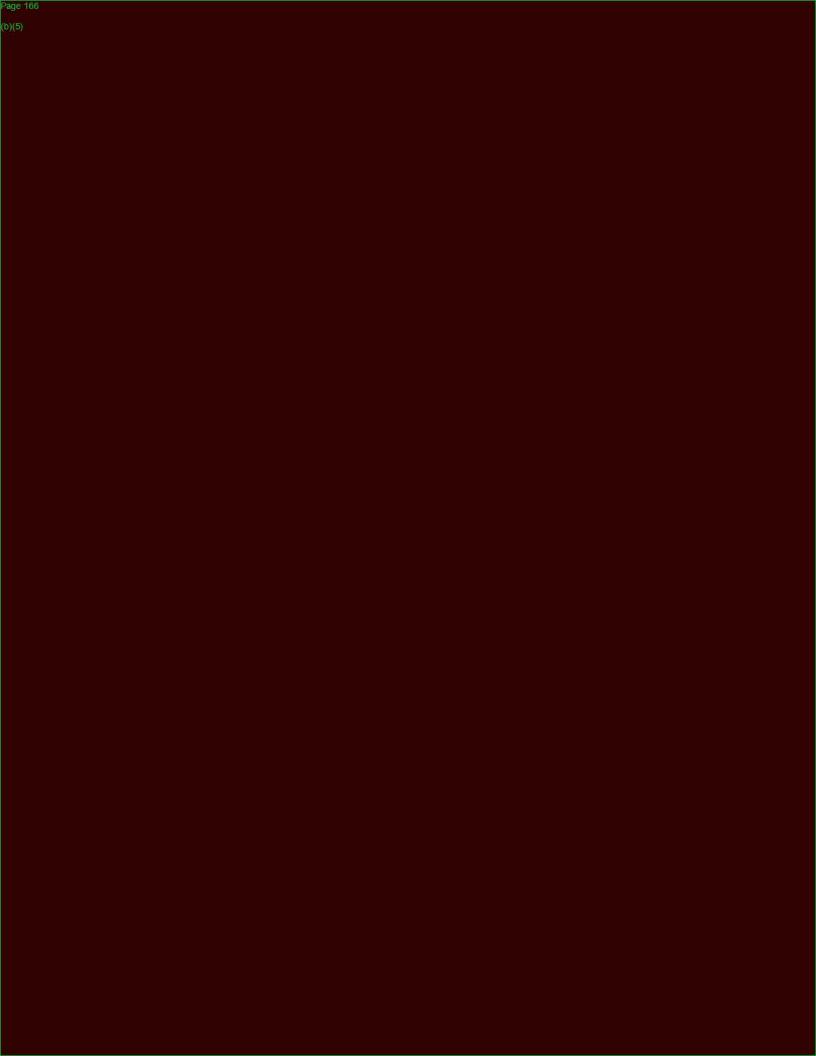
POC: CDC IMS 2019 NCOV Response IM-PDIM Special Assts

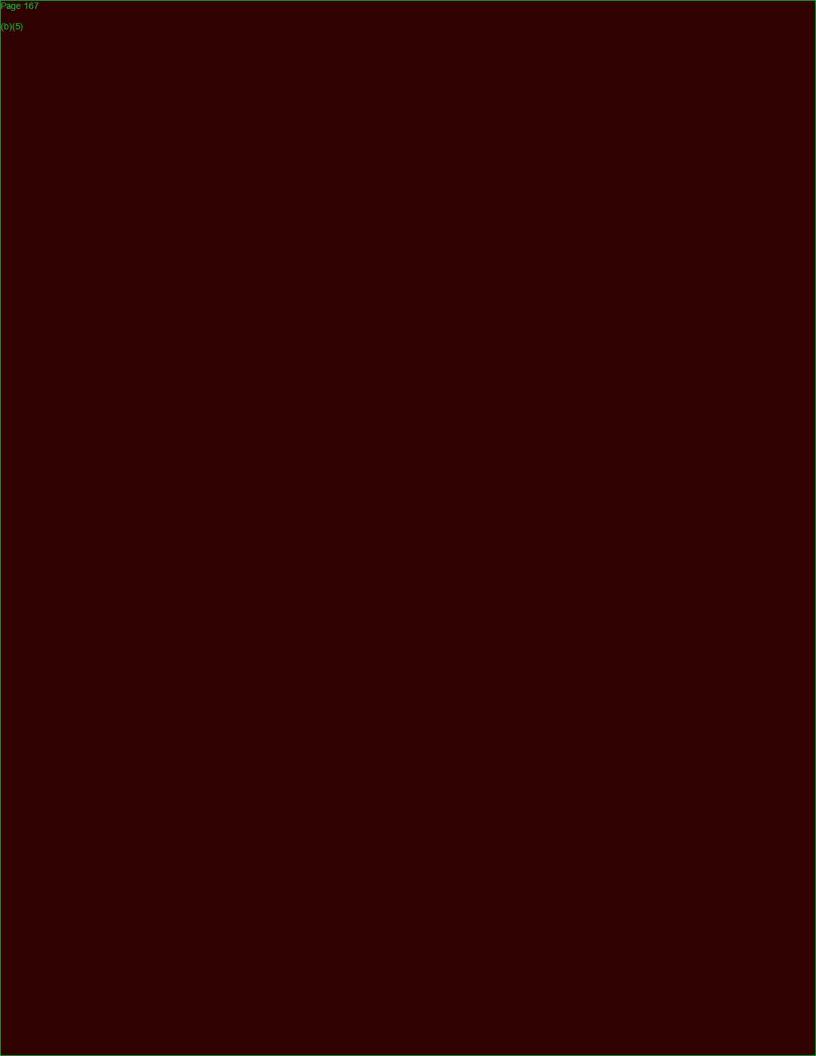
<eocevent446@cdc.gov>

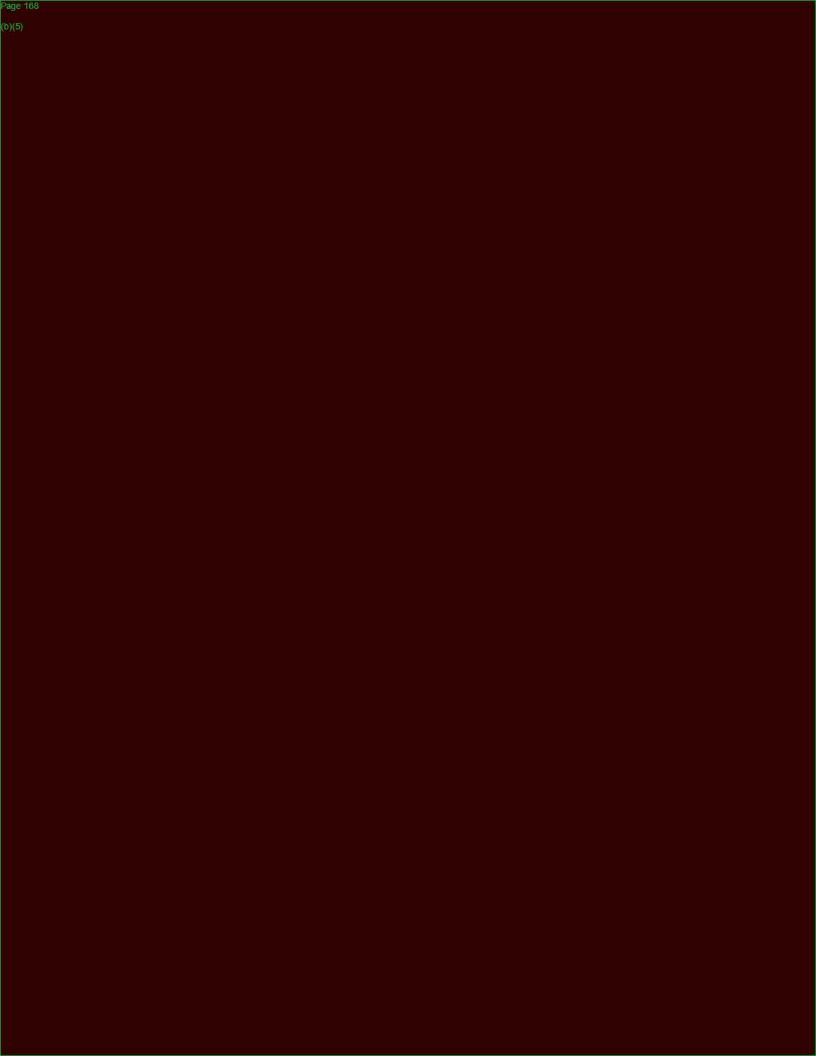


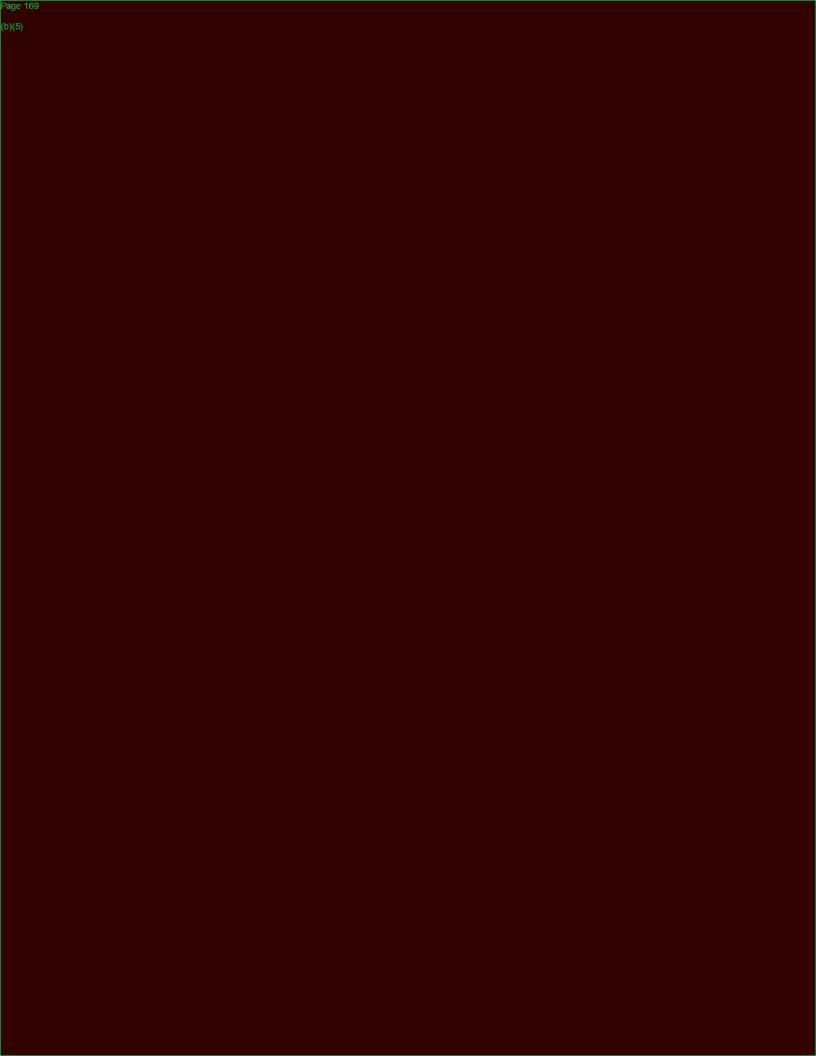
For any changes or updates to the agenda, please contact the EOC Watch Desk at <a href="mailto:EOCReport@cdc.gov">EOCReport@cdc.gov</a> or (770) 488-7100.

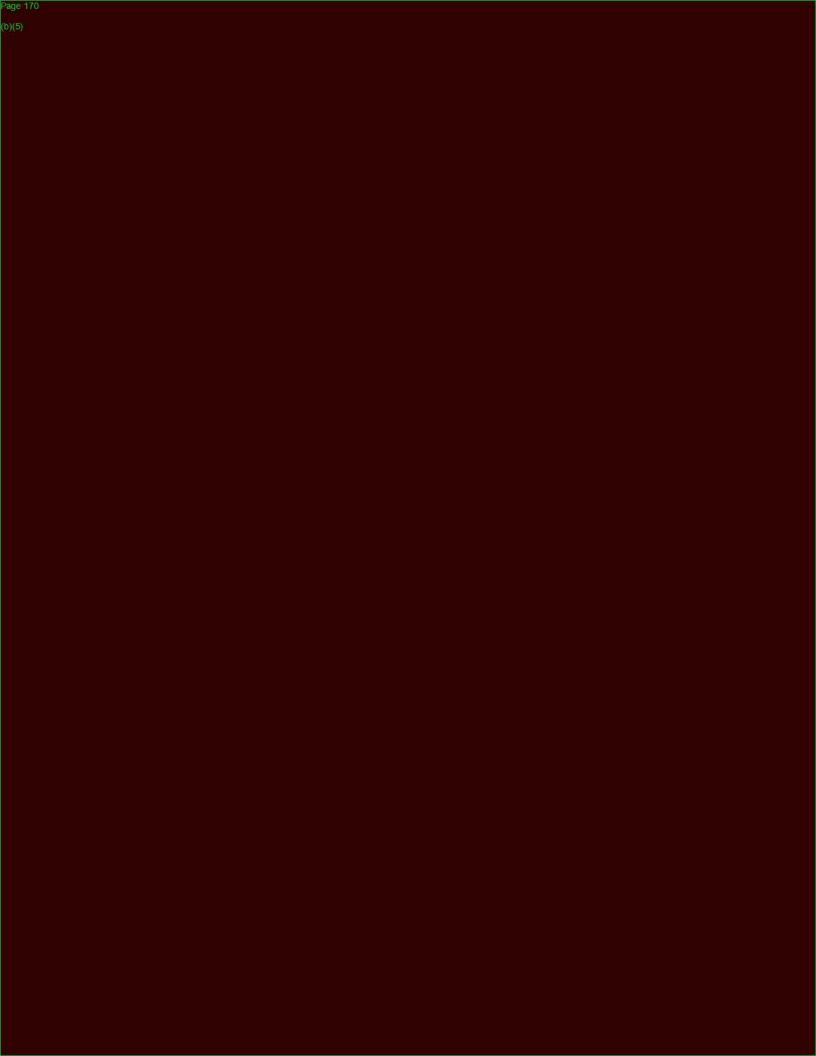












From: Beach, Michael J. (CDC/DDID/NCEZID/DFWED)

**Sent:** Fri, 26 Feb 2021 13:55:54 +0000

To: Berger, Sherri (CDC/OCOO/OD); Despres, Sarah; Jones, Christopher M.

(CDC/DDNID/NCIPC/OD); Pearlman, Aj; CDC IMS 2019 NCOV Response IM-PDIM Special Assts; Romanik,

Nikki Jo (CDC/OD/OCS); ian.sams@hhs.gov; Marandet, Angele G. (CDC/DDID/NCHHSTP/DHPIRS)

Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD); PaulR.Rodriguez@hhs.gov; Beach,

Michael J. (CDC/DDID/NCEZID/DFWED)

Subject: RE: COVID-19: CDC/HHS Product Awareness (Not for S/R)

Attachments: HHS Awareness week listing 03-01-2021.docx

Discussion guide for today. Talk with you soon Michael

Michael J. Beach, PhD
Principal Deputy Incident Manager
CDC COVID-19 Emergency Response
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4018
404-667-0718

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**To:** EOC Report (CDC); Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Berger, Sherri (CDC/OCOO/OD); Despres, Sarah; Jones, Christopher M. (CDC/DDNID/NCIPC/OD); Pearlman, Aj; CDC IMS 2019 NCOV Response IM-PDIM Special Assts; Romanik, Nikki Jo (CDC/OD/OCS); ian.sams@hhs.gov; Crowe, Samuel James (CDC/DDID/NCEZID/DFWED); Marandet, Angele G. (CDC/DDID/NCHHSTP/DHPIRS)

Cc: CDC IMS Response Coordinator -2; CDC IMS AV/Communications; Christie, Athalia

(CDC/DDPHSIS/CGH/OD); PaulR.Rodriguez@hhs.gov **Subject:** COVID-19: CDC/HHS Product Awareness (Not for S/R)

When: Friday, February 26, 2021 9:30 AM-10:00 AM (UTC-05:00) Eastern Time (US & Canada).

Where: Bldg. 21, 3025B and Zoom (b)(6)

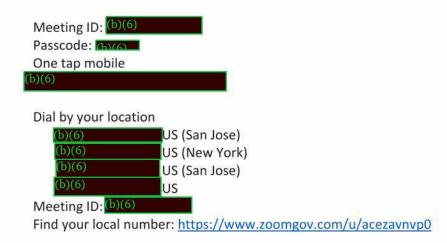
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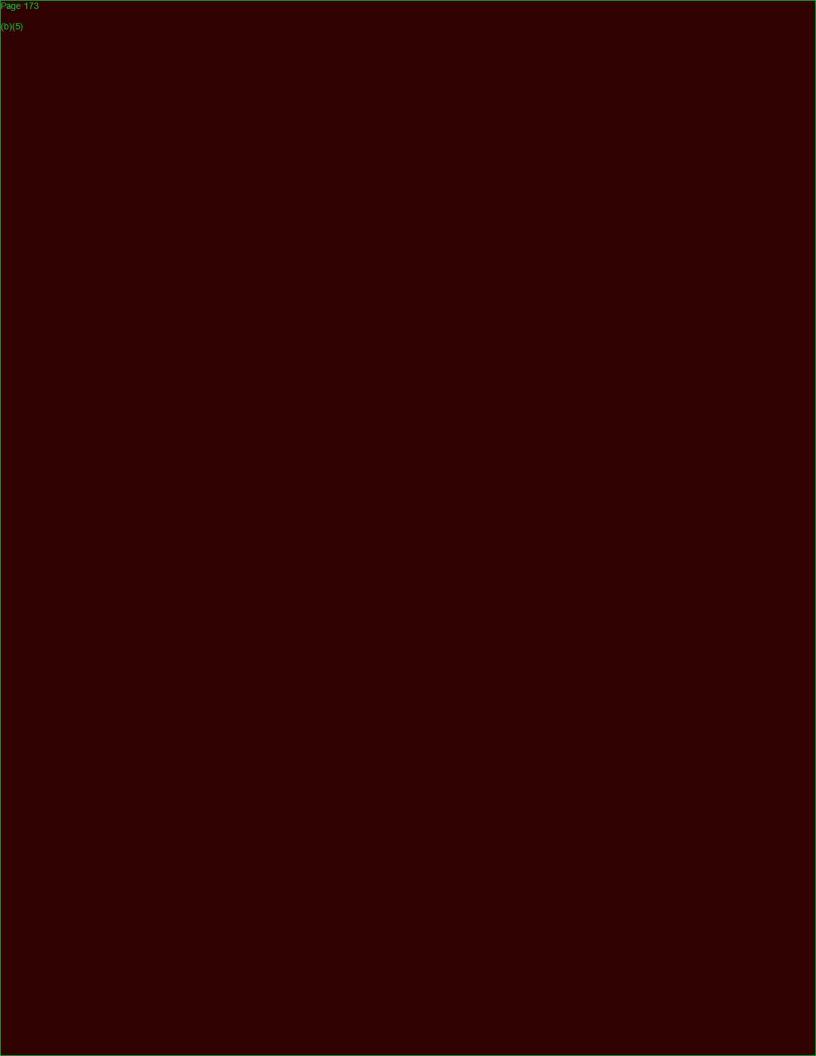
POC: CDC IMS 2019 NCOV Response IM-PDIM Special Assts

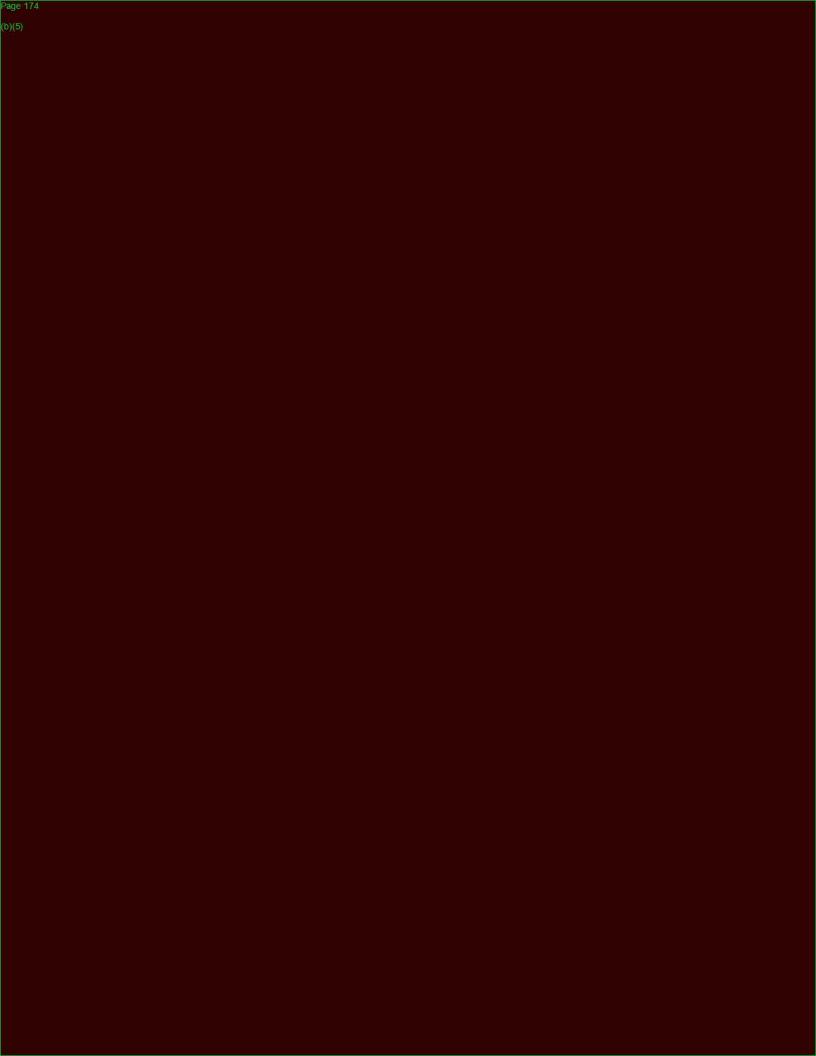
<eocevent446@cdc.gov>

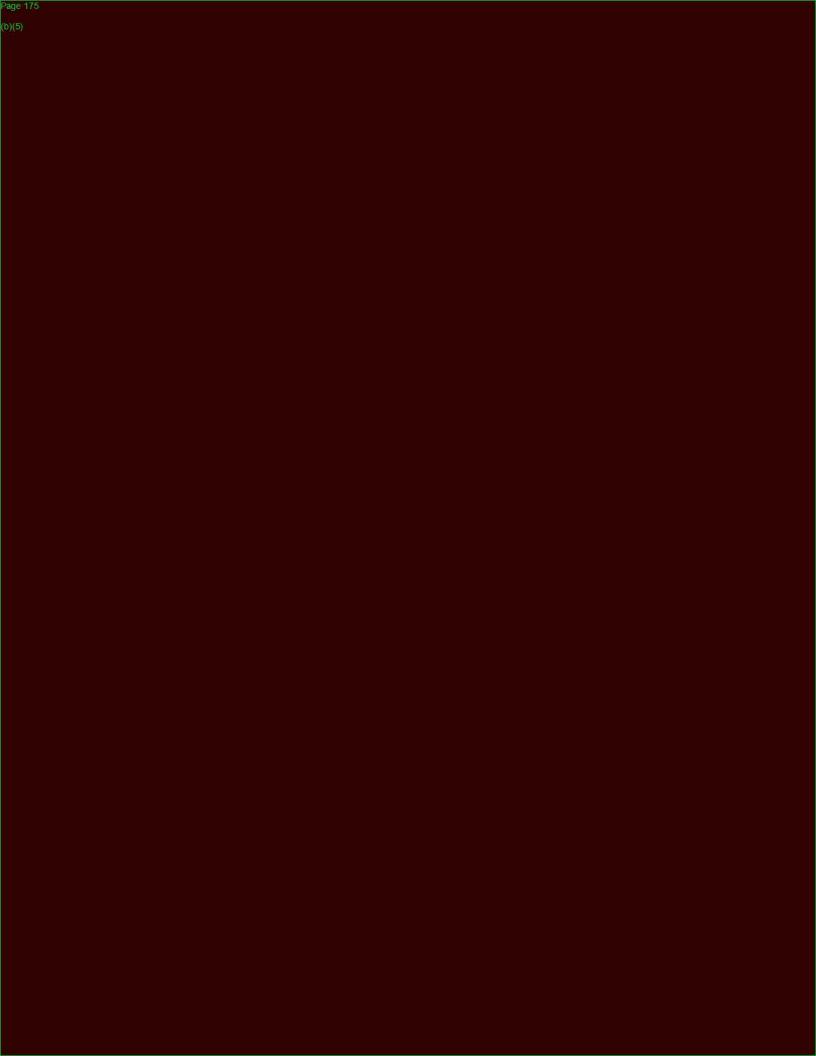
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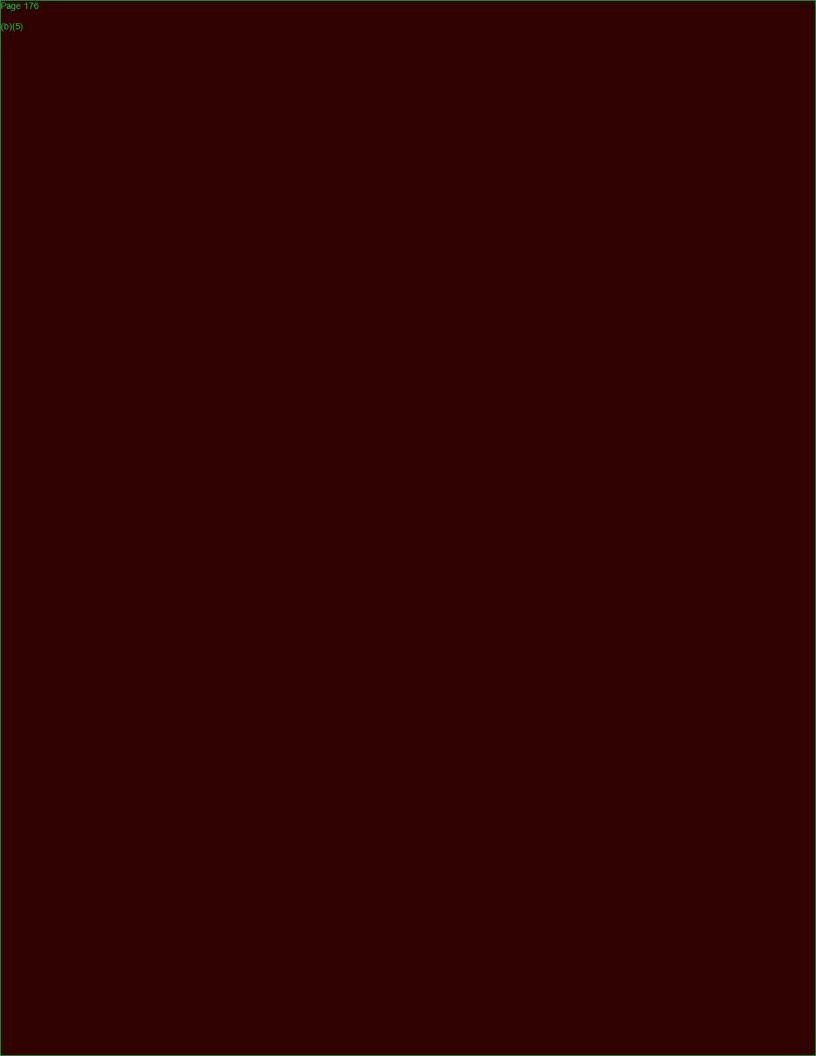


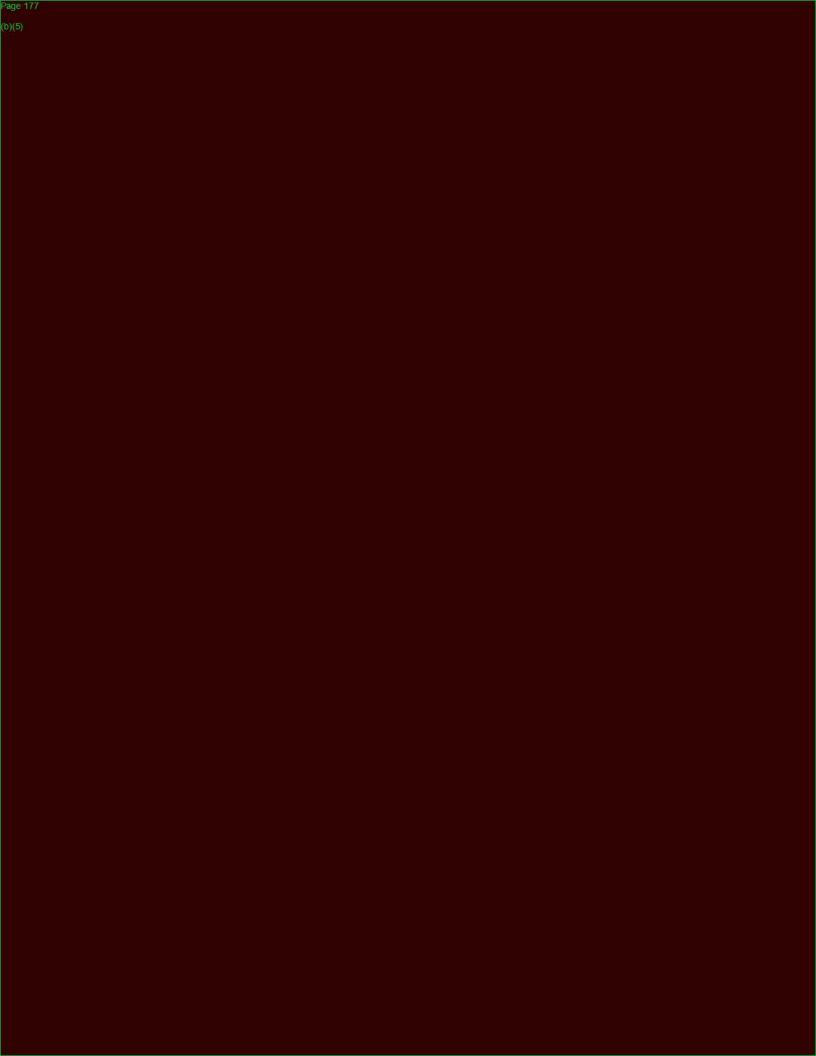
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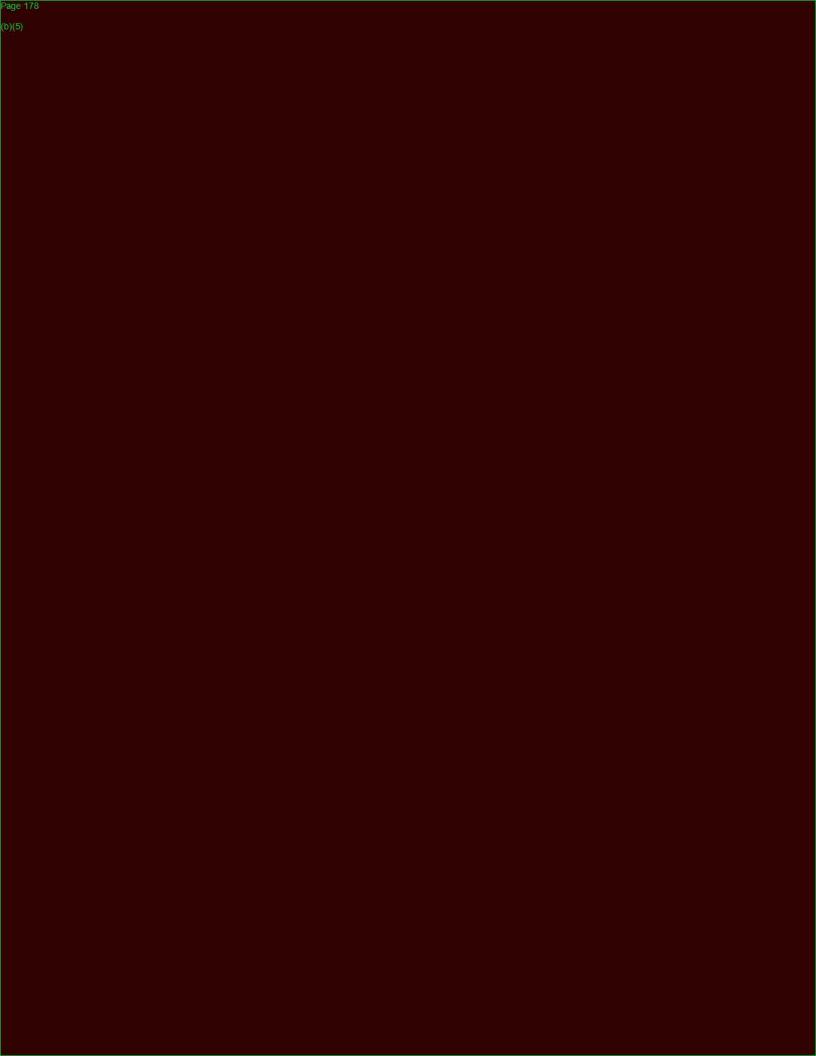












 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Sat, 22 May 2021 18:59:09 +0000

**To:** Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI); Berger, Sherri (CDC/OCOO/OD);

Schuchat, Anne MD (CDC/OD)

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Attachments: memo to Brooks.docx

Thank you, John,

I've reviewed the memo. Yes, please forward to them and ask for their reply. I'd be interested in this now myself so please keep me in the loop

+Anne as well (reattached for you, Anne).

Thank you, Rochelle

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Friday, May 21, 2021 6:29 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:kfw3@cdc.gov">hfw3@cdc.gov</a>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

# One follow-up on this:

I should have asked whether in addition to reaching out about myocarditis (had a good call with Celine and updated on her on what can be shared publicly), did you also (b)(5)



# -john

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Friday, May 21, 2021 7:17 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

John,
Can I ask you to please handle with VTF?
Thanks,
R

From: Celine Gounder, MD, ScM 6560 Sent: Thursday, May 20, 2021 9:56 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

**Subject:** Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Dear Rochelle and John,

Jeremy Faust and I are working on an op-ed for the NYT (already green lit) about the risks-benefits of COVID and COVID vaccination, including the risk of long-term side effects of COVID vaccination (low) versus the long-term risks of COVID (high).

As you know, one of the reasons many people give for not getting vaccinated is that there isn't enough long-term safety data on COVID vaccines. Another reason given for not vaccinating kids is that COVID is no worse than influenza in children.

- We're hearing more and more reports of post-vaccination myocarditis from MA and NY where
  Jeremy and I are based, as well as elsewhere across the country. Is there anything you can share
  about post-vaccination myocarditis cases (demographics? fatal / non-fatal?) Or other serious
  post-vaccination events?
- I previously shared a memo from Jeremy to John re: Qs on influenza and COVID morbidity/mortality among children. I'm attaching that memo again here. John, have you gotten any feedback on the Qs Jeremy outlined in his memo?

These data could just be shared with us on background. We just want to make sure that in framing our argument, we're not misrepresenting the facts.

Warmly, Céline

--

Céline Gounder, MD, ScM, FIDSA she / her / hers

CEO/Founder, JUST HUMAN PRODUCTIONS

Host/Producer, AMERICAN DIAGNOSIS & EPIDEMIC podcasts

Medical Analyst, CNN

Clinical Assistant Professor of Medicine & Infectious Diseases, <u>NYU School of Medicine</u> & Bellevue Hospital

Cell +1-917-275-2618

@celinegounder

#### Dear Dr. Brooks,

Twice now, *The New York Times*' David Leonhardt has <u>propagated</u> a CDC <u>statistic</u> that is dubious and potentially harmful. I'd like to point out that two CDC Centers currently provide the public with contradicting information. I also would like to underscore why during the COVID-19 pandemic, this discrepancy is contributing to a problem relating to vaccine interest among children and parents. My aim here is to will draw your attention to the statistic in question, persuade you that it matters, and to demonstrate to you which of the two numbers is correct. Further, I hope to convince you that eliminating the inaccurate figure from public reporting immediately is important, as that number and others like it are now being used to downplay the severity of COVID-19 among children, and thereby undermining vaccine interest precisely when we need it to be bolstered.

Leonhardt and others have used this particular statistic to conclude that COVID-19 is no more harmful to children than seasonal influenza; specifically, the NCIRD states that in a recent flu season (2017-2018), 528 US children ages 5-17 (CDC link, NCIRD). Meanwhile, by April of this year, around 260 children in this age range had died of COVID-19 since the outbreak began (CDC link) in February 2020.

Relying on this, Leonhardt stated in his 4/22 Times column, that COVID-19 had killed fewer Americans under the age of 18 than seasonal flu routinely does. To correct this, I wrote to him to point out that according to CDC Wonder (direct link to query ICD J9-J11), in most years (or seasons) seasonal influenza does not kill *anywhere close* to 528 US children ages 5-17. The real number, per CDC/NCHS) is between 100-165 in most recent years, and often less. (At that point, Leonhardt no longer engaged though I did notice that the *Times* quietly *deleted* the offending sentence that previous stated that fewer American children had died of COVID-19 than typically die from seasonal influenza. Now the column says they are comparable. As I'll show later, they are not). He repeated the assertion again today.

#### CDC discrepancy (NCIRD and NCHS/CDC Wonder).

Sensing that this problem could occur again, I reached out to two analysts at CDC/NCIRD several weeks ago. They politely replied that the difference between the NCIRD figure and the NCHS/Wonder figure is that the former is an *estimate*, while the latter is a *counted figure*. That's true enough. However, in this case, if we wish to resolve the conflict (and I believe we must), the counted figure from the NCHS/Wonder, and not the estimated figure from NCIRD must be the correct one. This is for three distinct reasons.

- 1. Seasonal influenza is a reportable death for children 0-17. Therefore, unlike adult influenza, there is no need to estimate the number of underlying cause mortality from seasonal influenza.
- 2. Related to #1, if the NCIRD figure is correct, the CDC is currently implicitly accusing US states/Departments of Health of failing to report an incredible 70% of all pediatric flu deaths among children ages 5-17 (528-160=328; 328/528=69.7%). This simply lacks face validity, given the substantial state and local department of health resources that are devoted to investigating every single medical death of children.
- 3. The NCIRD estimate (528 influenza deaths among children 5-17 during the 2017-2018 season) cannot be correct because it happens to exceed the TOTAL number of

deaths from ALL Diseases of the Respiratory System (J00-J98, <u>CDC Wonder Query link</u>) during the 2017-2018 season (week 40 of 2017-week 39 2018). This renders the NCIRD estimate to have been an unintentional exercise in *reductio ad absurdum*. It would seem that, in the face of basic scrutiny, the estimate made by the NCIRD faces an insurmountable problem; it overshoots the total number of deaths in the entire category of all respiratory diseases for the year for the age group. The lack of attention to external validity here is alarming.

I politely pointed out this discrepancy to two staffers at NCIRD. Their response was to reiterate why they feel estimating influenza deaths is necessary. However, even if some estimation is needed (and I remain unconvinced to that), surely any estimate must not be allowed to overshoot *all* diseases of the respiratory system combined, of which influenza is but one subgroup. In fact, the only way that the NCIRD can even be *close to correct* is if several hundred deaths attributed to other underlying causes are in fact routinely and completely misfiled, year after year. This could be possible but unlikely. For example, perhaps some of the couple dozen cystic fibrosis patients ages 5-17 who are thought to have died due to CF maybe in reality died of seasonal influenza. In such a case, those deaths, per the NCIRD reasoning, should not reside in the Metabolic Disorders category (E70-E88), but rather in the Diseases of the Respiratory System (J00-J98). (I am sure this recategorizing would come to the surprise to workers in that CF silo, which I believe is Genomics and Precision Public Health).

The larger point is that there are only a certain number of deaths in any age group per year, and for the NCHS influenza data to be wrong (and for NCIRD to be correct), a great many number of pediatric deaths in CDC Wonder would therefore have to be incorrect at this time. And yet public health researchers rely on these data for a legion of projects and active research. When confronted with this, NCIRD had no response.

Today, David Leonhardt again wrote about pediatric flu and COVID-19 in the *Times*, saying, "Most reassuring is the fact that Covid is no more serious for children on average than the flu." I find that hard to believe, as per above.

But even more pointedly, the implications for which number is the correct one are non-trivial. Please inspect the following table, assembled from CDC data.

US population ages 5-17			
	CDC Wonder flu (counted). 2018.	NCIRD flu (estimate). 2017-2018.	CDC Covid-19 (counted). 2/1/2020-present.
Deaths	160	528	267
Symptomatic/documented cases	7,512,601	7,512,601	2,681,542
CFR (per 100k population)	2.1	7.0	10.0
Season-((influenza) or outbreak- (COVID-19) fatality rate (per 100k population)	0.30	0.99	0.50

As the table shows, if the NCHS/Wonder reported figure is correct, then the CFR of COVID-19 for US children 5-17 is around 4.8x that of seasonal flu (10.0/2.1=4.8). If NCIRD is correct than the CFR of COVID-19 is just 1.4x.

But denominators can be problematic. Therefore, the seasonal flu population fatality rate (influenza 2017-2018) can be compared to the total-US-COVID-19 outbreak population fatality rate (I used 2019 population figures, 53.4 million, for all groups, to keep it simple). As you can see, if CDC Wonder is correct, the population fatality rate for COVID-19 since the outbreak began for US children 5-17 is 1.6x that of seasonal flu. But if NCIRD influenza estimates were to be correct, influenza would appear to be nearly twice as likely to cause death as COVID-19, *a qualitative reversal*.

Keep in mind that the COVID-19 data reflect the context of shelter-in-place and school closures of 2020-2021, while the influenza numbers from 2017-2018 reflect a normal year without masks or physical distancing. If schools had remained open all year the last 15 months, the pediatric COVID-19 fatality numbers would certainly be higher (by how much, we can't really know).

My concern is that advocates arguing against pediatric vaccinations are already weaponizing the NCIRD figure. I hope to have convinced you that the NCIRD estimate is both incorrect, and suddenly in the context of COVID-19, harmful in that it has already been co-opted to undermine vaccination efforts. Because seasonal influenza is a reportable death for children, there is simply no need to estimate pediatric flu deaths, as above, and certainly not one that appears to be as wildly inaccurate as the current one.

The CDC should resolve this issue by instructing the NCIRD to remove estimated influenza deaths for children from its reporting. Doing so will resolve a contradiction and increase accuracy in our ongoing assessments.

Best,

Jeremy Faust MD MS

Jeremy Samuel Faust, M.D., M.S., M.A., FACEP Brigham & Women's Hospital Department of Emergency Medicine Division of Health Policy and Public Health Instructor, Harvard Medical School From: Greco Kone, Rebecca (CDC/DDPHSIS/OD)

**Sent:** Fri, 14 May 2021 14:51:24 +0000 **To:** Berger, Sherri (CDC/OCOO/OD)

Cc: Schuchat, Anne MD (CDC/OD); Walke, Henry (CDC/DDID/NCEZID/DPEI)

Subject: RE: (b)(5)

vaccine update

Looks good! Thank you!!!

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Sent: Friday, May 14, 2021 10:35 AM

To: Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI)

<hfw3@cdc.gov>

Subject: RE: Help: (b)(5)

Please review/approve this



(b)(5)
(b)(5)
Thank you, Sherri
From: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a> Sent: Friday, May 14, 2021 10:09 AM  To: Berger, Sherri (CDC/OCOO/OD) < <a href="mailto:sob8@cdc.gov">sob8@cdc.gov</a> Cc: Schuchat, Anne MD (CDC/OD) < <a href="mailto:acs1@cdc.gov">acs1@cdc.gov</a> ; Walke, Henry (CDC/DDID/NCEZID/DPEI) < <a href="mailto:hfw3@cdc.gov">hfw3@cdc.gov</a> Subject: RE: Help: <a href="mailto:fb/6">fb/6</a> )
Hi Sherri –
Thanks so much for helping with this! The original intent (b)(5) (b)(5)
Thanks again! Rebecca
(b)(5)

b)(5)

Rebecca Greco Koné Co,-Lead, Vaccine Task Force COVID-19 Response Centers for Disease Control and Prevention

(o): 404-639-3224 (c): 404-543-8163 www.cdc.gov

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Friday, May 14, 2021 9:22 AM

To: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI)

<hfw3@cdc.gov>

Subject: Help:(b)(5)

Hi Rebecca – (b)(5)

(b)(5) Thanks

\*\*\*\*\*\*



(b)(5)

# (b)(5) Thank you, Sherri From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov> Sent: Friday, May 14, 2021 9:14 AM To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov> Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov> Subject: RE: (b)(5) Yes please. Thank you! From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov> Sent: Friday, May 14, 2021 9:11 AM To: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov> Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov> Subject: RE: (b)(5) Yes, missing Dan on To line. Want us to send for you? From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov> Sent: Friday, May 14, 2021 9:10 AM To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov> Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov> Subject: FW: (b)(5) Ok with you if I (b)(5) b)(5) DRAFT EMAIL

(b)(5)

)(5)
Thank you!
Description of Role:
Rebecca
From: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < ftm1@cdc.gov>
Sent: Thursday, May 13, 2021, 6:05 PM
To: Walke, Henry (CDC/DDID/NCEZID/DPEI); Cohn, Amanda (CDC/DDID/NCIRD/OD); Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)
Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD); Beach, Michael J. (CDC/DDID/NCEZID/DFWED)  Subject: (b)(5)
Henry, Dana, and Michael –
(5)
0(5)
0)(5)

# Thanks Rebecca

Rebecca Greco Koné Co,-Lead, Vaccine Task Force COVID-19 Response Centers for Disease Control and Prevention

(o): 404-639-3224 (c): 404-543-8163 www.cdc.gov From: Greco Kone, Rebecca (CDC/DDPHSIS/OD)

**Sent:** Fri, 14 May 2021 23:09:44 +0000 **To:** Berger, Sherri (CDC/OCOO/OD)

Subject: RE: Help: (b)(5)

vaccine update

Ok. Got it. Thanks

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Sent: Friday, May 14, 2021 7:09 PM

To: Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>

Subject: Re: Help: (b)(5)

Sherrie Bruce told me not to, she's handling. Thanks

From: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ttm1@cdc.gov">ftm1@cdc.gov</a>>

Sent: Friday, May 14, 2021 7:04:18 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Subject: RE: Help: (b)(5)

Hi!

Just checking in. Did you get a chance to send this yet? If not, we have already followed up with the

I edited the email below to take out the specific list.

Thanks RGK

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Friday, May 14, 2021 10:35 AM

To: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI)

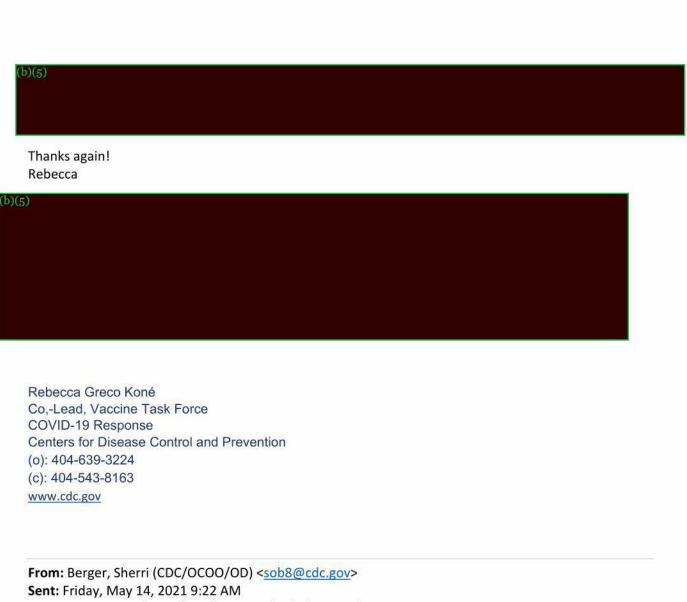
<hfw3@cdc.gov>

Subject: RE: Help: (b)(5)

Please review/approve this

(b)(5)





From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>
Sent: Friday, May 14, 2021 9:22 AM

To: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < ftm1@cdc.gov>
Cc: Schuchat, Anne MD (CDC/OD) < acs1@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>
Subject: Help: (b)(5)

Hi Rebecca — (b)(5)

Thanks



(b)(5)

(b)(5)

## (b)(5)

Thank you, Sherri

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Friday, May 14, 2021 9:14 AM

To: Berger, Sherri (CDC/OCOO/OD) <<u>sob8@cdc.gov</u>>
Cc: Schuchat, Anne MD (CDC/OD) <<u>acs1@cdc.gov</u>>

Subject: RE: (b)(5)

Yes please. Thank you!

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Friday, May 14, 2021 9:11 AM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Subject: RE: (b)(5)

Yes, missing Dan on To line. Want us to send for you?

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Friday, May 14, 2021 9:10 AM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov > Cc: Schuchat, Anne MD (CDC/OD) < acs1@cdc.gov >

Subject: FW:(b)(5)

Ok with you if I (b)(5)

b)(5)

# DRAFT EMAIL (b)(5) (b)(5) **Description of Role:** (b)(5) Rebecca From: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>> Sent: Thursday, May 13, 2021, 6:05 PM To: Walke, Henry (CDC/DDID/NCEZID/DPEI); Cohn, Amanda (CDC/DDID/NCIRD/OD); Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD); Beach, Michael J. (CDC/DDID/NCEZID/DFWED) Subject: (b)(5) Henry, Dana, and Michael -(b)(5) (b)(5)

(b)(5)	
(b)(5)	
I think (b)(5) (b)(5)	
(b)(5)	
(b)(5)	

Thanks Rebecca

Rebecca Greco Koné Co,-Lead, Vaccine Task Force COVID-19 Response Centers for Disease Control and Prevention

(o): 404-639-3224 (c): 404-543-8163

www.cdc.gov

From: Walensky, Rochelle (CDC/OD)

Sent: Fri, 14 May 2021 19:24:58 +0000

To: Cohn, Amanda (CDC/DDID/NCIRD/OD)

Subject: RE: touching base [EXTERNAL]

Got it...I just tried Dana, she is going to call me back in 5 min.

For sure...

R

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>

Sent: Friday, May 14, 2021 3:23 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Subject: Fwd: touching base [EXTERNAL]

Rochelle-

I have a conflict with the 5 pm call about this issue, but I wanted to share the below note from Jane Newburger, given you connection to BCH © This is part of the reason I think we need to say something about this issue.

#### Get Outlook for iOS

From: Newburger, Jane < Jane. Newburger@CARDIO.CHBOSTON.ORG>

Sent: Friday, May 14, 2021 1:54 PM

To: Cohn, Amanda (CDC/DDID/NCIRD/OD); Son, MaryBeth

**Cc:** Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) **Subject:** RE: touching base [EXTERNAL]

HI Amanda, Sarah, and Manish,

I am writing to keep you in the loop.

As we anticipated, the post-vaccine myocarditis events have risen to attention of leaders at our institution (this is also a topic of conversation among Chief Safety Officers at Children's hospitals). Mary Beth and I were emailed today by our hospital Emergency Management, stating "Our hospital is putting together messaging for clinicians to provide information on myocarditis in COVID-vaccinated individuals and give direction on what to do if they think their patient is a case" and asking for direction about to whom children should be referred.

We sent out the information re: direction of cases to the CDC sites.

Do you think CDC will be having any sort of official statement about this soon? Or will it have to wait till analysis of cases?

This is just for information for our hospital officials – I realize it is very unlikely for you to have a statement so soon.

Cheers,

Jane

Commonwealth Professor of Pediatrics

Harvard Medical School

Associate Cardiologist-in-Chief for Academic Affairs

Department of Cardiology

Children's Hospital Boston

300 Longwood Ave. Boston, MA 02115

email: jane.newburger@cardio.chboston.org

FAX: 617-739-3784 Phone: 617-355-5427

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) [mailto:anc0@cdc.gov]

**Sent:** Thursday, May 13, 2021 10:15 AM **To:** Son, MaryBeth; Newburger, Jane

Cc: Mbaeyi, Sarah (CDC/DDID/NCIRD/OD); Patel, Manish (CDC/DDID/NCIRD/ID)

**Subject:** RE: touching base [EXTERNAL]

#### \* External Email - Caution \*

Let's do 1-1:30, I'll send a zoom invite. Thank you so much!

From: Son, MaryBeth < MaryBeth.Son@childrens.harvard.edu>

Sent: Thursday, May 13, 2021 10:13 AM

To: Newburger, Jane < <u>Jane.Newburger@CARDIO.CHBOSTON.ORG</u>>; Cohn, Amanda

(CDC/DDID/NCIRD/OD) <anc0@cdc.gov>

Cc: Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) < vif6@cdc.gov>; Patel, Manish (CDC/DDID/NCIRD/ID)

<aul3@cdc.gov>

Subject: Re: touching base [EXTERNAL]

Of those times, I can do now til 10:30, 1-1:30 and 2-2:30. Mary Beth

From: "Newburger, Jane" < Jane. Newburger@CARDIO.CHBOSTON.ORG >

Date: Thursday, May 13, 2021 at 10:11 AM

To: Amanda Cooper <anc0@cdc.gov>, Mary Beth Son <MaryBeth.Son@childrens.harvard.edu>

Cc: "Mbaeyi, Sarah (CDC/DDID/NCIRD/OD)" < vif6@cdc.gov>, "Patel, Manish

(CDC/DDID/NCIRD/ID)" <a href="mailto:aul3@cdc.gov">aul3@cdc.gov</a> **Subject:** Re: touching base [EXTERNAL]

Yes, I can connect with you now till 11 AM or between 1 -2:30.

Mary Beth - do you have time?

Jane W. Newburger, M.D., M.P.H.
Commonwealth Professor of Pediatrics
Harvard Medical School
Associate Chief for Academic Affairs
Department of Cardiology
Children's Hospital
300 Longwood Ave.
Boston, MA 02115

Phone: 617-355-5427 FAX: 617-739-3784

e-mail: jane.newburger@cardio.chboston.org

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>

**Sent:** Thursday, May 13, 2021 9:58 AM **To:** Newburger, Jane; Son, MaryBeth

Cc: Mbaeyi, Sarah (CDC/DDID/NCIRD/OD); Patel, Manish (CDC/DDID/NCIRD/ID)

Subject: touching base [EXTERNAL]

### \* External Email - Caution \*

Hi Jane and MaryBeth,

I am currently the Exec Sec of ACIP and Sarah is the CMO of the Vaccine Task Force at CDC (Hi Marybeth, it's Amanda Cooper (3)) We spoke to Manish about the reports of myocarditis and MIS like syndromes after vaccination in adolescents. I know the vaccine safety team at CDC is aware and working on setting up CISA calls, but Sarah and I want to make sure we are on top of this from the program and communications perspective. Is there any chance one or both of you have some time today to connect? We can make our schedules work around yours.

Thanks! Amanda

Amanda Cohn, MD
CAPT, USPHS
Chief Medical Officer
National Center for Immunization and Respiratory Diseases
Centers for Disease Control and Prevention

From: Beach, Michael J. (CDC/DDID/NCEZID/DFWED)

**Sent:** Fri, 12 Mar 2021 14:20:36 +0000

To: Berger, Sherri (CDC/OCOO/OD); Despres, Sarah; Jones, Christopher M.

(CDC/DDNID/NCIPC/OD); Pearlman, Aj; Romanik, Nikki Jo (CDC/OD/OCS); ian.sams@hhs.gov; Marandet,

Angele G. (CDC/DDID/NCHHSTP/DHPIRS)

Cc: Christie, Athalia (CDC/DDPHSIS/CGH/OD); Beach, Michael J.

(CDC/DDID/NCEZID/DFWED)

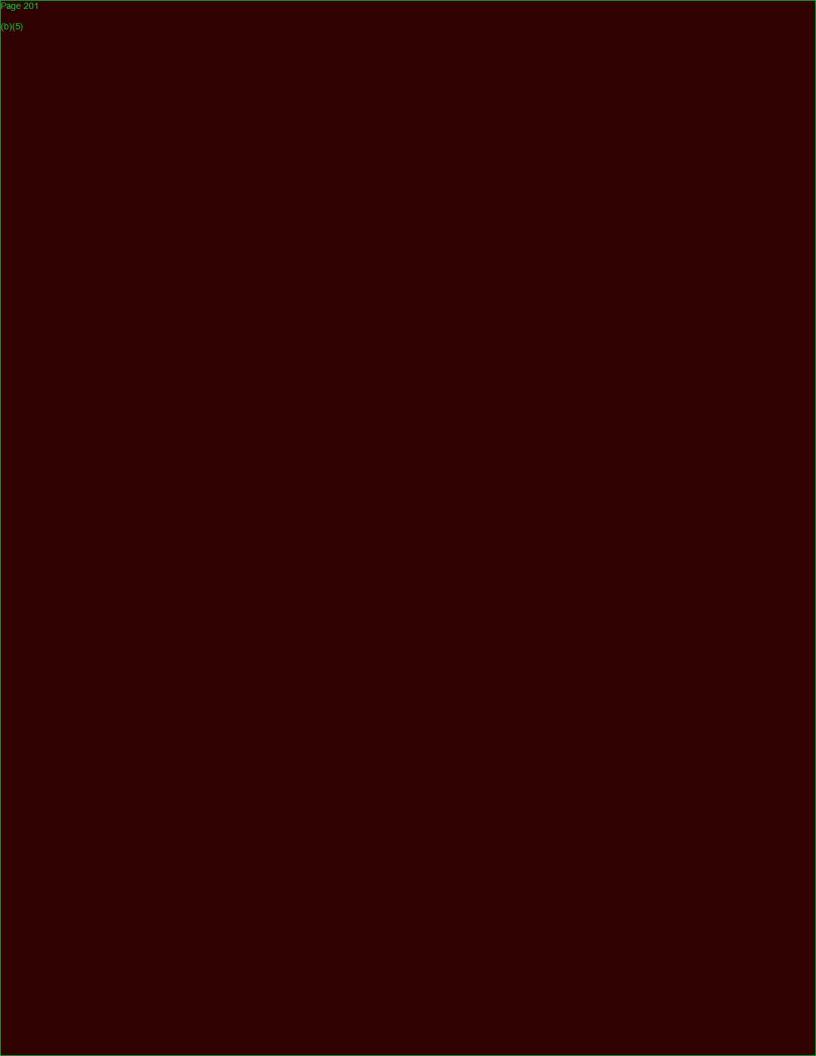
Subject: RE: COVID-19: CDC/HHS Product Awareness
Attachments: HHS Awareness week listing 03-15-2021.docx

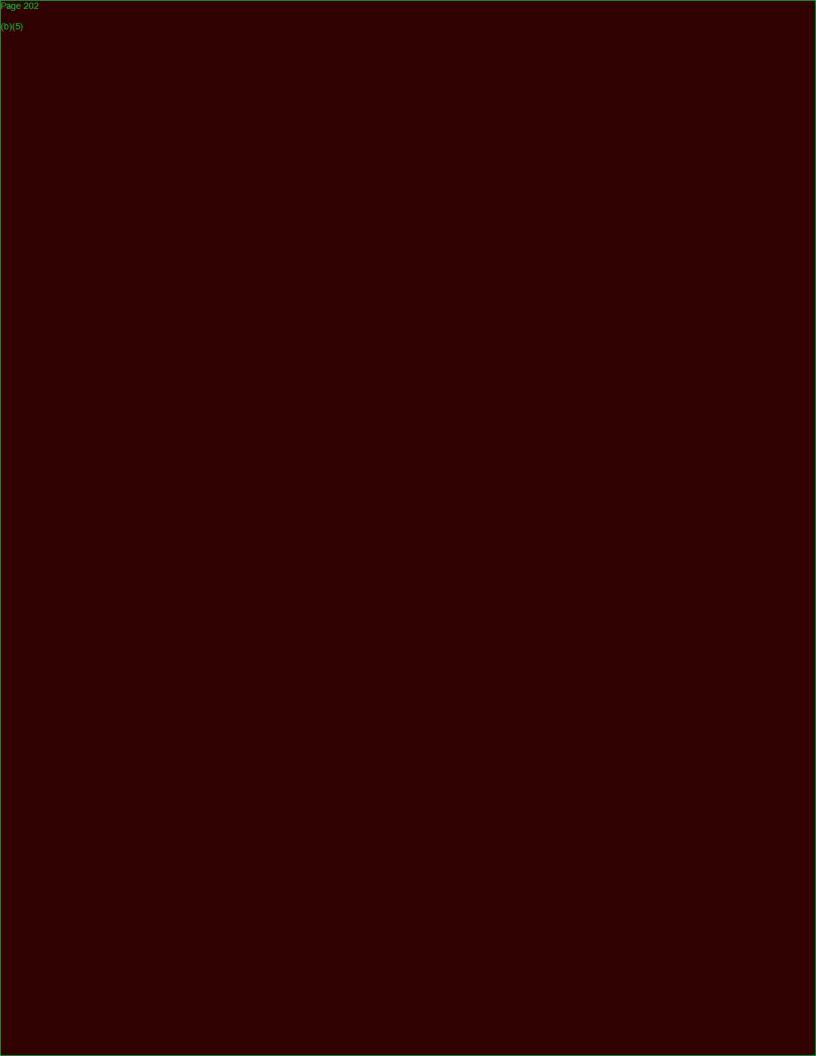
Discussion document for today Michael

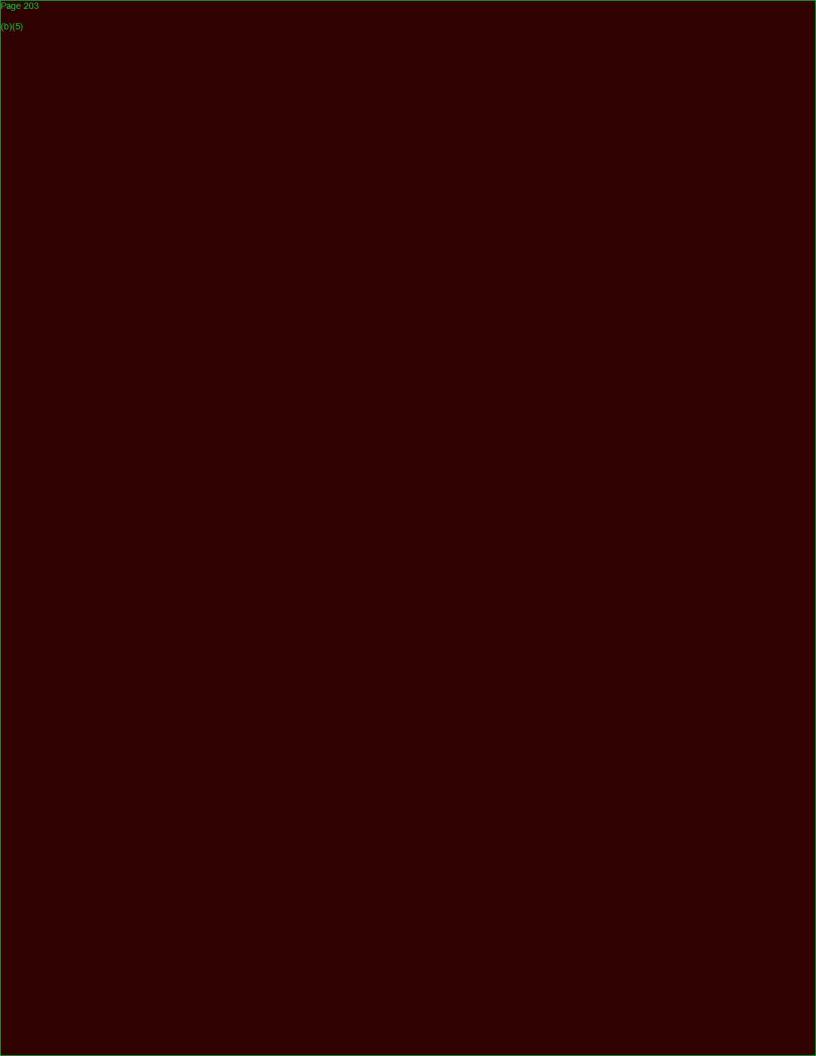
Michael J. Beach, PhD
Principal Deputy Incident Manager
CDC COVID-19 Emergency Response
Centers for Disease Control and Prevention
1600 Clifton Road
Atlanta, GA 30329-4018
404-667-0718

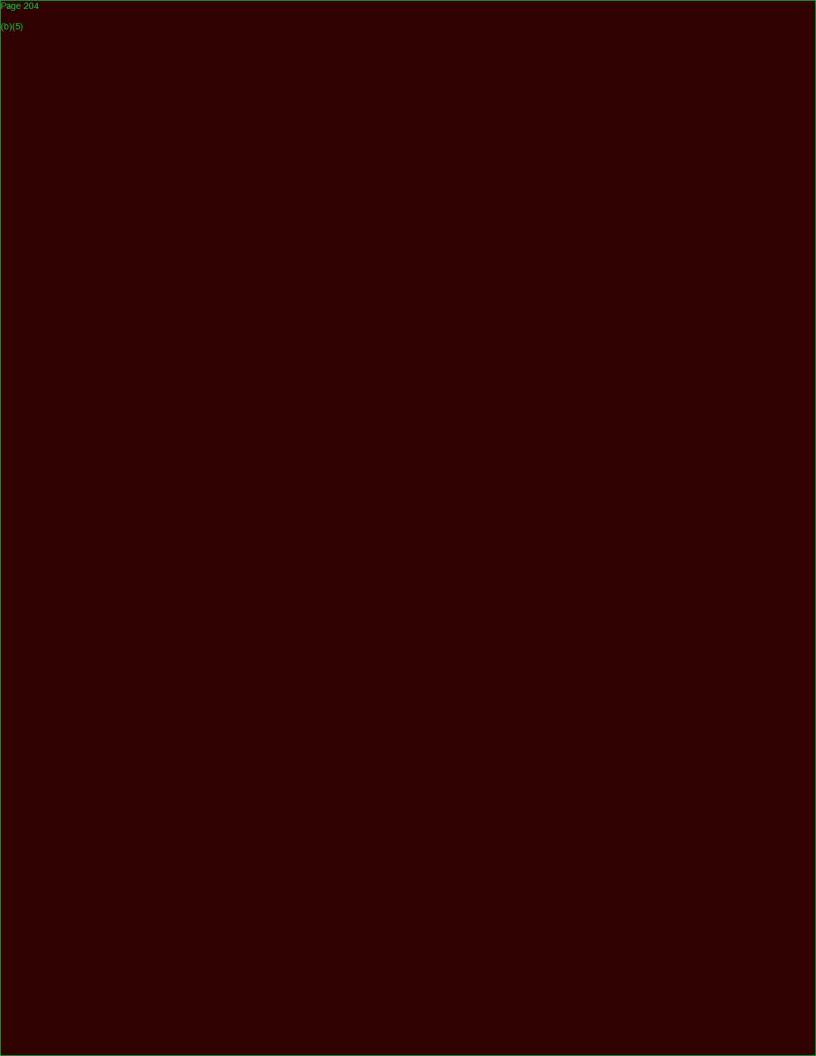
# Weekly CDC Forecasting of Materials for HHS Awareness Week of 03-15-2021

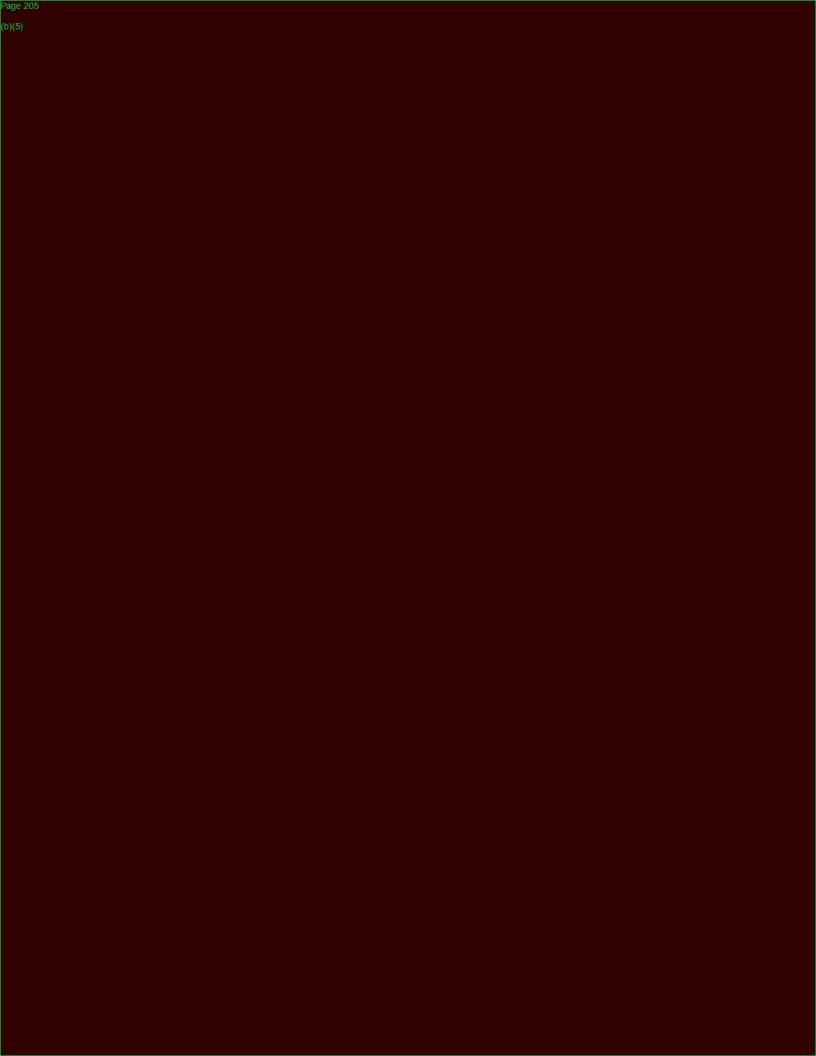
Intent:		
(b)(5)		

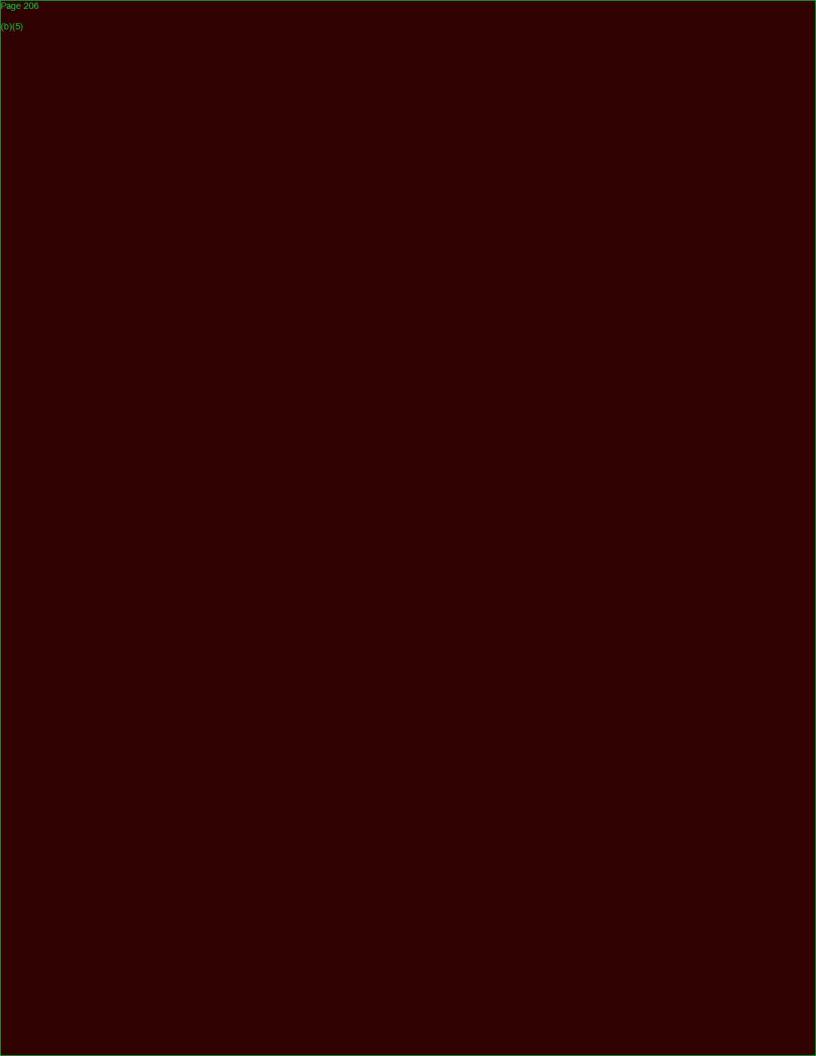












 From:
 Berger, Sherri (CDC/OCOO/OD)

 Sent:
 Fri, 14 May 2021 20:02:03 +0000

To: Bruce, Sherrie (CDC/DDID/NCEZID/DPEI)

Subject: Re: Help: (b)(5)

vaccine update

Deal

From: Bruce, Sherrie (CDC/DDID/NCEZID/DPEI) <smb3@cdc.gov>

Sent: Friday, May 14, 2021 4:00:43 PM

To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Subject: RE: Help:(b)(5)

Thanks Sherri – Michael and I think you can stand down on this request. We think we have addressed these needs this afternoon and have notified Rebecca.

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Sent: Friday, May 14, 2021 1:25 PM

To: Bruce, Sherrie (CDC/DDID/NCEZID/DPEI) <smb3@cdc.gov>

Subject: Re: Help: (b)(5)

Holding

From: Bruce, Sherrie (CDC/DDID/NCEZID/DPEI) <smb3@cdc.gov>

Sent: Friday, May 14, 2021 12:53:29 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Subject: FW: Help: (b)(5)

Hi Sherri – could you hold on this? (b)(5)

b)(5)

Not sure that it requires your attention yet.....

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Friday, May 14, 2021 9:25 AM

To: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <mjb3@cdc.gov>; Bruce, Sherrie

(CDC/DDID/NCEZID/DPEI) <smb3@cdc.gov>

Subject: FW: Help: (b)(5)

Sherri will help with below.

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Friday, May 14, 2021 9:22 AM

To: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI)

Thanks

<hfw3@cdc.gov>

Subject: Help: (b)(5)

Hi Rebecca – (b)(5)

(b)(5)

\*\*\*\*\*\*

Good morning,



Thank you, Sherri

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Friday, May 14, 2021 9:14 AM

To: Berger, Sherri (CDC/OCOO/OD) <<u>sob8@cdc.gov</u>>
Cc: Schuchat, Anne MD (CDC/OD) <<u>acs1@cdc.gov</u>>

Subject: RE: (b)(5)

Yes please. Thank you!

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Sent: Friday, May 14, 2021 9:11 AM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov> Subject: RE: (b)(5) Yes, missing Dan on To line. Want us to send for you? From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov> Sent: Friday, May 14, 2021 9:10 AM To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov> Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov> Subject: FW: (b)(5) Ok with you if I ask (b)(5) DRAFT EMAIL (b)(5) **Description of Role:** (b)(5) Rebecca

From: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < ftm1@cdc.gov>

Sent: Thursday, May 13, 2021, 6:05 PM

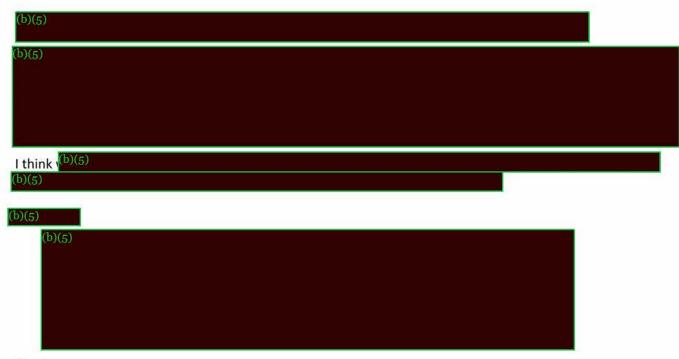
To: Walke, Henry (CDC/DDID/NCEZID/DPEI); Cohn, Amanda (CDC/DDID/NCIRD/OD); Meaney Delman,

Dana M. (CDC/DDNID/NCBDDD/DBDID)

Cc: Fox, Kimberley (CDC/DDID/NCIRD/DBD); Beach, Michael J. (CDC/DDID/NCEZID/DFWED)

Subject: (b)(5)

Henry, Dana, and Michael -



Thanks Rebecca

Rebecca Greco Koné Co,-Lead, Vaccine Task Force COVID-19 Response Centers for Disease Control and Prevention (o): 404-639-3224 (c): 404-543-8163

(c): 404-543-8163 www.cdc.gov From: (b)(4); (b)(6)

 Sent:
 Tue, 25 May 2021 21:58:16 +0000

 To:
 Capozzola, Christa (CDC/OCOO/OFR)

Cc: Berger, Sherri (CDC/OCOO/OD); (b)(4); (b)(6)

Subject: RE: EOC All Hands

Attachments: IMS All Hands Summary to Staff\_052521\_Updated cc streamlined\_update.docx

Thanks, took out references to 'changes below' and other minor edits.

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 5:53 PM

To:(b)(4); (b)(6)

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; (b)(4); (b)(6)

b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

I got it – here's my edit. Still checking but take a look. Thanks.

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 5:52 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: EOC All Hands

(b)(5)

Let me resend in 2 mins. Think good to get both emails out today.

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

**Sent:** Tuesday, May 25, 2021 5:49 PM

To:(b)(4);(b)(6)

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; (b)(4); (b)(6)

(b)(4): (b)(6)

Subject: [EXT] RE: EOC All Hands

(b)(5)

What do you all think?

Thanks.

Christa

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 5:31 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: EOC All Hands

Update attached. If it's too long, you could include the Q&A as an attachment.

# (b)(4); (b)(6)

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 5:20 PM

To:(b)(4);(b)(6)

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

I think it's actually more important – people are multi-tasking during an all hands, so they'll definitely want to catch what they missed!

I don't think we need much in the intro section – that's a way to shorten a bit.

Thanks!

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 5:07 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

**Cc:** Berger, Sherri (CDC/OCOO/OD) <<u>sob8@cdc.gov</u>>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: EOC All Hands

We can add if you want - did not include in All Staff mostly because of length.

#### (b)(4); (b)(6)

Deloitte Services LP

Mobile: (b)(a): (b)(6)
www.deloitte.com

On May 25, 2021, at 4:57 PM, Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov > wrote:

Yes.

I also would suggest that Henry's message to staff include the Q/A and summary of remarks – as the headline – instead of just the summary of changes.

Is there any reason why you didn't include that in his message to staff?

Thanks.

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

**Sent:** Tuesday, May 25, 2021 4:56 PM

To: (b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<<u>KQR5@cdc.gov></u>
Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

Ok, Christa do you want to run by Henry please before I send?

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 4:55 PM

To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

The all staff one should, but I think the SL should come from you as it is written.

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

**Sent:** Tuesday, May 25, 2021 4:54 PM

To: (b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

Should they both come from Henry?

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 4:31 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

Sherri and Christa,

Draft IMS staff email and SL email are attached; if possible it would be good to send today to keep information flowing in a timely way. We wrote these with that timeframe in mind (e.g., "today's All Hands Meeting..."), but we can re-work if they will not go out today. Also, the SL email includes excerpts from the Q&A, which adds length but will help with transparency.

Please let us know what changes you need.

#### b)(4): (b)(6)

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Tuesday, May 25, 2021 3:53 PM

To:(b)(4); (b)(6)

Capozzola, Christa (CDC/OCOO/OFR)

Berger, Sherri (CDC/OCOO/OD)

<KQR5@cdc.gov>; (b)(4); (b)(6)

b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

awesome

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 3:52 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov >; (b)(4); (b)(6)

Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >;

b)(4); (b)(6)

Subject: RE: EOC All Hands

That's great. I will send draft of key points for senior leaders shortly.

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 3:50 PM

To: (b)(4); (b)(6)

<sob8@cdc.gov>; (b)(4); (b)(6)

Cc: (b)(4); (b)(6)

Subject: [EXT] EOC All Hands

Hi – sharing some data I got today – over 2000 people were in the All Hands (the largest prior was 1500'ish).

PDIMs are receiving unsolicited and unexpected feedback that is very positive and encouraging them to do this more often.

From: (b)(4); (b)(6)

Sent: Monday, May 17, 2021 8:31 AM

**To:** Berger, Sherri (CDC/OCOO/OD) < <u>sob8@cdc.gov</u>>; (b)(4); (b)(6)

Cc: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov >; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: Weekly IMS update meeting

We can do as a call as we do not need to project slides. Angela will update the appointment with the slides so you have those in advance. Thanks.

b)(4); (b)(6)

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On May 17, 2021, at 7:37 AM, Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov> wrote:

Thanks all. I may have to join via telephone (v video).

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Monday, May 17, 2021 7:18:13 AM

To (b)(4): (b)(6)

Berger, Sherri (CDC/OCOO/OD)

<<u>sob8@cdc.gov></u> **Cc:** (b)(4); (b)(6)

Subject: RE: Weekly IMS update meeting

Hi – thanks - beyond updates, one issue I'd like to get everyone's input on is (b)(5)

(b)(5)

Christa

From: (b)(4); (b)(6)

Sent: Sunday, May 16, 2021 9:09 PM

To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: Weekly IMS update meeting

Sherri and Christa,

Please let us know if there are topics you would like to cover at the IMS weekly update meeting tomorrow at 11:30am.

From our end, we want to touch on 1) communication items, 2) three deliverables we are working on for the end of the month, and 3) support, if any, needed at the end of this four-week transition period.

Angela will send slides in advance, and we will add anything you want to cover.

Thank you,

(b)(4); (b)(6)

# (b)(4); (b)(6)

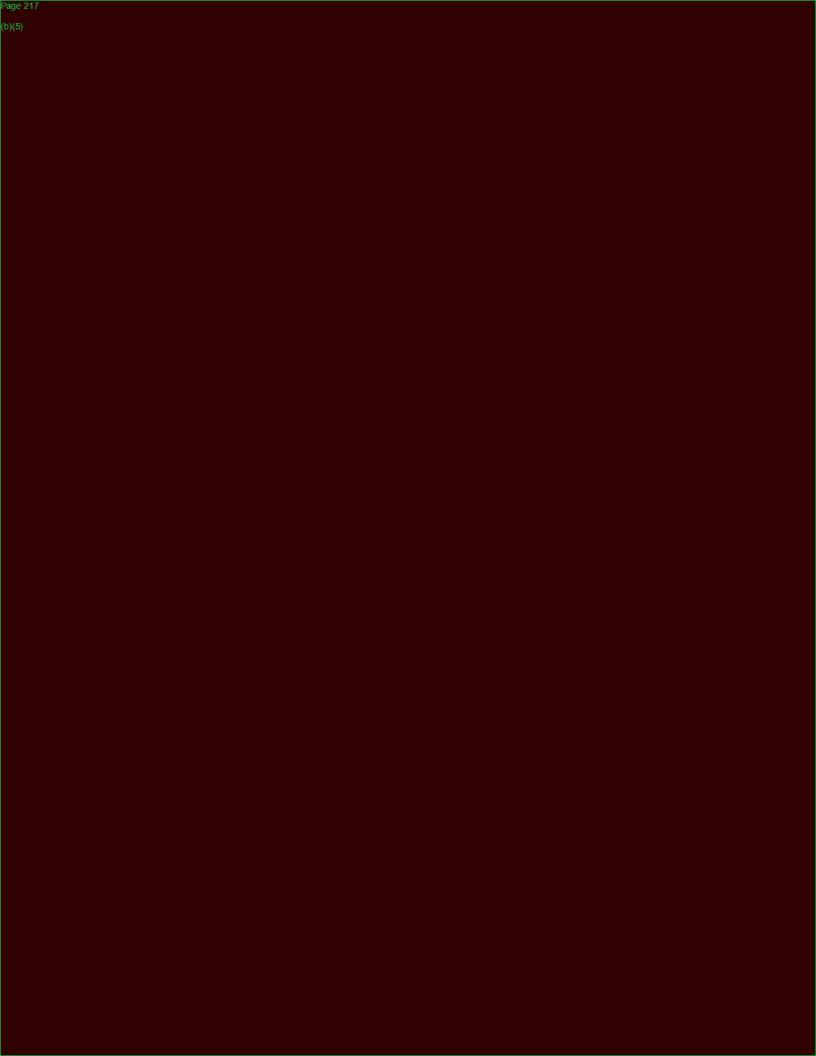
Deloitte Services LP

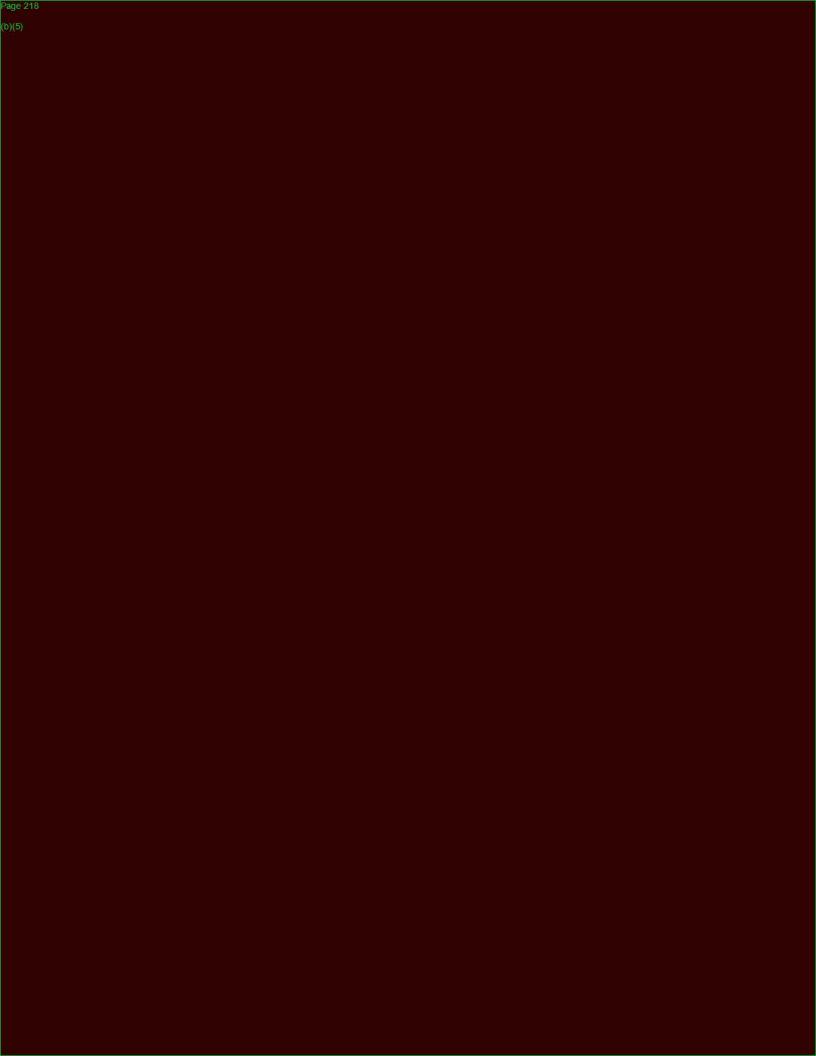
Mobile: (b)(A)-(b)(6)
www.deloitte.com

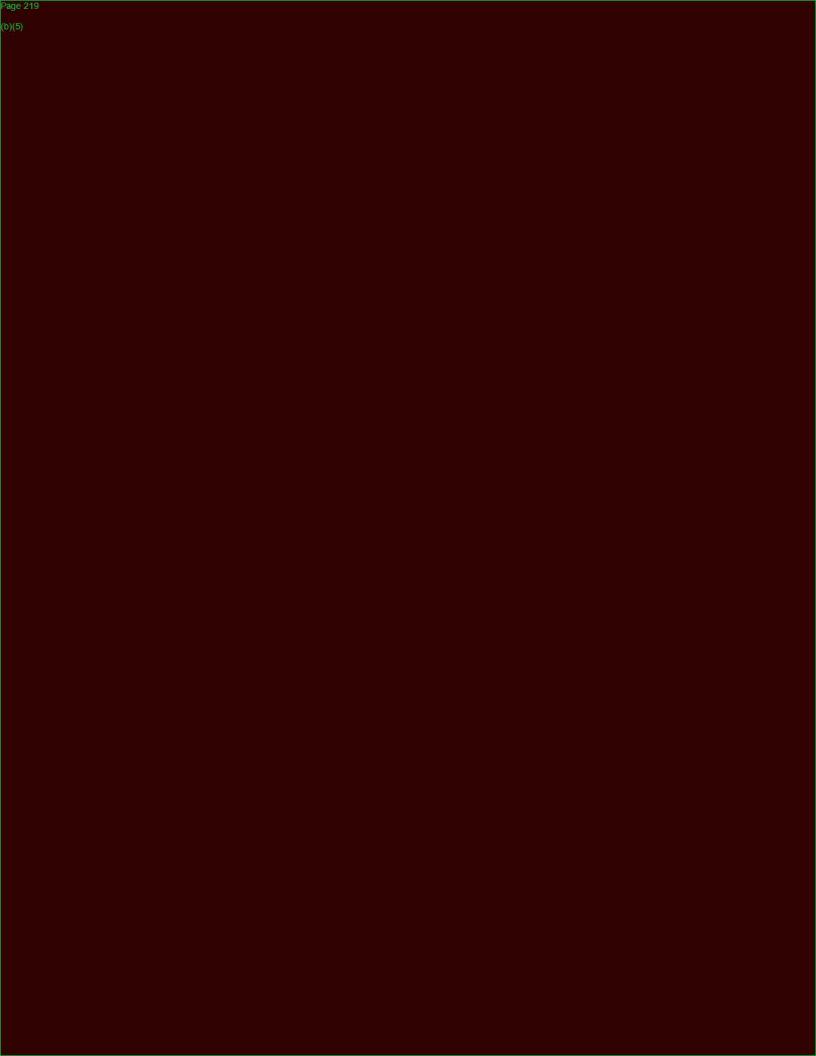
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From: Capozzola, Christa (CDC/OCOO/OFR)
Sent: Tue, 25 May 2021 21:53:15 +0000

To: (b)(4); (b)(6)

Cc: Berger, Sherri (CDC/OCOO/OD); (b)(4); (b)(6)

Subject: RE: EOC All Hands

Attachments: IMS All Hands Summary to Staff\_052521\_Updated cc streamlined.docx

I got it – here's my edit. Still checking but take a look. Thanks.

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 5:52 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; (b)(4); (b)(6)

b)(4); (b)(6)

Subject: RE: EOC All Hands

I would (b)(5)

Let me resend in 2 mins. Think good to get both emails out today.

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 5:49 PM

To: (b)(4); (b)(6)

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>;(b)(4);(b)(6)

(b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

(b)(5)

What do you all think?

Thanks. Christa

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 5:31 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: EOC All Hands

Update attached. If it's too long, you could include the Q&A as an attachment.

(b)(4): (b)(6)

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Tuesday, May 25, 2021 5:20 PM

To: (b)(4); (b)(6)

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>;(b)(4); (b)(6)

#### (b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

I think it's actually more important – people are multi-tasking during an all hands, so they'll definitely want to catch what they missed!

I don't think we need much in the intro section – that's a way to shorten a bit.

Thanks!

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 5:07 PM

To: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; (b)(4); (b)(6)

#### (b)(4); (b)(6)

Subject: RE: EOC All Hands

We can add if you want - did not include in All Staff mostly because of length.

### (b)(4); (b)(6)

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On May 25, 2021, at 4:57 PM, Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov> wrote:

Yes.

I also would suggest that (b)(5)

#### (b)(5)

Is there any reason why you didn't include that in his message to staff? Thanks.

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Tuesday, May 25, 2021 4:56 PM

To: (b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

Ok, Christa do you want to run by Henry please before I send?

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 4:55 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

The all staff one should, but I think the SL should come from you as it is written.

From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

**Sent:** Tuesday, May 25, 2021 4:54 PM

To: (b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

Should they both come from Henry?

From: (b)(4); (b)(6)

Sent: Tuesday, May 25, 2021 4:31 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov >; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: EOC All Hands

Sherri and Christa,

Draft IMS staff email and SL email are attached; if possible it would be good to send today to keep information flowing in a timely way. We wrote these with that timeframe in mind (e.g., "today's All Hands Meeting..."), but we can re-work if they will not go out today. Also, the SL email includes excerpts from the Q&A, which adds length but will help with transparency.

Please let us know what changes you need.

## (b)(4); (b)(6)

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

**Sent:** Tuesday, May 25, 2021 3:53 PM

To:(b)(4); (b)(6) Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: [EXT] RE: EOC All Hands

awesome

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Sent: Tuesday, May 25, 2021 3:52 PM

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o)(4); (b)(6)

Subject: RE: EOC All Hands

That's great. I will send draft of key points for senior leaders shortly.

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Sent: Tuesday, May 25, 2021 3:50 PM

To:(b)(4);(b)(6)

Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; (b)(4); (b)(6)

Cc: (b)(4); (b)(6)

Subject: [EXT] EOC All Hands

Hi – sharing some data I got today – over 2000 people were in the All Hands (the largest prior was 1500'ish).

PDIMs are receiving unsolicited and unexpected feedback that is very positive and encouraging them to do this more often.

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Sent: Monday, May 17, 2021 8:31 AM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>; (b)(4); (b)(6)

Cc: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>; (b)(4); (b)(6)

(b)(4); (b)(6)

Subject: RE: Weekly IMS update meeting

We can do as a call as we do not need to project slides. Angela will update the appointment with the slides so you have those in advance. Thanks.

### (b)(4); (b)(6)

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On May 17, 2021, at 7:37 AM, Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov> wrote:

Thanks all. I may have to join via telephone (v video).

From: Capozzola, Christa (CDC/OCOO/OFR) < KQR5@cdc.gov>

Sent: Monday, May 17, 2021 7:18:13 AM

**To:** (b)(4); (b)(6) Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: RE: Weekly IMS update meeting

Hi – thanks - beyond updates, one issue I'd like to get everyone's input on is (b)(5)

(b)(5)

Christa

From: (b)(4); (b)(6)

Sent: Sunday, May 16, 2021 9:09 PM

To: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>; Capozzola, Christa (CDC/OCOO/OFR)

<KQR5@cdc.gov>

Cc: (b)(4); (b)(6)

Subject: Weekly IMS update meeting

Sherri and Christa,

Please let us know if there are topics you would like to cover at the IMS weekly update meeting tomorrow at 11:30am.

(b)(5)

will send slides in advance, and we will add anything you want to cover.

Thank you,

(b)(4); (b)(6)

### (b)(4); (b)(6)

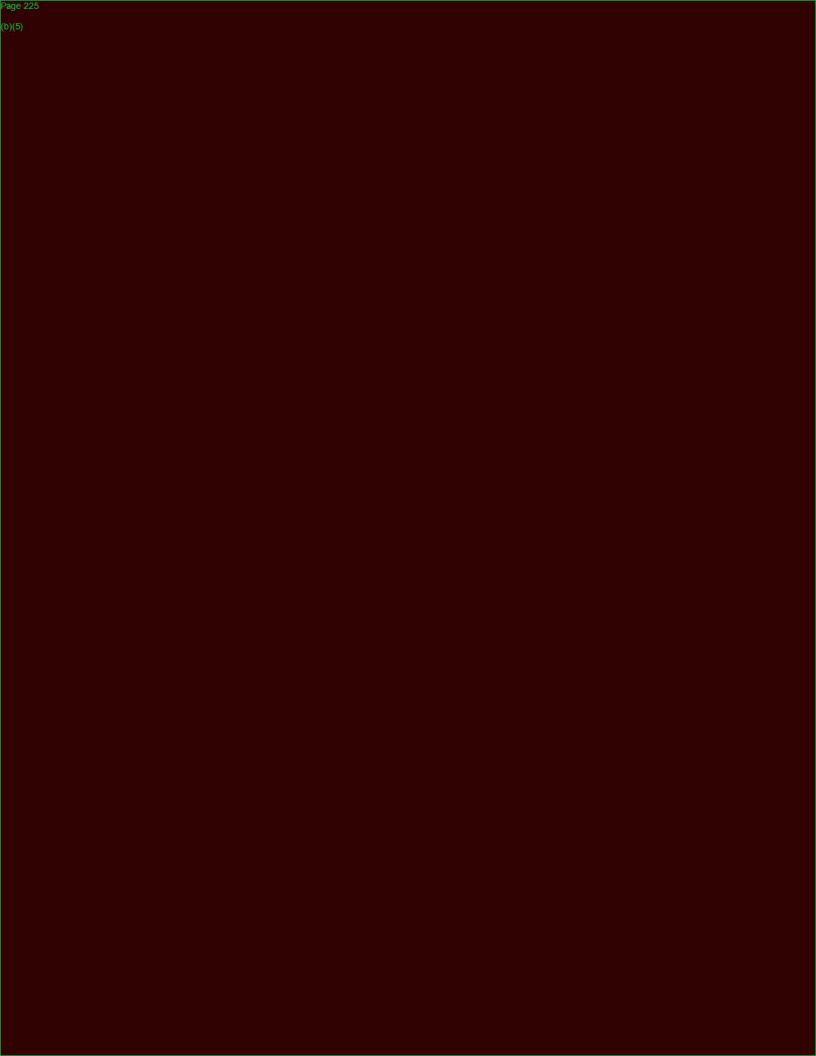
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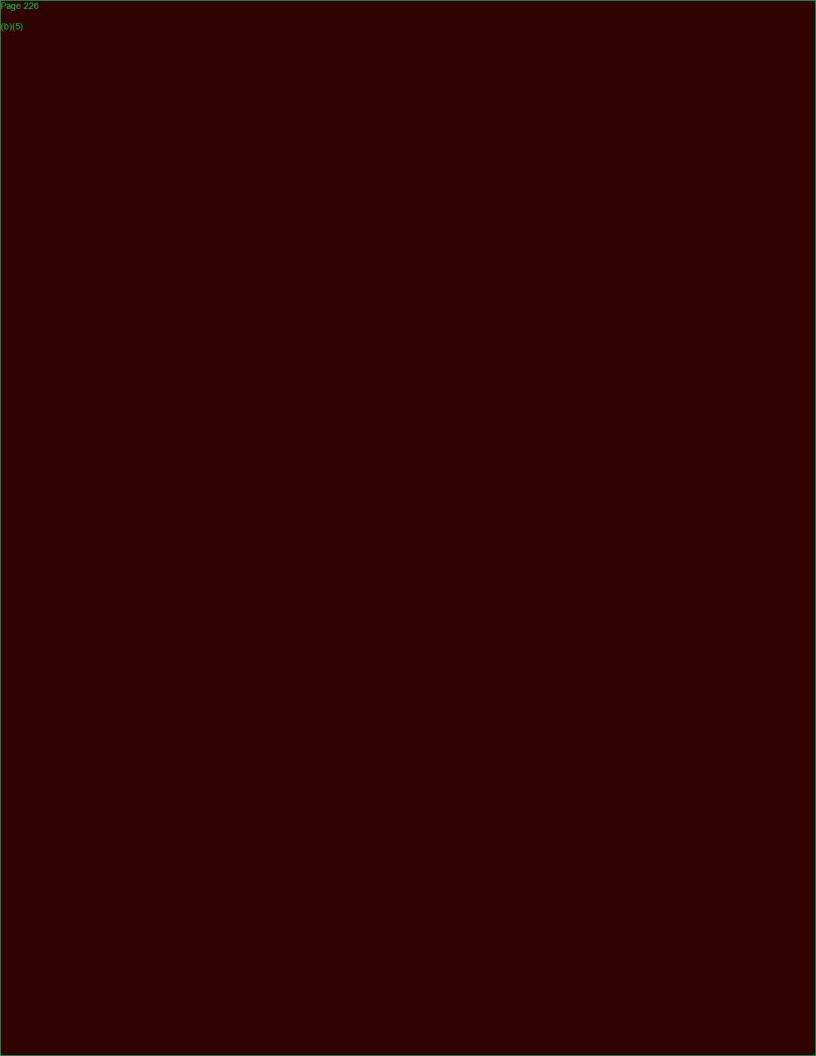
Mobile: (b)(A)-(b)(6)
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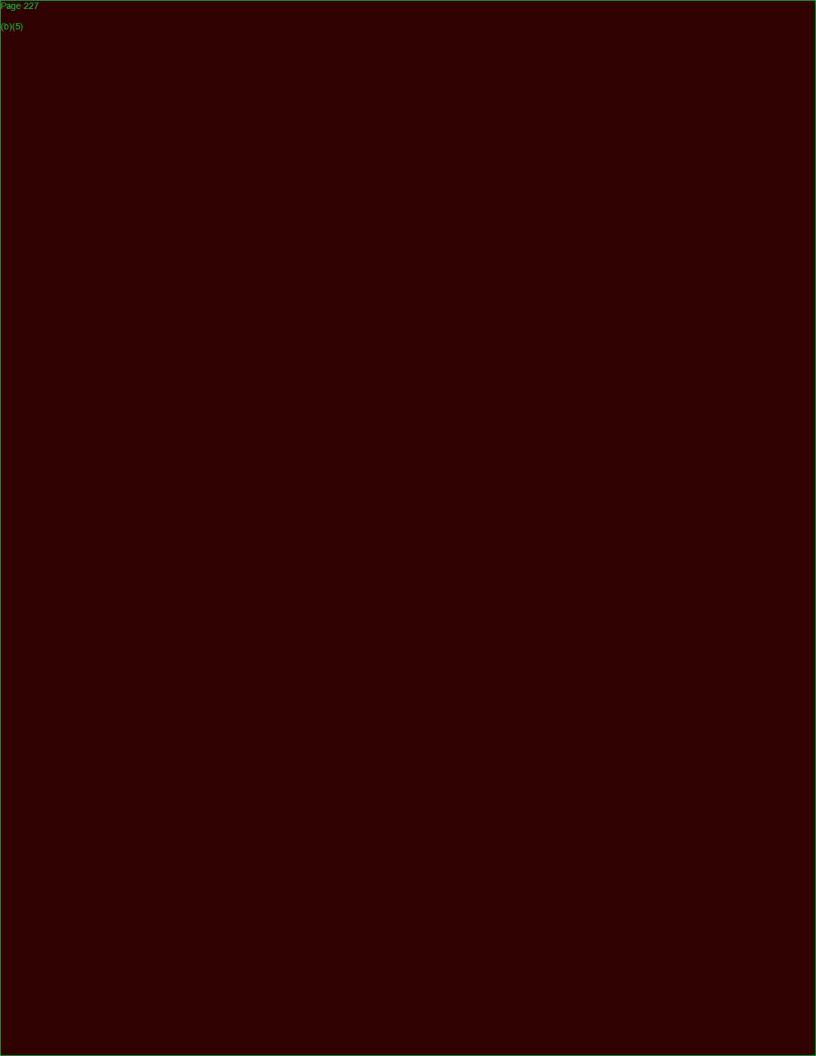
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From: Berger, Sherri (CDC/OCOO/OD)
Sent: Thu, 27 May 2021 12:15:08 +0000

To: Anne Schuchat MD (CDC/OD) (acs1@cdc.gov)

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Attachments: Pediatric Mortality Estimates\_faust response\_FINAL.docx

Hi! (b)(5) Thanks

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Tuesday, May 25, 2021 10:23 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov> Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Here's the response from NCIRD influenza experts.

BIG thanks to Burns, Erin (CDC/DDID/NCIRD/ID) <a href="mailto:eub5@cdc.gov">eub5@cdc.gov</a>, Fry, Alicia (CDC/DDID/NCIRD/ID) <a href="mailto:agf1@cdc.gov">agf1@cdc.gov</a>; Reed, Carrie (CDC/DDID/NCIRD/ID) <a href="mailto:ggi2@cdc.gov">ggi2@cdc.gov</a>; Iuliano, A. Danielle CDC/OID/NCIRD (CDC/DDID/NCIRD/ID) <a href="mailto:aoi0@cdc.gov">aoi0@cdc.gov</a>!!

Cheers,

-john

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Sunday, May 23, 2021 7:13 AM

To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Thank you, Anne.

John, Can you please reach out to NCIRD for a response?

(b)(5)

(b)(5)

want to be

sure we adequately respond to his concerns.

Thanks,

R

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Sent: Saturday, May 22, 2021 4:01 PM

To: Walensky, Rochelle (CDC/OD) < aux7@cdc.gov >; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

My two cents for the reply to Dr Faust (ps - what a name...):



From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Saturday, May 22, 2021 2:59 PM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Thank you, John,

I've reviewed the memo. Yes, please forward to them and ask for their reply. I'd be interested in this now myself so please keep me in the loop

+Anne as well (reattached for you, Anne).

Thank you, Rochelle

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Friday, May 21, 2021 6:29 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

# One follow-up on this:

I should have asked whether in addition to reaching out about myocarditis (had a good call with Celine and updated on her on what can be shared publicly), did you also (b)(5)



## -john

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Friday, May 21, 2021 7:17 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

John,
Can I ask you to please handle with VTF?

Thanks, R

From: Celine Gounder, MD, ScM 6560 Sent: Thursday, May 20, 2021 9:56 PM

To: Walensky, Rochelle (CDC/OD) < aux7@cdc.gov >; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Subject: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Dear Rochelle and John,

Jeremy Faust and I are working on an op-ed for the NYT (already green lit) about the risks-benefits of COVID and COVID vaccination, including the risk of long-term side effects of COVID vaccination (low) versus the long-term risks of COVID (high).

As you know, one of the reasons many people give for not getting vaccinated is that there isn't enough long-term safety data on COVID vaccines. Another reason given for not vaccinating kids is that COVID is no worse than influenza in children.

We're hearing more and more reports of post-vaccination myocarditis from MA and NY where
 Jeremy and I are based, as well as elsewhere across the country. Is there anything you can share

- about post-vaccination myocarditis cases (demographics? fatal / non-fatal?) Or other serious post-vaccination events?
- I previously shared a memo from Jeremy to John re: Qs on influenza and COVID morbidity/mortality among children. I'm attaching that memo again here. John, have you gotten any feedback on the Qs Jeremy outlined in his memo?

These data could just be shared with us on background. We just want to make sure that in framing our argument, we're not misrepresenting the facts.

Warmly, Céline

--

<u>Céline Gounder</u>, MD, ScM, FIDSA she / her / hers

CEO/Founder, JUST HUMAN PRODUCTIONS

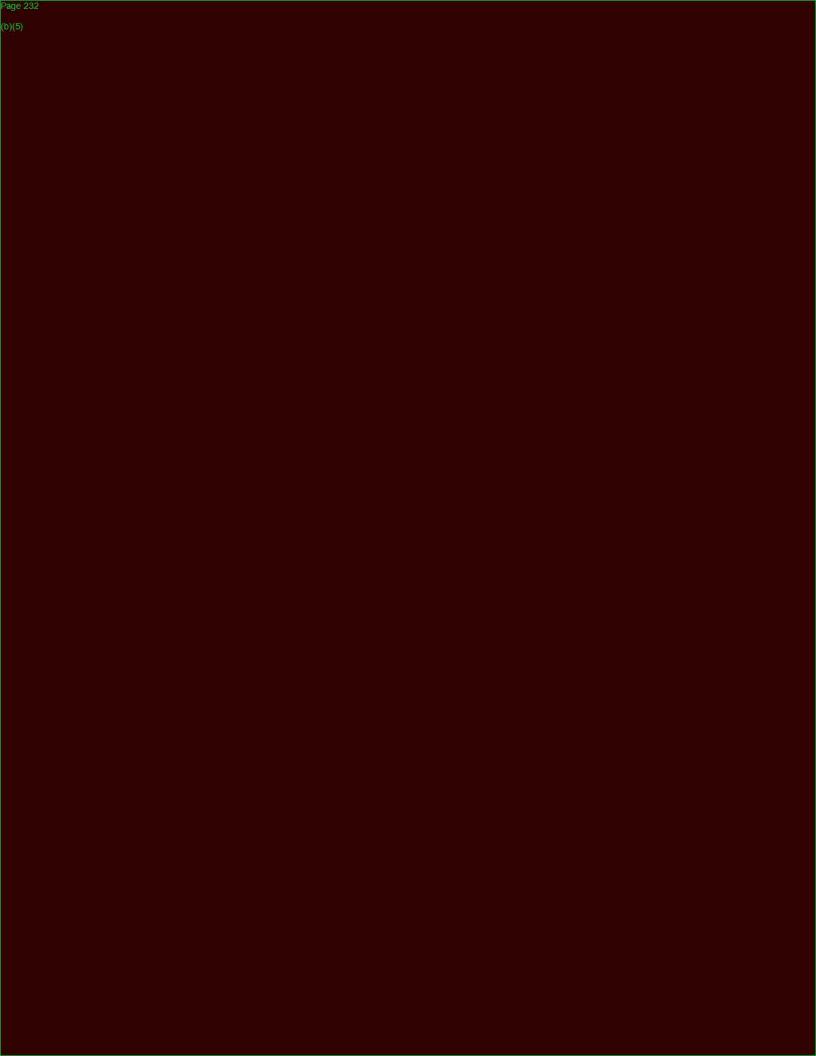
Host/Producer, AMERICAN DIAGNOSIS & EPIDEMIC podcasts

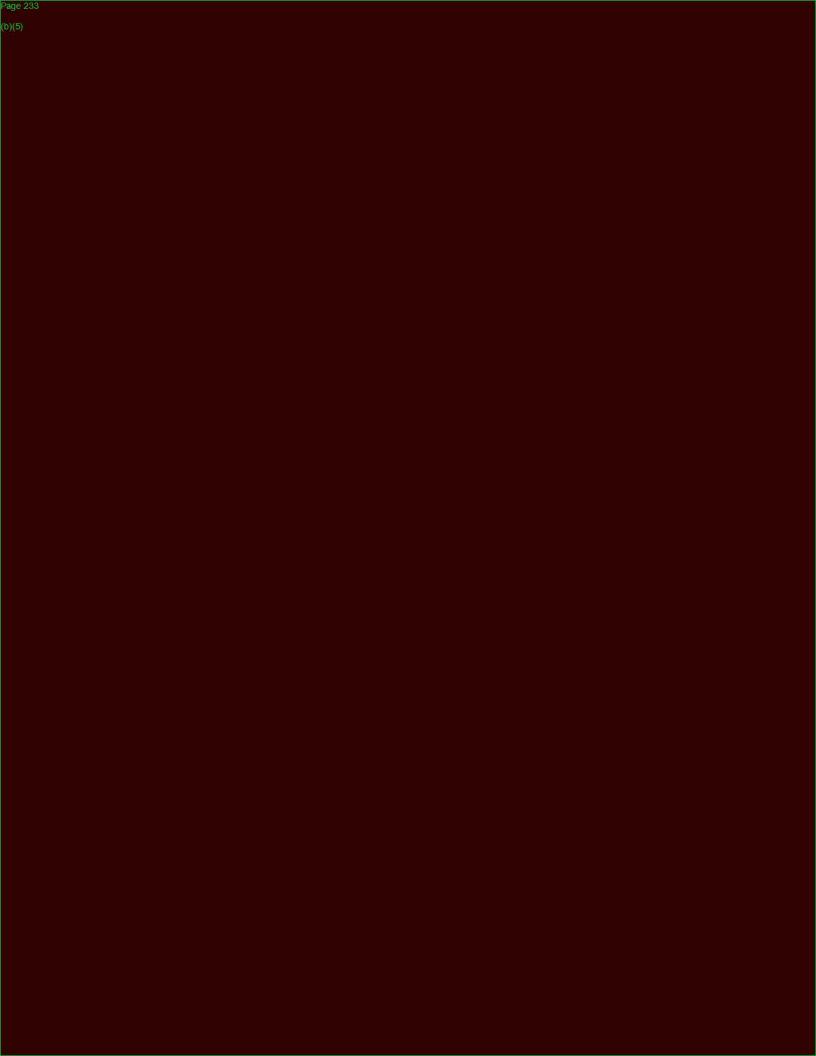
Medical Analyst, CNN

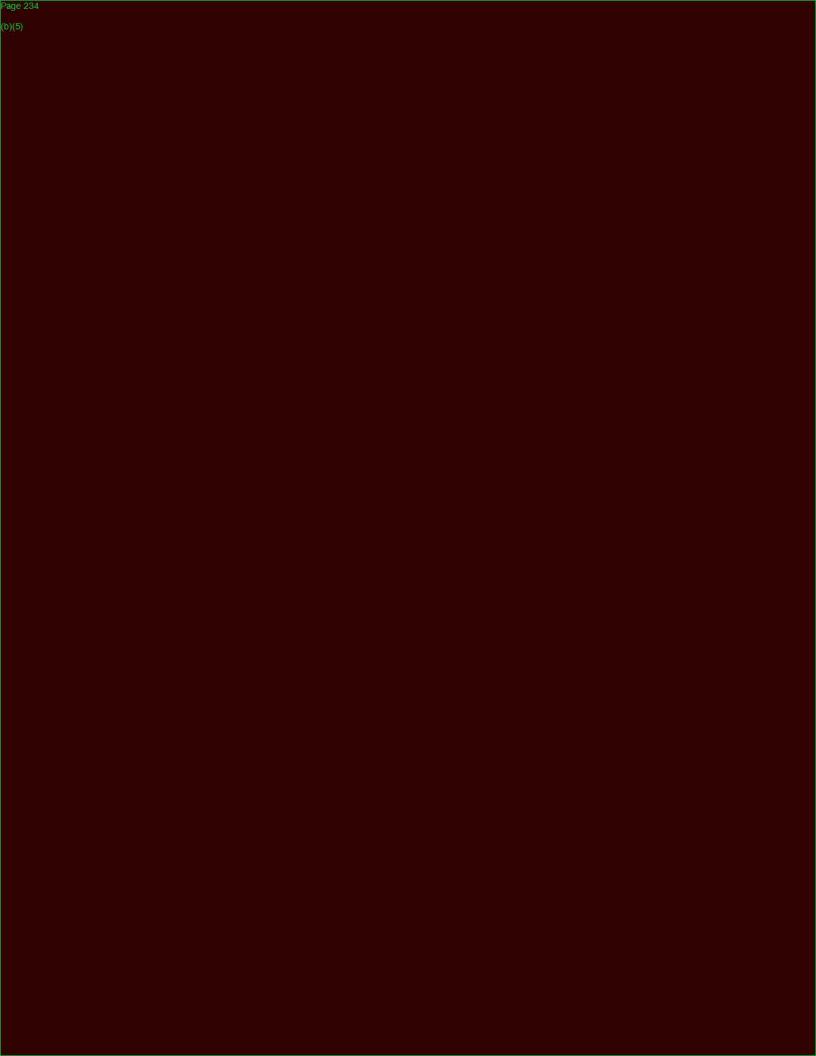
Clinical Assistant Professor of Medicine & Infectious Diseases, <u>NYU School of Medicine</u> & Bellevue Hospital

Cell +1-917-275-2618

@celinegounder







 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Wed, 26 May 2021 11:42:47 +0000

To: Berger, Sherri (CDC/OCOO/OD); Schuchat, Anne MD (CDC/OD)

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Attachments: Pediatric Mortality Estimates\_faust response\_FINAL.docx

Can we discuss this please.

Thanks,

R

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Tuesday, May 25, 2021 10:23 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:kfw3@cdc.gov">hfw3@cdc.gov</a>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

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BIG thanks to Burns, Erin (CDC/DDID/NCIRD/ID) <a href="mailto:eub5@cdc.gov">eub5@cdc.gov</a>, Fry, Alicia (CDC/DDID/NCIRD/ID) <a href="mailto:agf1@cdc.gov">agf1@cdc.gov</a>; Reed, Carrie (CDC/DDID/NCIRD/ID) <a href="mailto:ggi2@cdc.gov">ggi2@cdc.gov</a>; Iuliano, A. Danielle CDC/OID/NCIRD (CDC/DDID/NCIRD/ID) <a href="mailto:aoi0@cdc.gov">aoi0@cdc.gov</a>!!

Cheers,

-john

From: Walensky, Rochelle (CDC/OD) <a ux 7@cdc.gov>

Sent: Sunday, May 23, 2021 7:13 AM

To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

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Thank you, Anne.

John, Can you please reach out to NCIRD for a response? (b)(5)

(b)(5)

I want to be

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<zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

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Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Thank you, John,

I've reviewed the memo. Yes, please forward to them and ask for their reply. I'd be interested in this now myself so please keep me in the loop

+Anne as well (reattached for you, Anne).

Thank you, Rochelle

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Friday, May 21, 2021 6:29 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

# One follow-up on this:

I should have asked whether in addition to reaching out about myocarditis (had a good call with Celine and updated on her on what can be shared publicly), did you also (b)(5)



## -john

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Friday, May 21, 2021 7:17 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

John,

Can I ask you to please handle with VTF?

Thanks,

R

From: Celine Gounder, MD, ScM (1)(6) Sent: Thursday, May 20, 2021 9:56 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Subject: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Dear Rochelle and John,

Jeremy Faust and I are working on an op-ed for the NYT (already green lit) about the risks-benefits of COVID and COVID vaccination, including the risk of long-term side effects of COVID vaccination (low) versus the long-term risks of COVID (high).

As you know, one of the reasons many people give for not getting vaccinated is that there isn't enough long-term safety data on COVID vaccines. Another reason given for not vaccinating kids is that COVID is no worse than influenza in children.

We're hearing more and more reports of post-vaccination myocarditis from MA and NY where
Jeremy and I are based, as well as elsewhere across the country. Is there anything you can share
about post-vaccination myocarditis cases (demographics? fatal / non-fatal?) Or other serious
post-vaccination events?

 I previously shared a memo from Jeremy to John re: Qs on influenza and COVID morbidity/mortality among children. I'm attaching that memo again here. John, have you gotten any feedback on the Qs Jeremy outlined in his memo?

These data could just be shared with us on background. We just want to make sure that in framing our argument, we're not misrepresenting the facts.

Warmly, Céline

--

<u>Céline Gounder</u>, MD, ScM, FIDSA she / her / hers

CEO/Founder, JUST HUMAN PRODUCTIONS

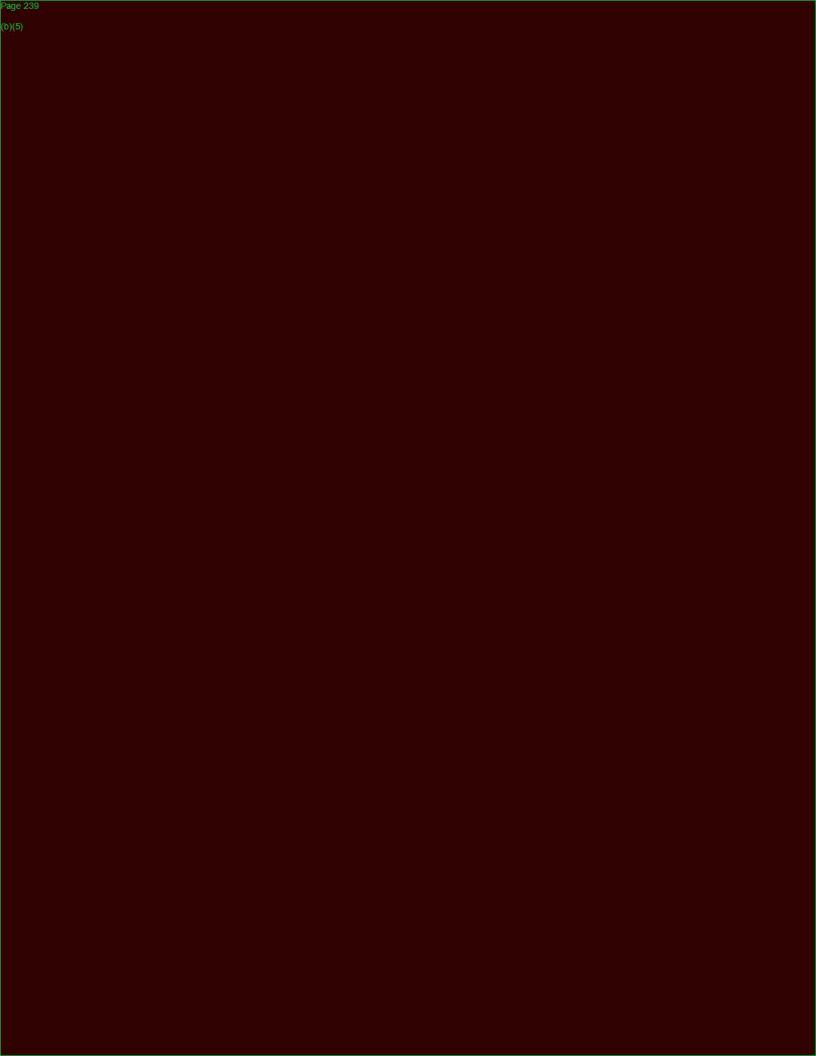
Host/Producer, AMERICAN DIAGNOSIS & EPIDEMIC podcasts

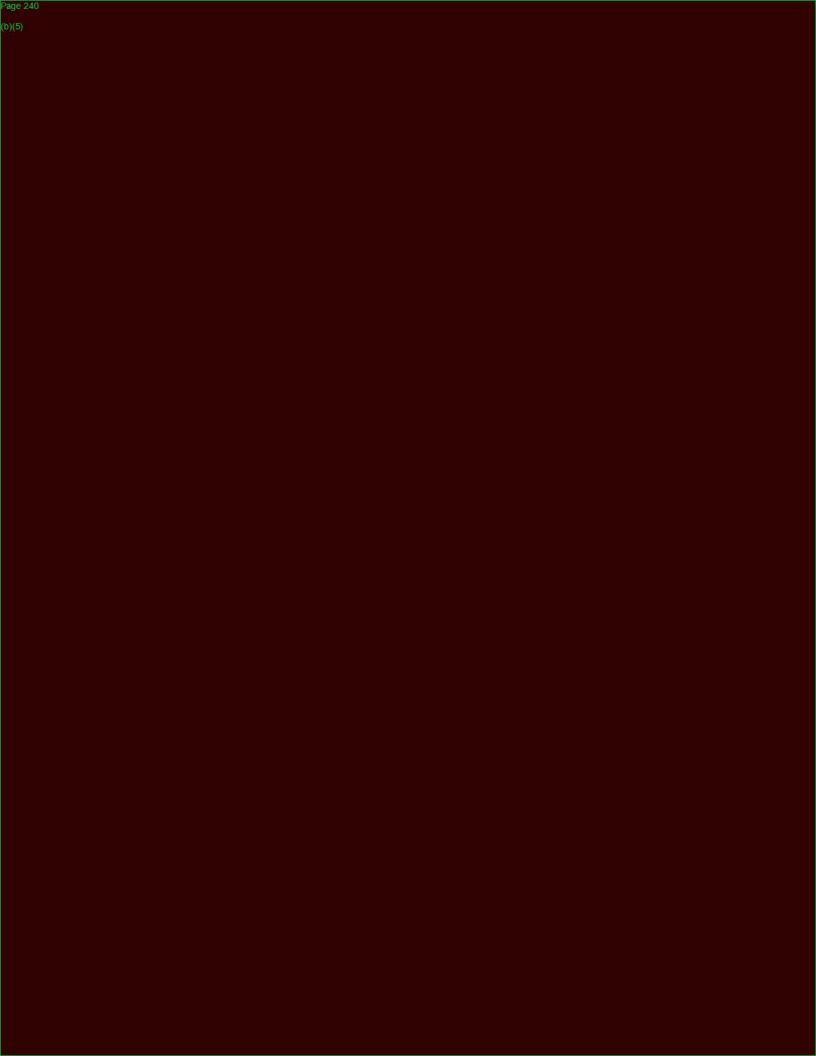
Medical Analyst, CNN

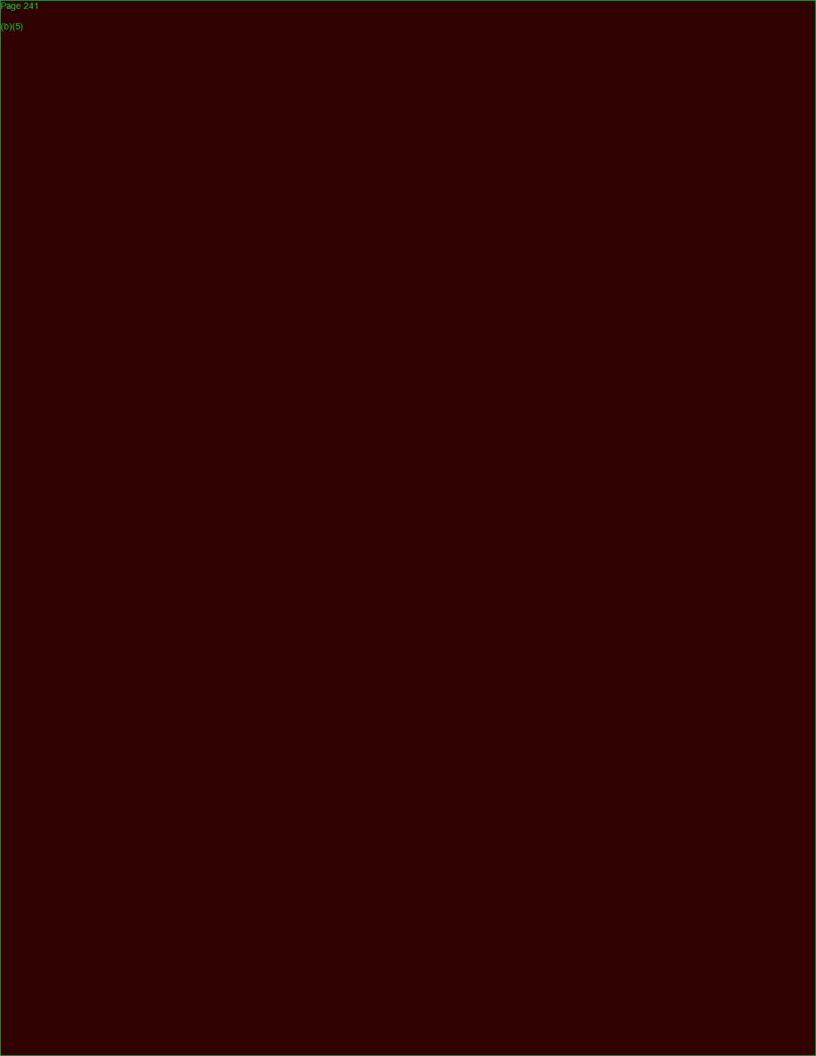
Clinical Assistant Professor of Medicine & Infectious Diseases, <u>NYU School of Medicine</u> & Bellevue Hospital

Cell +1-917-275-2618

@celinegounder







From: Marissa Padilla

**Sent:** Mon, 24 May 2021 20:15:27 +0000

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD); Berger, Sherri (CDC/OCOO/OD);

Goldstein, Robert (CDC/OD/OADPS)

Subject: RE: Governors Call TPs

Attachments: Reactive on myocarditis and Tough QA\_05232021 Mp.docx

Thank you Abbigail. I've made some suggested edits and comments in this document for consideration.

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Sent: Monday, May 24, 2021 12:59 PM

To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS)

<qyd2@cdc.gov>

Cc: Marissa Padilla <mpadilla@globalstrategygroup.com>

Subject: RE: Governors Call TPs

### [EXT EMAIL]

That sounds great! Here are some of the topline messages. Marissa and I spoke a bit about these last night. She will have good thoughts.

Reactive on myocarditis



Topline on MMWR tomorrow (website: (b)(5)

(b)(5)

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Sent: Monday, May 24, 2021 10:47 AM

To: Goldstein, Robert (CDC/OD/OADPS) < <a href="mailto:qyd2@cdc.gov">gyd2@cdc.gov</a>; Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

<aws8@cdc.gov>

Cc: Marissa Padilla < mpadilla@globalstrategygroup.com >

Subject: RE: Governors Call TPs

### +Marissa

From: Goldstein, Robert (CDC/OD/OADPS) < avd2@cdc.gov>

Sent: Monday, May 24, 2021 10:46 AM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

**Subject:** Governors Call TPs

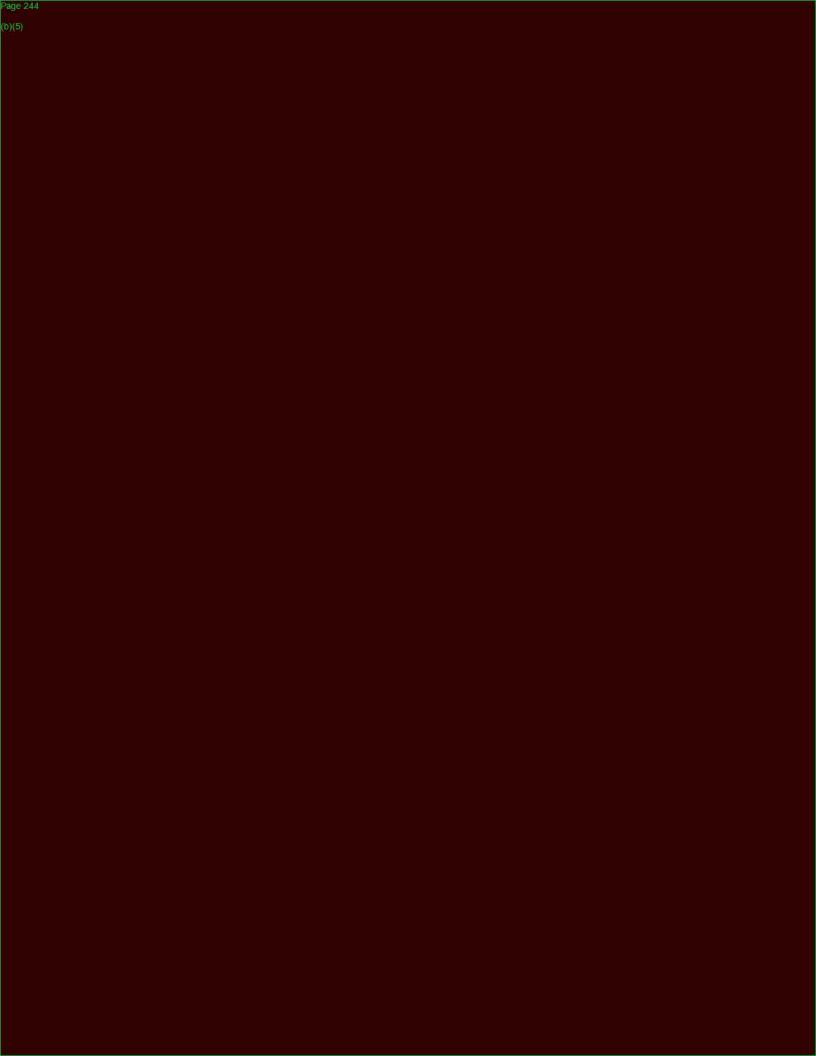
Abbigail,

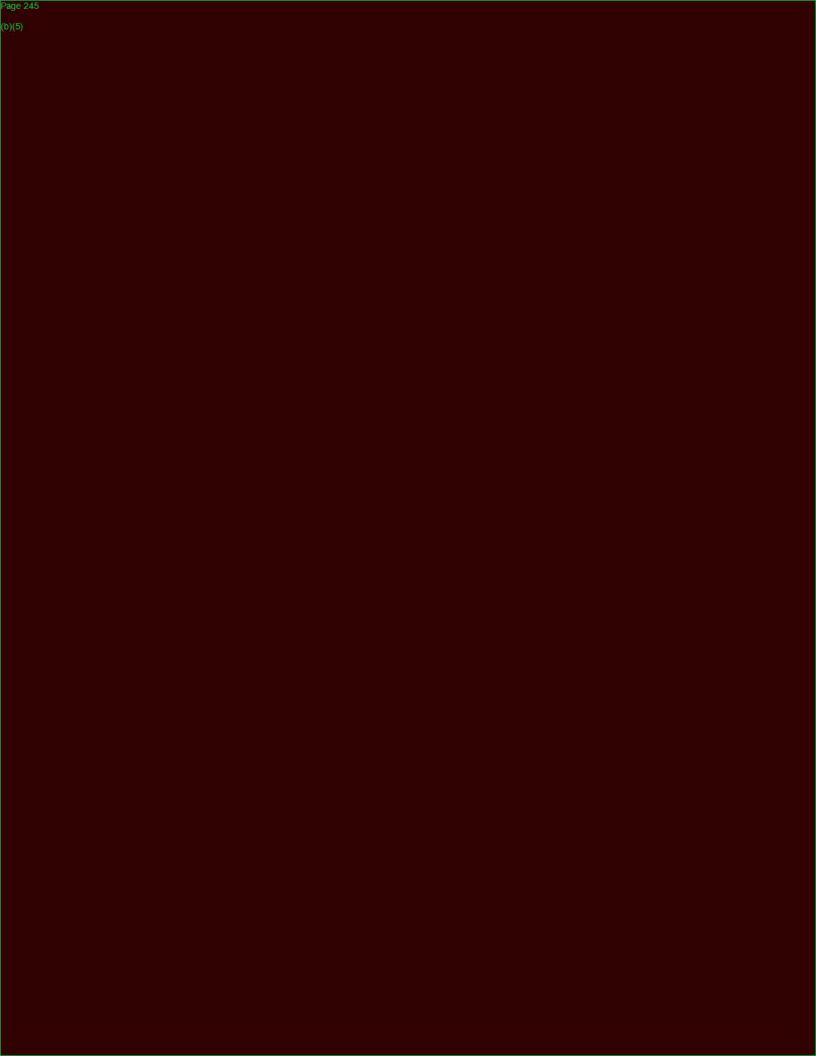
I'm pulling together talking points for Rochelle's 10-15 minutes with the Governors tomorrow. Was thinking of the following, but wanted to make sure it fits with your goals for Comms this week:



I haven't seen any specific asks from the WH or the Governors.

-RObbie

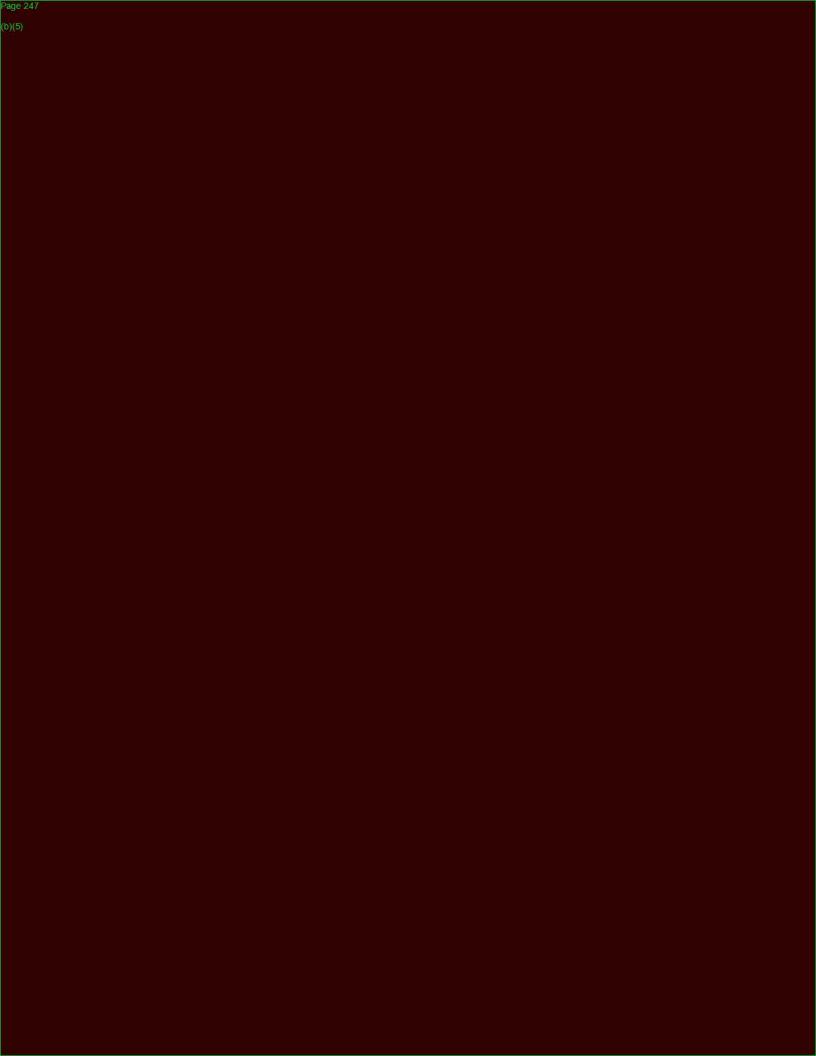


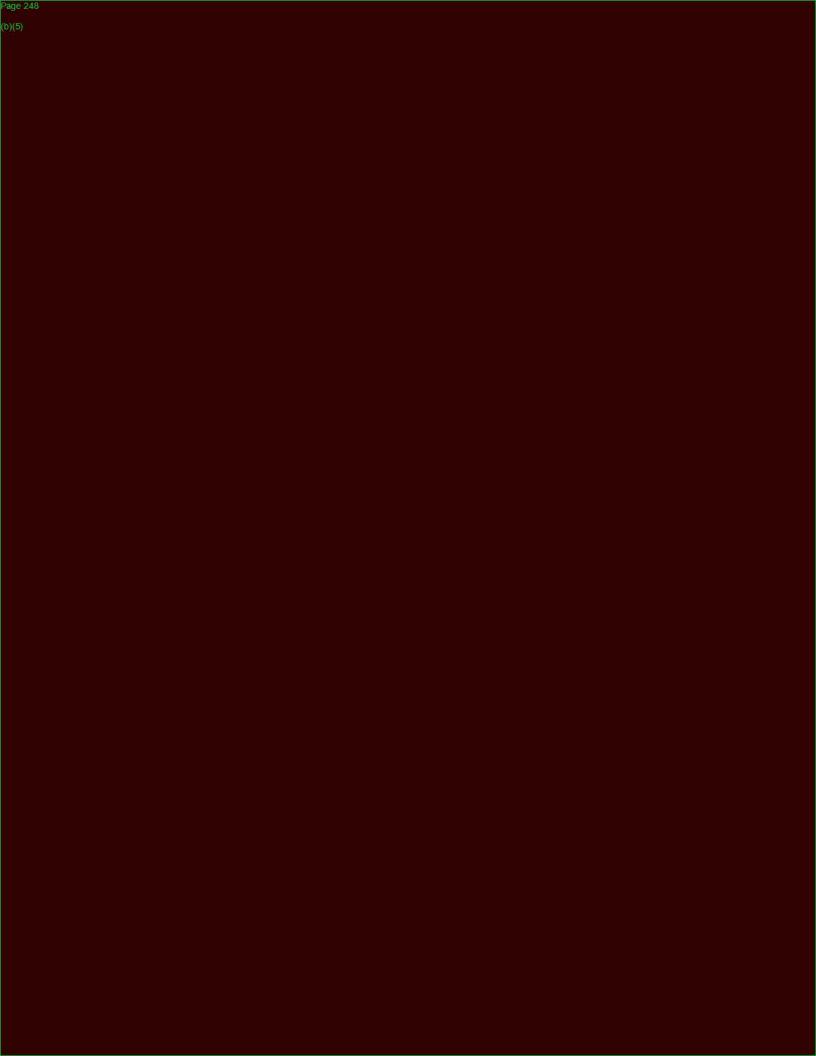


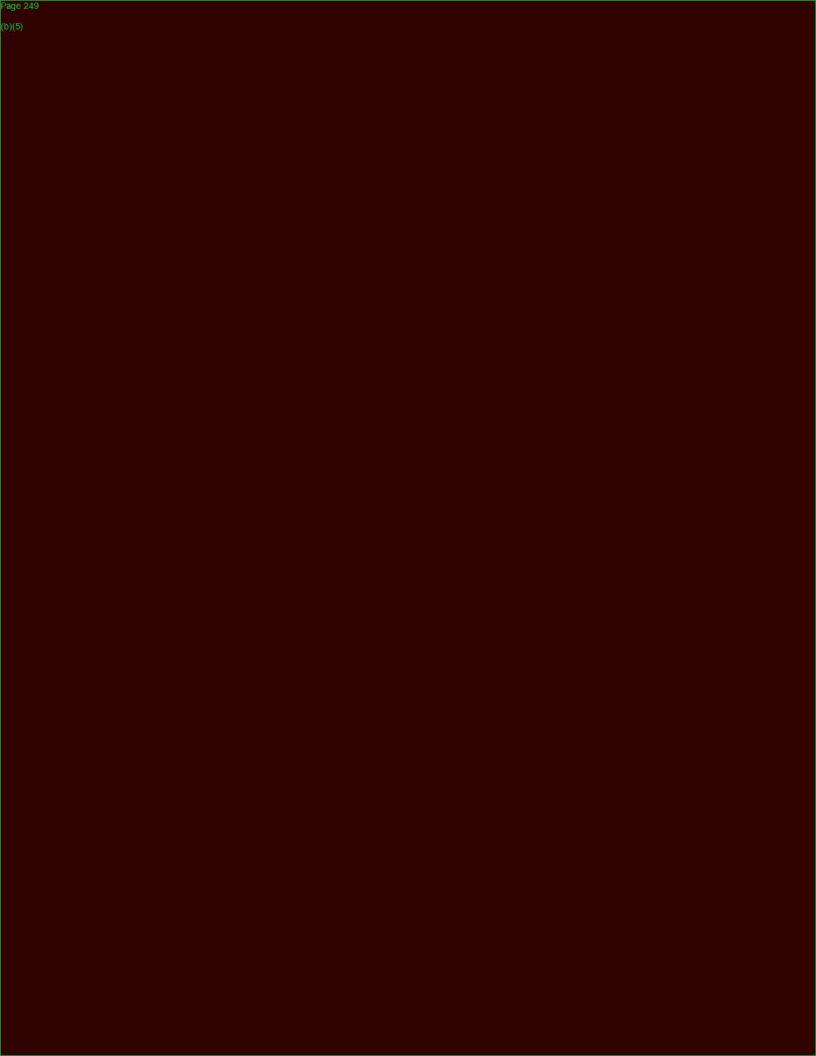
From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Sun, 23 May 2021 17:12:18 +0000
To: Walensky, Rochelle (CDC/OD)

Subject:DRAFT\_Myocarditis\_Advisory\_05232021\_1109Attachments:DRAFT\_Myocarditis\_Advisory\_05232021\_1109.docx

Latest HAN.







 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Fri, 21 May 2021 14:04:26 +0000

To: Walke, Henry (CDC/DDID/NCEZID/DPEI); Daskalakis, Demetre

(CDC/DDID/NCHHSTP/DHP)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD)

**Subject:** RE: WA DOH to issue a HAN alert

Great, thank you!

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Friday, May 21, 2021 10:03 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP)

<yzq5@cdc.gov>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Subject: RE: WA DOH to issue a HAN alert

Peggy is calling Washington right now for more info.

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Friday, May 21, 2021 9:51 AM

To: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>; Walke, Henry

(CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Subject: RE: WA DOH to issue a HAN alert

(b)(5)

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) < yzq5@cdc.gov>

Sent: Friday, May 21, 2021 9:45 AM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>;

Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Subject: RE: WA DOH to issue a HAN alert

Thanks. (b)(5)

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Friday, May 21, 2021 9:40 AM

To: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) < yzq5@cdc.gov>

Cc: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>;

Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Subject: Fwd: WA DOH to issue a HAN alert

From: Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) < mrh7@cdc.gov>

Sent: Friday, May 21, 2021 9:34:31 AM

To: Beach, Michael J. (CDC/DDID/NCEZID/DFWED) <mjb3@cdc.gov>; Walke, Henry

(CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov >; Christie, Athalia (CDC/DDPHSIS/CGH/OD) < akc9@cdc.gov >

Cc: Rose, Dale A. (CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov>

Subject: FW: WA DOH to issue a HAN alert

Are you looped in on this?

Margaret (Peggy) Honein, PhD, MPH
State, Tribal, Local, and Territorial Support
COVID-19 Emergency Response
U.S. Centers for Disease Control and Prevention
mrh7@cdc.gov



From: Byrkit, Ramona (CDC/DDID/NCEZID/DPEI) < apa1@cdc.gov>

Sent: Friday, May 21, 2021 9:33 AM

To: Honein, Margaret (Peggy) (CDC/DDID/NCEZID/DPEI) <a href="mrh7@cdc.gov"></a>; Rose, Dale A.

(CDC/DDID/NCEZID/DPEI) < ido8@cdc.gov > Subject: FW: WA DOH to issue a HAN alert

From: Byrne, Jennifer (CDC/DDID/NCEZID/DPEI) < bgq0@cdc.gov>

Sent: Friday, May 21, 2021 8:15 AM

To: Fehrenbach, Nicole (CDC/DDNID/NCBDDD/DBDID) < ekk5@cdc.gov>; Byrkit, Ramona

(CDC/DDID/NCEZID/DPEI) < apa1@cdc.gov>

Cc: Pullani, Anita (CDC/DDNID/NCIPC/DOP) < who5@cdc.gov >; Harrison, Leslie

(CDC/DDNID/NCCDPHP/DRH) < If10@cdc.gov >

Subject: WA DOH to issue a HAN alert

### Good morning!

Just wanted to alert you both to this case, entered by Kia this morning. We are sending it out to VTF, but thought you might like awareness as well that WA is likely to issue a HAN alert on this:



Best,

## Jennifer

## Jennifer Byrne, MPH

Task Force Liaison (TF LNO) Team Lead Health Department Section State, Tribal, Local & Territorial Support Task Force COVID-19 Emergency Response US Centers for Disease Control and Prevention Office: (770) 488-6833 Cell: (678) 575-8184

bgq0@cdc.gov

eocevent441@cdc.gov

 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Sun, 23 May 2021 13:00:27 +0000

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP); Schuchat, Anne MD (CDC/OD)

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI); Berger, Sherri (CDC/OCOO/OD)

Subject: Re: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

For sure...thank you! Get Outlook for iOS

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Sunday, May 23, 2021 8:42:19 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov> Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: Re: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Yes, I sent a request to them yesterday with Anne's note as well. Alicia Fry's team is working on a response. Due you think Monday COB would suffice?

John T. Brooks, MD - Chief Medical Officer

CDC, COVID-19 Response

Apologies for errors made due to my need to dictate or my thick thumbs.

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Sunday, May 23, 2021 7:13:29 AM

**To:** Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Thank you, Anne.

John, Can you please reach out to NCIRD for a response? (b)(5)

h)(5)

I want to be

sure we adequately respond to his concerns.

Thanks,

R

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Sent: Saturday, May 22, 2021 4:01 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

My two cents for the reply to Dr Faust (ps - what a name...):

(b)(5)



From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Saturday, May 22, 2021 2:59 PM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:hfw3@cdc.gov">hfw3@cdc.gov</a>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Thank you, John,

I've reviewed the memo. Yes, please forward to them and ask for their reply. I'd be interested in this now myself so please keep me in the loop

+Anne as well (reattached for you, Anne).

Thank you, Rochelle

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Friday, May 21, 2021 6:29 PM

To: Walensky, Rochelle (CDC/OD) < aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

# One follow-up on this:

I should have asked whether in addition to reaching out about myocarditis (had a good call with Celine and updated on her on what can be shared publicly), did you also (b)(5)

(b)(5)

### -john

From: Walensky, Rochelle (CDC/OD) < aux7@cdc.gov>

Sent: Friday, May 21, 2021 7:17 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov >; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

John, Can I ask you to please handle with VTF? Thanks, R

From: Celine Gounder, MD, ScM (b)(6)

Sent: Thursday, May 20, 2021 9:56 PM

To: Walensky, Rochelle (CDC/OD) <a href="mailto:aux7@cdc.gov">aux7@cdc.gov</a>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Subject: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Dear Rochelle and John,

Jeremy Faust and I are working on an op-ed for the NYT (already green lit) about the risks-benefits of COVID and COVID vaccination, including the risk of long-term side effects of COVID vaccination (low) versus the long-term risks of COVID (high).

As you know, one of the reasons many people give for not getting vaccinated is that there isn't enough long-term safety data on COVID vaccines. Another reason given for not vaccinating kids is that COVID is no worse than influenza in children.

- We're hearing more and more reports of post-vaccination myocarditis from MA and NY where
  Jeremy and I are based, as well as elsewhere across the country. Is there anything you can share
  about post-vaccination myocarditis cases (demographics? fatal / non-fatal?) Or other serious
  post-vaccination events?
- I previously shared a memo from Jeremy to John re: Qs on influenza and COVID morbidity/mortality among children. I'm attaching that memo again here. John, have you gotten any feedback on the Qs Jeremy outlined in his memo?

These data could just be shared with us on background. We just want to make sure that in framing our argument, we're not misrepresenting the facts.

Warmly, Céline

--

CEO/Founder, JUST HUMAN PRODUCTIONS

Host/Producer, AMERICAN DIAGNOSIS & EPIDEMIC podcasts

Medical Analyst, CNN

Clinical Assistant Professor of Medicine & Infectious Diseases, NYU School of Medicine & Bellevue Hospital

Cell +1-917-275-2618

@celinegounder

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

**Sent:** Wed, 26 May 2021 17:49:23 +0000

To: Walensky, Rochelle (CDC/OD); Schuchat, Anne MD (CDC/OD)

Cc: Goldstein, Robert (CDC/OD/OADPS); Berger, Sherri (CDC/OCOO/OD); McDonald,

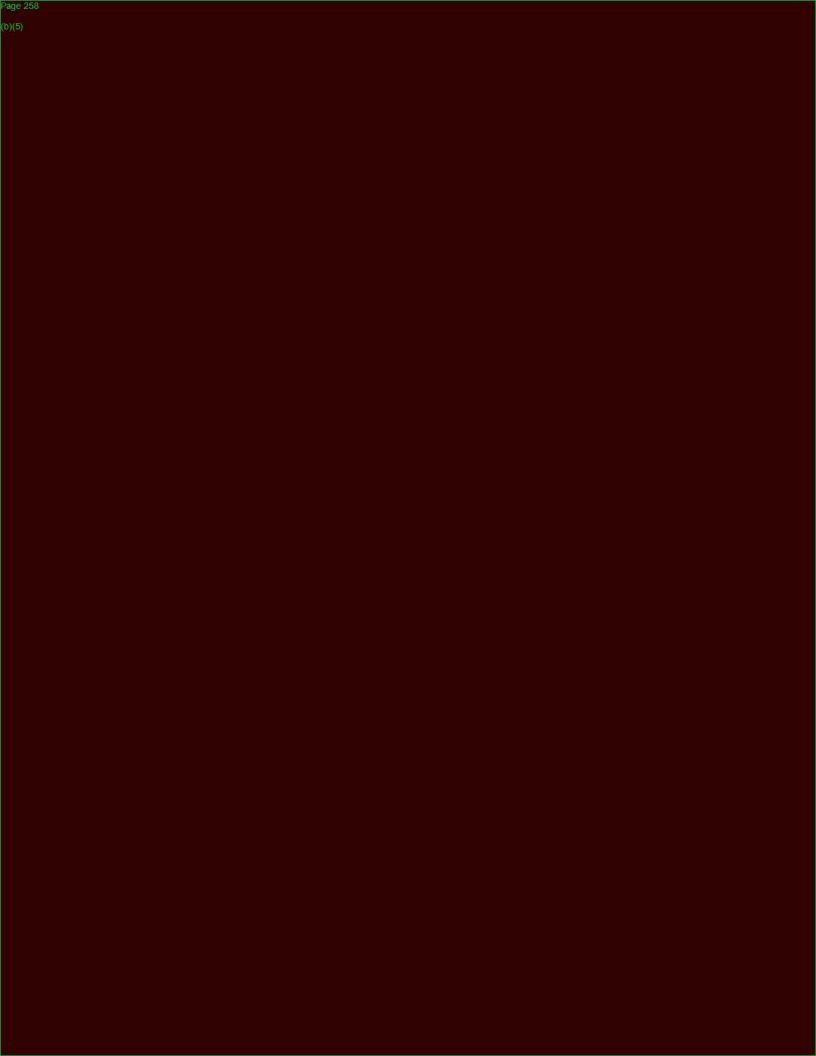
Jason (CDC/OD/OADC)

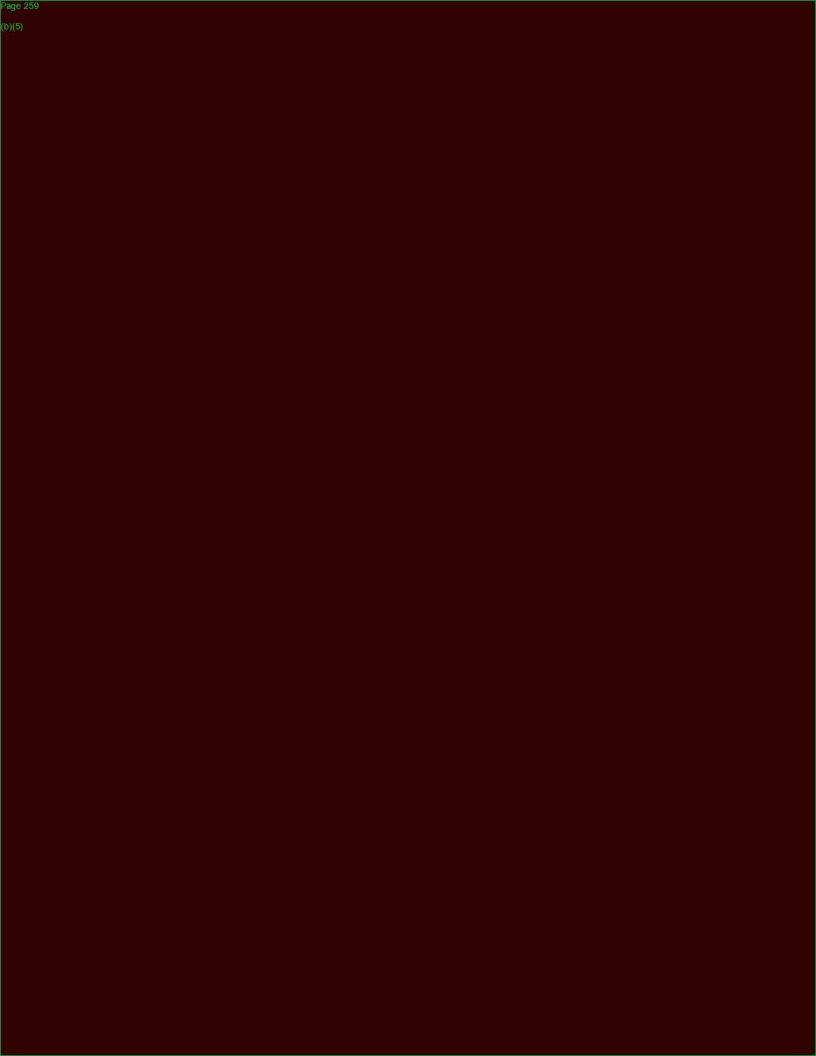
Subject: Draft HAN - still in clearance

Attachments: DRAFT Brief Myocarditis HAN 5.25.2021 to JIC - clean.docx

Draft attached. This is still in clearance.

Sharing as preview.





From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

**Sent:** Mon, 24 May 2021 16:58:59 +0000

To: Berger, Sherri (CDC/OCOO/OD); Goldstein, Robert (CDC/OD/OADPS)

Cc: Marissa Padilla

Subject: RE: Governors Call TPs

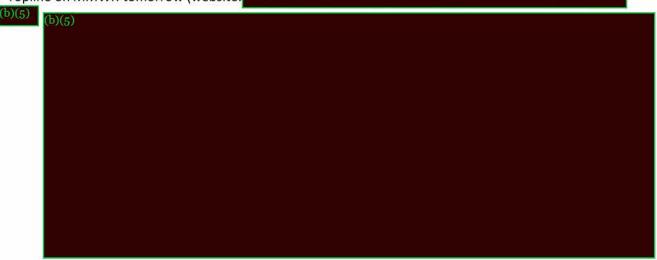
Attachments: Reactive on myocarditis and Tough QA\_05232021.docx

That sounds great! Here are some of the topline messages. Marissa and I spoke a bit about these last night. She will have good thoughts.

#### Reactive on myocarditis



### Topline on MMWR tomorrow (website: (b)(5)



From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Sent: Monday, May 24, 2021 10:47 AM

To: Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

<aws8@cdc.gov>

Cc: Marissa Padilla <mpadilla@globalstrategygroup.com>

Subject: RE: Governors Call TPs

#### +Marissa

From: Goldstein, Robert (CDC/OD/OADPS) < gyd2@cdc.gov>

Sent: Monday, May 24, 2021 10:46 AM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov">aws8@cdc.gov</a>

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

**Subject:** Governors Call TPs

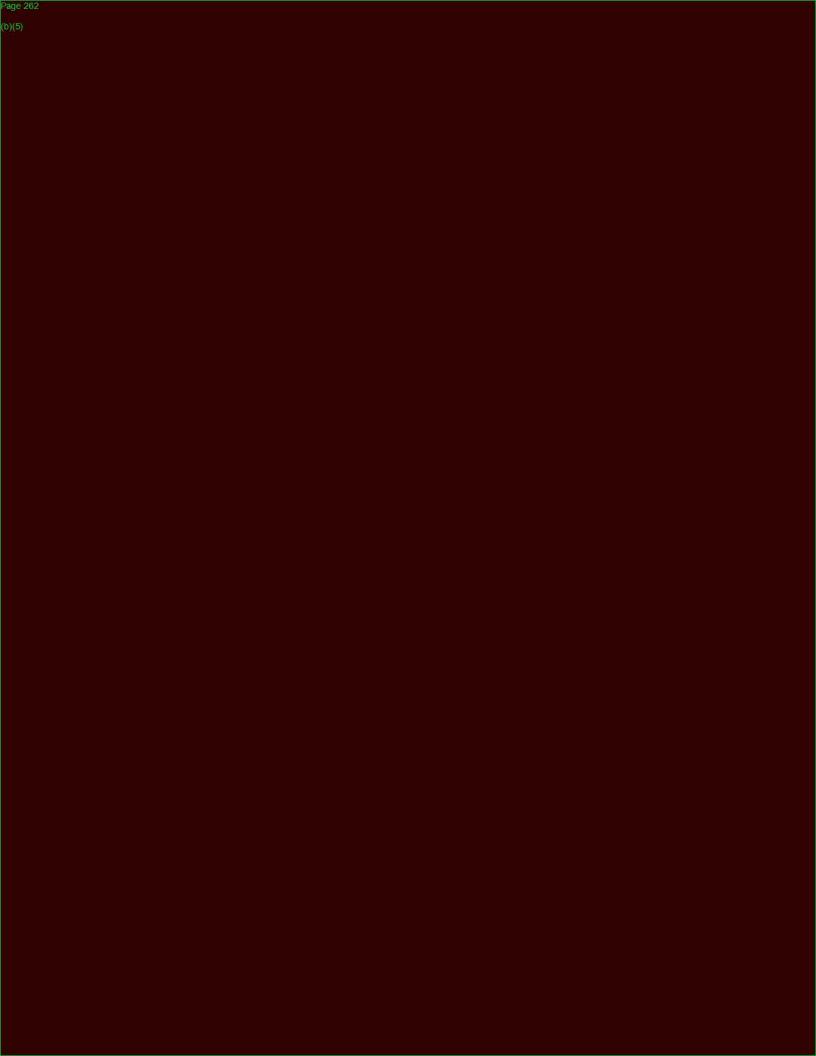
#### Abbigail,

I'm pulling together talking points for Rochelle's 10-15 minutes with the Governors tomorrow. Was thinking of the following, but wanted to make sure it fits with your goals for Comms this week:



I haven't seen any specific asks from the WH or the Governors.

-RObbie



From: Goldstein, Robert (CDC/OD/OADPS) Sent: Mon, 24 May 2021 23:29:16 +0000

Walensky, Rochelle (CDC/OD) To:

Berger, Sherri (CDC/OCOO/OD); Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) Cc:

Subject: **Governors Call TPs** 

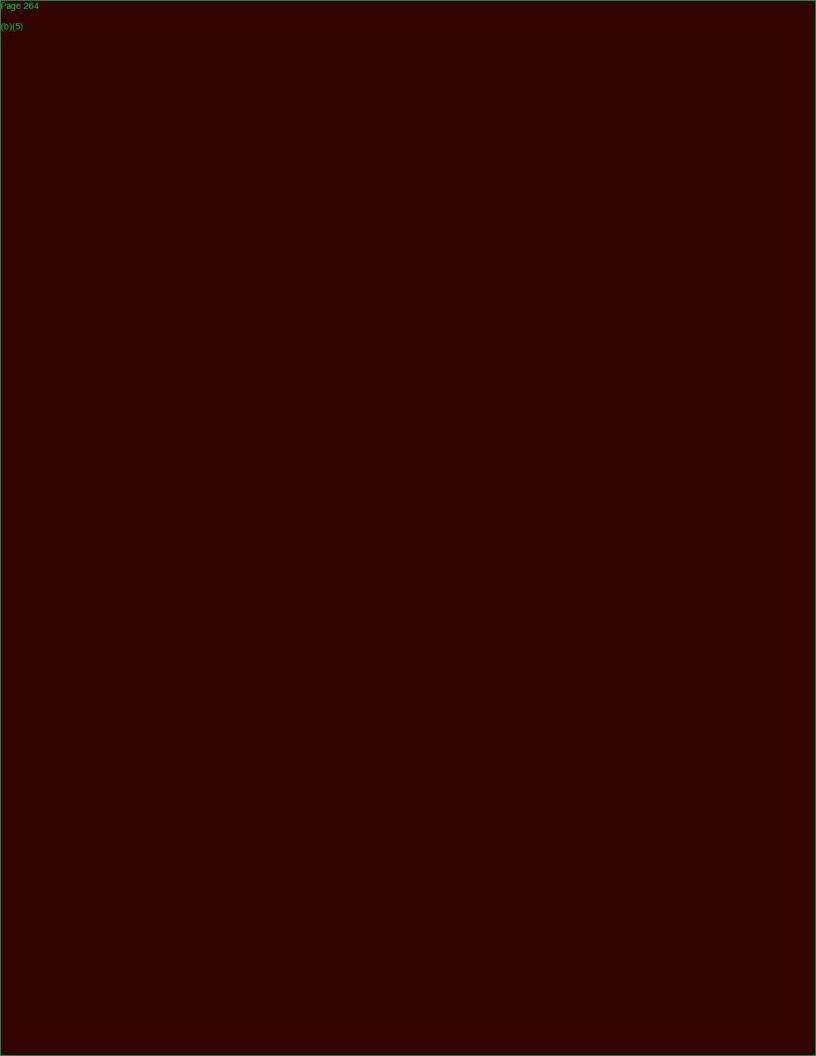
Attachments: Governor's Call\_05252021.docx

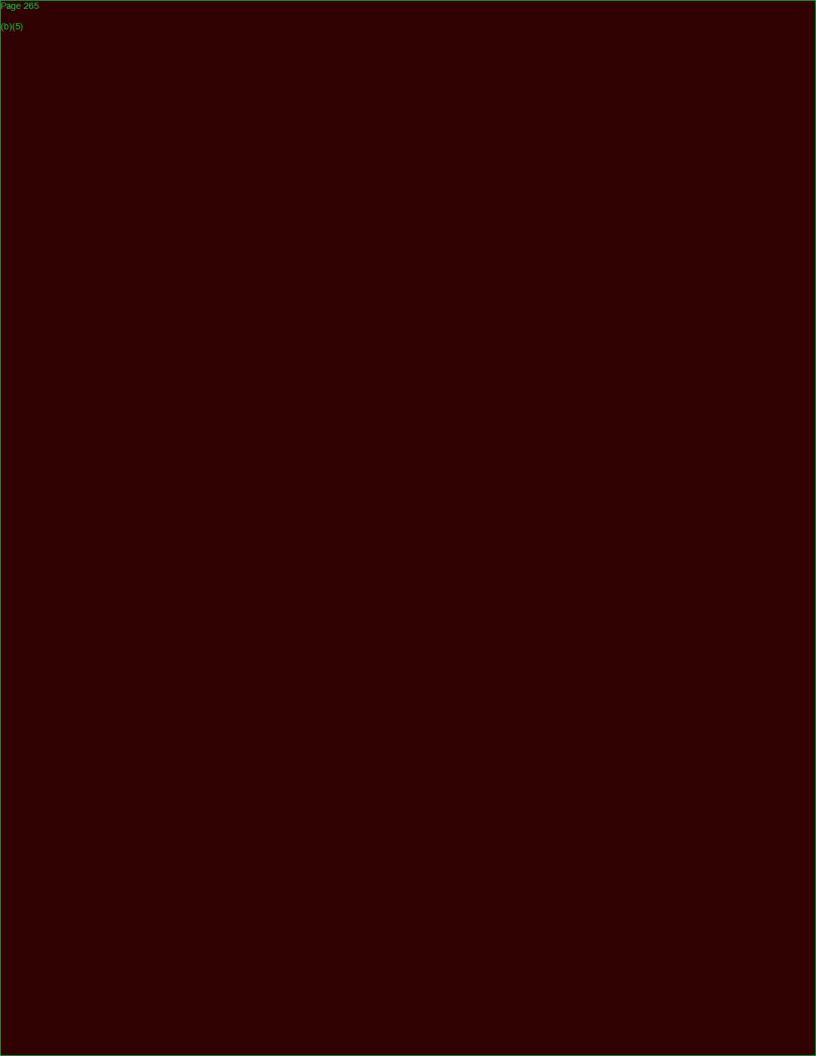
#### Rochelle,

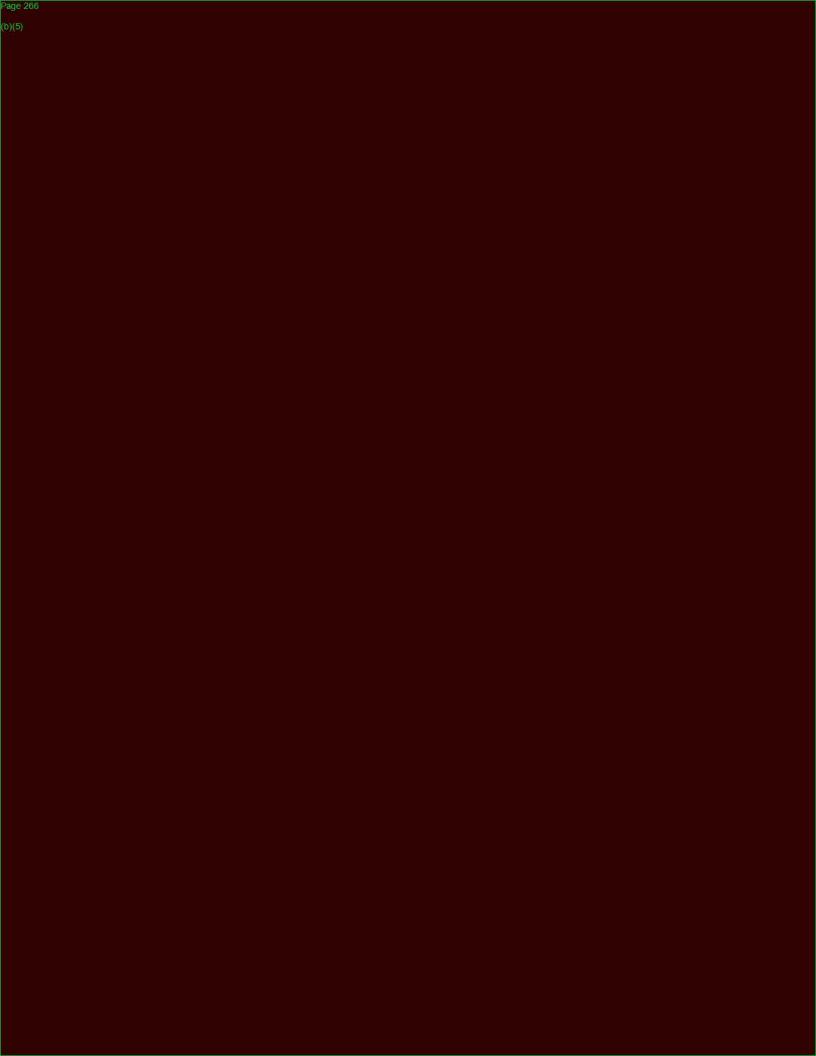
Attached are talking points for tomorrow's call with the Governors - starting with key metrics, talking briefly about breakthroughs (related to the MMWR for tomorrow), and then closing with myocarditis. I included the Q&As at the end in case you want them for reference.

One note - tomorrow we will document that 50% of adults are fully vaccinated in the country. Those numbers won't be released until after the call, but it will come out during the Press Briefing and thought you could foreshadow during this call, as well.

-Robbie







 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Fri, 14 May 2021 09:42:11 +0000

To: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD)

Subject: Re: Adolescent vaccine update

Many thanks, Henry. Please keep me close in the loop as these conversations and plans evolve.

#### Get Outlook for iOS

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>

Sent: Thursday, May 13, 2021 10:27 PM

To: Walensky, Rochelle (CDC/OD)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD)

Subject: FW: Adolescent vaccine update

#### b)(5)

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Sent: Thursday, May 13, 2021 9:46 PM

To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Posner, Sam (CDC/DDID/NCIRD/OD)

<shp5@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>

Cc: Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD)

<kaf6@cdc.gov>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>; Patel, Manish

(CDC/DDID/NCIRD/ID) <aul3@cdc.gov>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) <lem2@cdc.gov>;

Wharton, Melinda (CDC/DDID/NCIRD/ISD) < mew2@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) <vif6@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>; Mahon, Barbara (CDC/DDID/NCIRD/OD)

<bdd><bdm3@cdc.gov>

Subject: Re: Adolescent vaccine update

All,

Thanks for the call these evening.

My understanding of where things landed is (b)(5)
(b)(5)

b)(5)

If people have additional concerns or suggestions, please respond to this email.

Best

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>

Sent: Thursday, May 13, 2021 7:08:58 PM

**To:** Posner, Sam (CDC/DDID/NCIRD/OD) < shp5@cdc.gov>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Cc: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < <a href="mailto:kaf6@cdc.gov">kaf6@cdc.gov</a>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < <a href="mailto:ttnc4@cdc.gov">ttnc4@cdc.gov</a>; Patel, Manish (CDC/DDID/NCIRD/ID) < <a href="mailto:dem2@cdc.gov">gedc.gov</a>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) < <a href="mailto:mew2@cdc.gov">mew2@cdc.gov</a>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>; Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) < <a href="mailto:viif6@cdc.gov">viif6@cdc.gov</a>> <a href="mailto:Subject: RE: Adolescent vaccine update">Subject: RE: Adolescent vaccine update</a>

One follow-up. Peter Marks called me about something else and we discussed this briefly. He agreed communications around this is incredibly challenging and this is not the same as TTS. Once we decide if we are putting anything out to providers, he would like to see a draft in advance.

Thanks! Amanda

From: Posner, Sam (CDC/DDID/NCIRD/OD) <shp5@cdc.gov>

Sent: Thursday, May 13, 2021 4:46 PM

To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc@cdc.gov>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) <<u>vmo0@cdc.gov</u>>; Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:hfw3@cdc.gov">hfw3@cdc.gov</a>>

Cc: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < <a href="mailto:kaf6@cdc.gov">kaf6@cdc.gov</a>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < <a href="mailto:ttnc4@cdc.gov">tnc4@cdc.gov</a>; Patel, Manish (CDC/DDID/NCIRD/ID) < <a href="mailto:aul3@cdc.gov">aul3@cdc.gov</a>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) < <a href="mailto:mew2@cdc.gov">mew2@cdc.gov</a>; Shimabukuro, Tom (CDC/DDID/NCIRD/DD) < <a href="mailto:vif6@cdc.gov">vif6@cdc.gov</a>> Subject: RE: Adolescent vaccine update

#### Amanda and colleagues,

Thank you for this update. I concur with the approach and message. I can talk in five as well if needed. Definitely need to input from Drs W and S. Sam

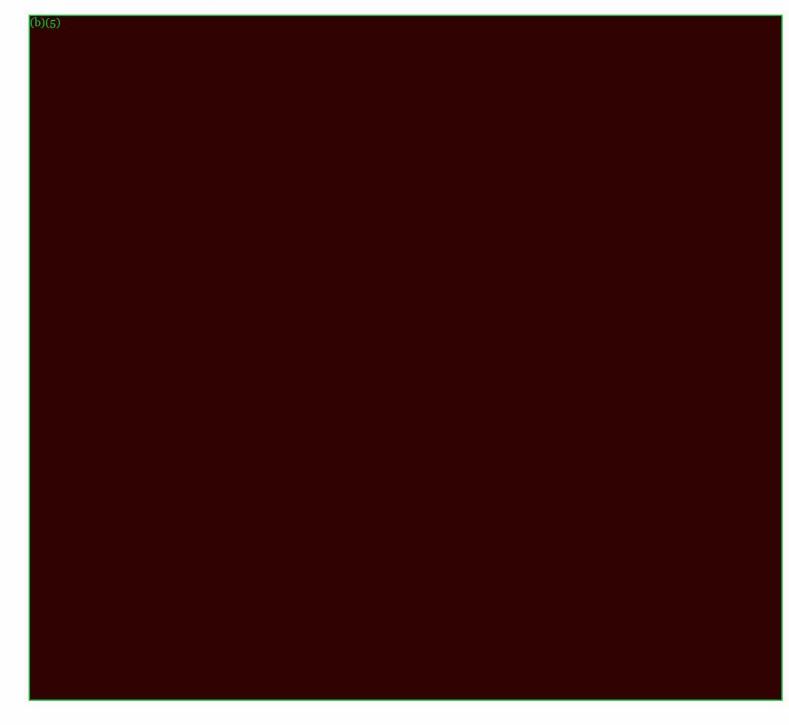
From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>

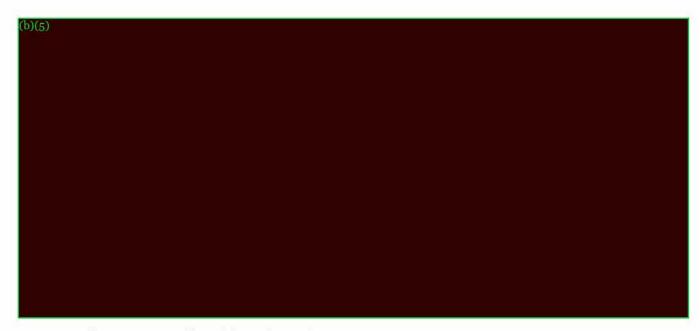
Sent: Thursday, May 13, 2021 4:28 PM

**To:** Posner, Sam (CDC/DDID/NCIRD/OD) < shp5@cdc.gov >; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov >; Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov >

Cc: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < <a href="mailto:kaf6@cdc.gov">kaf6@cdc.gov</a>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < <a href="mailto:ttnc4@cdc.gov">tnc4@cdc.gov</a>; Patel, Manish (CDC/DDID/NCIRD/ID) < <a href="mailto:aul3@cdc.gov">aul3@cdc.gov</a>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:ttnc4@cdc.gov">tem2@cdc.gov</a>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) < <a href="mailto:mew2@cdc.gov">mew2@cdc.gov</a>; Shimabukuro, Tom (CDC/DDID/NCIRD/DD) < <a href="mailto:viif6@cdc.gov">viif6@cdc.gov</a>> Subject: Adolescent vaccine update

Hi Sam, Dana, and Henry,





Do you all concur or would you like to discuss?

Thank you, Amanda

Amanda Cohn, MD CAPT, USPHS Chief Medical Officer, Vaccine Task Force CDC COVID-19 Response 
 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Sat, 15 May 2021 09:52:36 +0000

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD); Schuchat, Anne MD (CDC/OD);

Berger, Sherri (CDC/OCOO/OD); Goldstein, Robert (CDC/OD/OADPS)

Subject: RE: For Awareness: Monitoring Reports of Myocarditis

Grateful, Abbigail.

R

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

**Sent:** Friday, May 14, 2021 8:37 PM

**To:** Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>

Subject: Fwd: For Awareness: Monitoring Reports of Myocarditis

FYI.

Get Outlook for iOS

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) < hok4@cdc.gov>

Sent: Friday, May 14, 2021 8:35 PM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD); McNeill, Lorrie (FDA/CBER); Sams, Ian (HHS/ASPA)

Subject: FW: For Awareness: Monitoring Reports of Myocarditis

FYI

From: NCIRD Immunization Grantee Mailbox (CDC) <nipgrant@cdc.gov>

Sent: Friday, May 14, 2021 8:34 PM

To: NCIRD Immunization Grantee Mailbox (CDC) < nipgrant@cdc.gov>

Subject: For Awareness: Monitoring Reports of Myocarditis

Good evening,

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination. CDC is aware of these reports, which are rare given the number of vaccine doses administered, and continues to monitor available data.

Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. While myocarditis can be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart rhythms, shortness of breath, or chest pain.

As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the <u>Vaccine Adverse Event Reporting System (VAERS)</u> and the <u>Vaccine Safety Datalink (VSD)</u>.

To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and report all cases to VAERS.

CDC continues to recommend COVID-19 vaccination for people 12 years and older.

Thank you

### PLEASE DO NOT RESPOND OR REPLY DIRECTLY TO THIS E-MAIL

This message has been sent to program managers and field staff. Please review the individual announcements for contact information. If you do not see any contact information and need additional information, please contact your program manager. If you need access to the ISD Awardee SharePoint site, please contact your supervisor or your CDC project officer for more information.

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

**Sent:** Fri, 14 May 2021 20:55:18 +0000

To: Walke, Henry (CDC/DDID/NCEZID/DPEI); Walensky, Rochelle (CDC/OD); Butler,

Jay C. (CDC/DDID/OD); Cohn, Amanda (CDC/DDID/NCIRD/OD)

Subject: Reports re myocarditis

**FYI** 

From: Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Sent: Friday, May 14, 2021 3:09 PM

To: Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Fitter, David L. (CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>

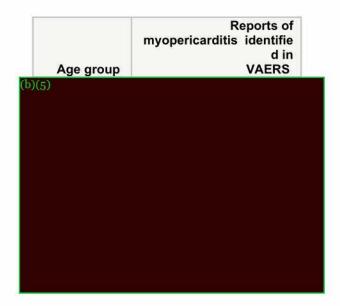
Cc: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>; Destefano, Frank (CDC/DDID/NCEZID/DHQP)

<fxd1@cdc.gov>; Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) <dbc0@cdc.gov>

Subject: RE: Reports re myocarditis

ALCON:

Please see below data:



Please be aware that these case reports are the result of an automated search, and includes reports among people 18 years and younger that are currently under review.

Please let me know if you have any questions. Thanks!

v/r,

John

John R. Su, M.D., Ph.D., M.P.H.

Lead, VAERS Team
CAPT, U.S. Public Health Service
NCEZID/ Division of Healthcare Quality Promotion
Centers for Disease Control and Prevention
1600 Clifton Road, MS V18-4
Atlanta, GA 30329-4027
ezu2@cdc.gov
404-498-0698 (office)
404-498-0666 (FAX)

From: Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>

Sent: Friday, May 14, 2021 1:14 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a yo 6 @cdc.gov >; Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Cc: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>; Meaney Delman, Dana M.

(CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Subject: RE: Reports re myocarditis

Thanks again Tom. Is it possible to send that number and the context to Dana before 3:30?

Copying her here for awareness.

RGK

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Sent: Friday, May 14, 2021 12:22 PM

To: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>; Fitter, David L. (CDC/DDPHSIS/CGH/GID)

<vid3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Cc: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Subject: RE: Reports re myocarditis

We can always provide automated counts. They are informative in the sense that they give you the high end of the possible case reports. To date, we have not observed anything unusual or unexpected.

From: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ttm1@cdc.gov">ttm1@cdc.gov</a>>

Sent: Friday, May 14, 2021 12:19 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>; Fitter, David L.

(CDC/DDPHSIS/CGH/GID) <vid3@cdc.gov>; Su, John (CDC/DDID/NCEZID/DHQP) <ezu2@cdc.gov>

Cc: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) <tnc4@cdc.gov>

Subject: RE: Reports re myocarditis

Thanks all! I think leadership is looking for a number soon if that is possible.

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a >ayv6@cdc.gov>

Sent: Friday, May 14, 2021 12:17 PM

To: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov >; Su, John (CDC/DDID/NCEZID/DHQP)

<ezu2@cdc.gov>

Cc: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov >; Greco Kone, Rebecca

(CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a> **Subject:** RE: Reports re myocarditis

Hi David – We have been monitoring myocarditis/pericarditis as a VAERS adverse event of special interest from the beginning. All these case reports are reviewed and attempts are made to follow-up to collect medical records. These cases are broken down by total identified via an automated search strategy, confirmed reports, and reports under review. We are in the process of updating the status on these reports and potentially reaching out to gather additional information on selected pediatric cases if necessary to prepare for an ACIP VaST call on Monday.

I'm Cc'ing John who can provide details; however, the number of pediatric cases is small.

From: Fitter, David L. (CDC/DDPHSIS/CGH/GID) < vid3@cdc.gov>

Sent: Friday, May 14, 2021 12:06 PM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v6@cdc.gov>

Cc: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov >; Greco Kone, Rebecca

(CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a> **Subject:** Reports re myocarditis

Hi Tom -

Was wondering (b)(5)

b)(5)

I recognize that we have just

started moving on this, but asks are starting to come.

Thanks, David From: Berger, Sherri (CDC/OCOO/OD)
Sent: Thu, 27 May 2021 12:23:43 +0000
To: Schuchat, Anne MD (CDC/OD)

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

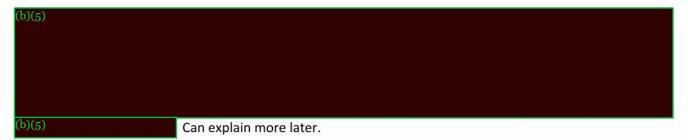
#### Thank you very much

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Sent: Thursday, May 27, 2021 8:18 AM

To: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)



From: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Sent: Thursday, May 27, 2021 8:15 AM

To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Hi! (b)(5) Thanks

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) <zud4@cdc.gov>

Sent: Tuesday, May 25, 2021 10:23 PM

To: Walensky, Rochelle (CDC/OD) <a href="mailto:sux7@cdc.gov">aux7@cdc.gov">; Schuchat, Anne MD (CDC/OD) <a href="mailto:schucken:acs1@cdc.gov">cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:hfw3@cdc.gov">hfw3@cdc.gov</a>>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Here's the response from NCIRD influenza experts.

BIG thanks to Burns, Erin (CDC/DDID/NCIRD/ID) <a href="mailto:eub5@cdc.gov">eub5@cdc.gov</a>, Fry, Alicia (CDC/DDID/NCIRD/ID) <a href="mailto:agf1@cdc.gov">agf1@cdc.gov</a>; Reed, Carrie (CDC/DDID/NCIRD/ID) <a href="mailto:ggi2@cdc.gov">ggi2@cdc.gov</a>; Iuliano, A. Danielle CDC/OID/NCIRD (CDC/DDID/NCIRD/ID) <a href="mailto:aoi0@cdc.gov">aoi0@cdc.gov</a>!!

Cheers,

## -john

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Sunday, May 23, 2021 7:13 AM

To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Thank you, Anne.

John, Can you please reach out to NCIRD for a response? (b)(5)

(b)(5)

sure we adequately respond to his concerns.

Thanks,

R

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Sent: Saturday, May 22, 2021 4:01 PM

To: Walensky, Rochelle (CDC/OD) < aux7@cdc.gov >; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

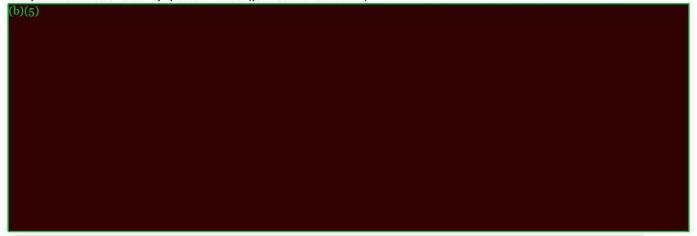
<zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov >; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

My two cents for the reply to Dr Faust (ps - what a name...):



From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Saturday, May 22, 2021 2:59 PM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov >; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Thank you, John,

I've reviewed the memo. Yes, please forward to them and ask for their reply. I'd be interested in this now myself so please keep me in the loop

+Anne as well (reattached for you, Anne).

Thank you, Rochelle

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Friday, May 21, 2021 6:29 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov >; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

## One follow-up on this:

I should have asked whether in addition to reaching out about myocarditis (had a good call with Celine and updated on her on what can be shared publicly), did you also (b)(5)

```
(b)(5)
```

# -john

From: Walensky, Rochelle (CDC/OD) < aux7@cdc.gov>

Sent: Friday, May 21, 2021 7:17 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov >; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

John,

Can I ask you to please handle with VTF?

Thanks,

R

From: Celine Gounder, MD, ScM (b)(6)

Sent: Thursday, May 20, 2021 9:56 PM

To: Walensky, Rochelle (CDC/OD) < aux7@cdc.gov >; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Subject: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Dear Rochelle and John,

Jeremy Faust and I are working on an op-ed for the NYT (already green lit) about the risks-benefits of COVID and COVID vaccination, including the risk of long-term side effects of COVID vaccination (low) versus the long-term risks of COVID (high).

As you know, one of the reasons many people give for not getting vaccinated is that there isn't enough long-term safety data on COVID vaccines. Another reason given for not vaccinating kids is that COVID is no worse than influenza in children.

- We're hearing more and more reports of post-vaccination myocarditis from MA and NY where
  Jeremy and I are based, as well as elsewhere across the country. Is there anything you can share
  about post-vaccination myocarditis cases (demographics? fatal / non-fatal?) Or other serious
  post-vaccination events?
- I previously shared a memo from Jeremy to John re: Qs on influenza and COVID morbidity/mortality among children. I'm attaching that memo again here. John, have you gotten any feedback on the Qs Jeremy outlined in his memo?

These data could just be shared with us on background. We just want to make sure that in framing our argument, we're not misrepresenting the facts.

Warmly, Céline

--

Céline Gounder, MD, ScM, FIDSA she / her / hers

CEO/Founder, JUST HUMAN PRODUCTIONS

Host/Producer, AMERICAN DIAGNOSIS & EPIDEMIC podcasts

Medical Analyst, CNN

Clinical Assistant Professor of Medicine & Infectious Diseases, <u>NYU School of Medicine</u> & Bellevue Hospital

Cell +1-917-275-2618 @celinegounder From: Gershman, Lynn E. (CDC/OD/OCS)

Sent: Fri, 28 May 2021 13:58:59 +0000

To: Berger, Sherri (CDC/OCOO/OD)

Subject: RE: Myocarditis Materials

Thank you!

Kindest Regards,

Lynn

Wisdom is knowing the right path to take; Integrity is taking it.

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

**Sent:** Friday, May 28, 2021 9:59 AM

To: (b)(6)

Cc: Gershman, Lynn E. (CDC/OD/OCS) <veu4@cdc.gov>

**Subject:** Myocarditis Materials

Good morning, see below. Thanks

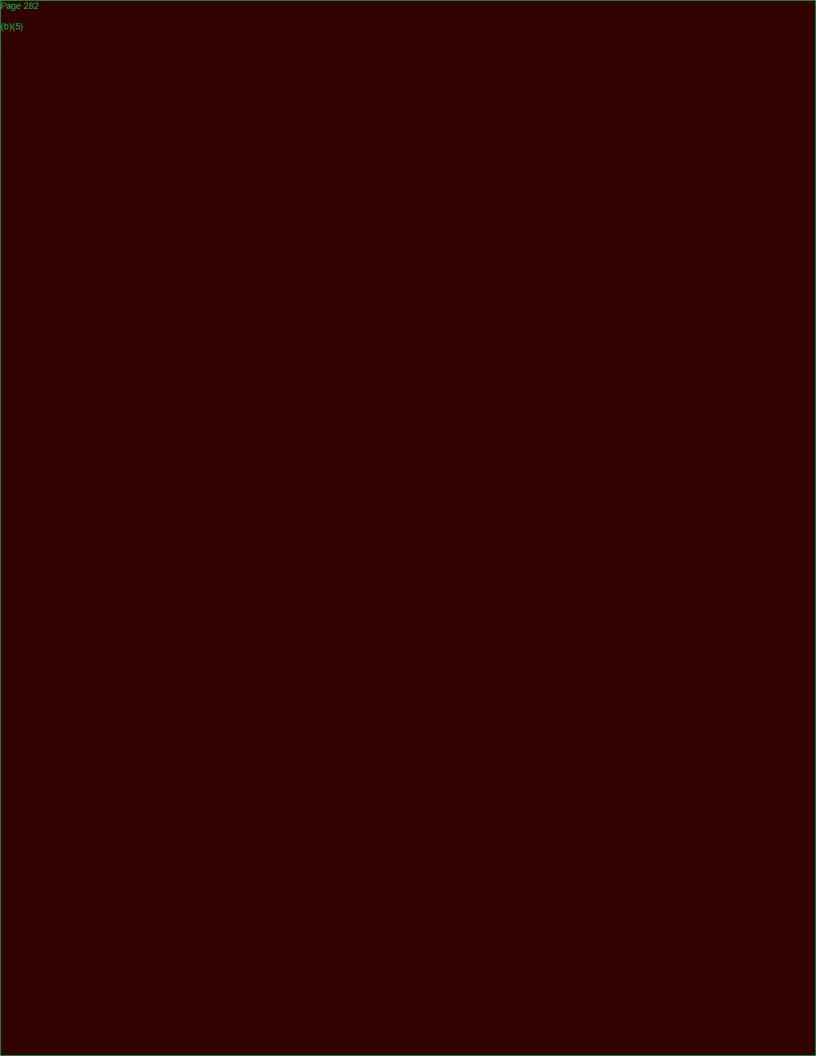
Public content: https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html

Clinical Considerations: <a href="https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html">https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html</a>

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

**Sent:** Fri, 14 May 2021 20:01:06 +0000 **To:** Walensky, Rochelle (CDC/OD)

Subject:Myocarditis\_V2Attachments:Myocarditis\_V2.docx



From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Thu, 13 May 2021 20:59:31 +0000
To: Walensky, Rochelle (CDC/OD)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD)

Subject: FW: Adolescent vaccine update

FYI, following up with VTF to for options on way forward.

From: Cohn, Amanda (CDC/DDID/NCIRD/OD) <ancoleration | control | ancoleration | a

Sent: Thursday, May 13, 2021 4:28 PM

**To:** Posner, Sam (CDC/DDID/NCIRD/OD) < shp5@cdc.gov >; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov >; Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov >

Cc: Greco Kone, Rebecca (CDC/DDPHSIS/OD) < <a href="mailto:ftm1@cdc.gov">ftm1@cdc.gov</a>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) < <a href="mailto:kaf6@cdc.gov">kaf6@cdc.gov</a>; Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < <a href="mailto:tnc4@cdc.gov">tnc4@cdc.gov</a>; Patel, Manish (CDC/DDID/NCIRD/ID) < <a href="mailto:qual3@cdc.gov">qual3@cdc.gov</a>; Markowitz, Lauri (CDC/DDID/NCIRD/DVD) < <a href="mailto:lem2@cdc.gov">lem2@cdc.gov</a>; Wharton, Melinda (CDC/DDID/NCIRD/ISD) < <a href="mailto:mew2@cdc.gov">mew2@cdc.gov</a>; Shimabukuro, Tom (CDC/DDID/NCIRD/DD) < <a href="mailto:vif6@cdc.gov">vif6@cdc.gov</a>; Mbaeyi, Sarah (CDC/DDID/NCIRD/OD) < <a href="mailto:vif6@cdc.gov">vif6@cdc.gov</a>>

Subject: Adolescent vaccine update

Hi Sam, Dana, and Henry,





Do you all concur or would you like to discuss?

Thank you, Amanda

Amanda Cohn, MD CAPT, USPHS Chief Medical Officer, Vaccine Task Force CDC COVID-19 Response 
 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Fri, 21 May 2021 15:39:54 +0000

**To:** Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI); Berger, Sherri (CDC/OCOO/OD)

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

LOL...was fun ©

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Sent: Friday, May 21, 2021 10:58 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:kfw3@cdc.gov">hfw3@cdc.gov</a>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Yes, was on it and will continue?

Did you get a (b)(

### -john

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Friday, May 21, 2021 7:17 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < <a href="mailto:zud4@cdc.gov">zud4@cdc.gov</a>>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

John,

Can I ask you to please handle with VTF?

Thanks,

R

From: Celine Gounder, MD, ScM (b)(6)

Sent: Thursday, May 20, 2021 9:56 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Subject: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Dear Rochelle and John,

Jeremy Faust and I are working on an op-ed for the NYT (already green lit) about the risks-benefits of COVID and COVID vaccination, including the risk of long-term side effects of COVID vaccination (low) versus the long-term risks of COVID (high).

As you know, one of the reasons many people give for not getting vaccinated is that there isn't enough long-term safety data on COVID vaccines. Another reason given for not vaccinating kids is that COVID is no worse than influenza in children.

- We're hearing more and more reports of post-vaccination myocarditis from MA and NY where
  Jeremy and I are based, as well as elsewhere across the country. Is there anything you can share
  about post-vaccination myocarditis cases (demographics? fatal / non-fatal?) Or other serious
  post-vaccination events?
- I previously shared a memo from Jeremy to John re: Qs on influenza and COVID morbidity/mortality among children. I'm attaching that memo again here. John, have you gotten any feedback on the Qs Jeremy outlined in his memo?

These data could just be shared with us on background. We just want to make sure that in framing our argument, we're not misrepresenting the facts.

Warmly, Céline

--

Céline Gounder, MD, ScM, FIDSA she / her / hers
CEO/Founder, JUST HUMAN PRODUCTIONS
Host/Producer, AMERICAN DIAGNOSIS & EPIDEMIC podcasts
Medical Analyst, CNN
Clinical Assistant Professor of Medicine & Infectious Diseases, NYU School of Medicine & Bellevue
Hospital
Cell +1-917-275-2618
@celinegounder

Abbigail Tumpey, MPH CHES
Acting Associate Director for Communication
Centers for Disease Control and Prevention
1600 Clifton Rd. NE
Atlanta, GA

Phone: 404-639-1125 Cell: 404-259-7064

Email: atumpey@cdc.gov

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) < hok4@cdc.gov>

Sent: Thursday, May 27, 2021 6:13 PM

To: Caccomo, Stephanie (FDA/OC) < <a href="mailto:Stephanie.Caccomo@fda.hhs.gov">Stephanie (FDA/CBER)</a>); McNeill, Lorrie (FDA/CBER)

<Lorrie.McNeill@fda.hhs.gov>

Cc: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) < aws8@cdc.gov >; Schindelar, Jessica (CDC/DDID/NCEZID/DHQP) < ghq1@cdc.gov >; Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov >; Stryker, Jo Ellen (CDC/DDID/NCHHSTP/DHPIRS) < gux6@cdc.gov >

Subject: Updated myocarditis documents

Importance: High

Stephanie and Lorrie,

Thanks for jumping on the phone with us earlier this afternoon to talk through the language around aftercare



Thanks, Kristen

Kristen Nordlund
CDC Public Affairs

p. 404.639.7387 | c. 404.956.0336 | e. hok4@cdc.gov

Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) From:

Sent: Sun, 23 May 2021 19:18:45 +0000 To: Walensky, Rochelle (CDC/OD)

Cc: Goldstein, Robert (CDC/OD/OADPS); Berger, Sherri (CDC/OCOO/OD); McDonald,

Jason (CDC/OD/OADC); Walke, Henry (CDC/DDID/NCEZID/DPEI); Daskalakis, Demetre

(CDC/DDID/NCHHSTP/DHP)

Subject: Re: Short media statement

Got it.

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Sunday, May 23, 2021 3:16 PM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

Cc: Goldstein, Robert (CDC/OD/OADPS); Berger, Sherri (CDC/OCOO/OD); McDonald, Jason

(CDC/OD/OADC); Walke, Henry (CDC/DDID/NCEZID/DPEI); Daskalakis, Demetre

(CDC/DDID/NCHHSTP/DHP)

Subject: RE: Short media statement

A quick thought -(b)(5) b)(5)

I think (b)(5)

R

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Sent: Sunday, May 23, 2021 1:25 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>; Walke, Henry

(CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP)

<yzq5@cdc.gov>

Subject: Short media statement

Rochelle,

Here is a short media statement that people are reviewing.



#### Regards,

#### Abbigail

Abbigail Tumpey, MPH CHES
Acting Associate Director for Communication
Centers for Disease Control and Prevention
1600 Clifton Rd. NE
Atlanta, GA

Phone: 404-639-1125 Cell: 404-259-7064

Email: atumpey@cdc.gov

From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Fri, 21 May 2021 13:41:17 +0000

To: Walensky, Rochelle (CDC/OD); Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP)

Cc: Berger, Sherri (CDC/OCOO/OD); Schuchat, Anne MD (CDC/OD)

Subject: Re: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

+ Anne

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>

Sent: Friday, May 21, 2021 9:31:33 AM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:kfw3@cdc.gov">hfw3@cdc.gov</a>; Walensky, Rochelle (CDC/OD)

<aux7@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Subject: RE: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

#### I think (b)(5)

#### (b)(5)

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>

Sent: Friday, May 21, 2021 9:30 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP)

<yzq5@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Subject: Re: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

#### (b)(5)

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) < yzq5@cdc.gov>

Sent: Friday, May 21, 2021 9:26:48 AM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:kfw3@cdc.gov">hfw3@cdc.gov</a>; Walensky, Rochelle (CDC/OD)

<aux7@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) < sob8@cdc.gov>

Subject: Quick Follow ups from 830: Myocarditis and Retail Pharmacy Updates

#### (b)(5)

#### Demetre C. Daskalakis, M.D., M.P.H.

COVID CDC Response Role: Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention

1600 Clifton Road, NE (Mailstop US8-5)

Atlanta, GA 30329-4027

Tel: 404-639-0900 | Fax: 404-639-0897 Email: <u>ddaskalakis@cdc.gov</u> or <u>yzq5@cdc.gov</u> Pronouns: He/His/Him

From: Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

**Sent:** Fri, 21 May 2021 14:58:31 +0000 **To:** Berger, Sherri (CDC/OCOO/OD)

Subject: RE: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

#### Also working on response to your earlier query

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Friday, May 21, 2021 7:17 AM

To: Brooks, John T. (CDC/DDID/NCHHSTP/DHP) < zud4@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>

Subject: FW: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

John,

Can I ask you to please handle with VTF?

Thanks,

R

From: Celine Gounder, MD, ScM (6)(6)

**Sent:** Thursday, May 20, 2021 9:56 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Brooks, John T. (CDC/DDID/NCHHSTP/DHP)

<zud4@cdc.gov>

Subject: Qs re: NYT oped Jeremy Faust and I are writing (already green lit)

Dear Rochelle and John,

Jeremy Faust and I are working on an op-ed for the NYT (already green lit) about the risks-benefits of COVID and COVID vaccination, including the risk of long-term side effects of COVID vaccination (low) versus the long-term risks of COVID (high).

As you know, one of the reasons many people give for not getting vaccinated is that there isn't enough long-term safety data on COVID vaccines. Another reason given for not vaccinating kids is that COVID is no worse than influenza in children.

- We're hearing more and more reports of post-vaccination myocarditis from MA and NY where
  Jeremy and I are based, as well as elsewhere across the country. Is there anything you can share
  about post-vaccination myocarditis cases (demographics? fatal / non-fatal?) Or other serious
  post-vaccination events?
- I previously shared a memo from Jeremy to John re: Qs on influenza and COVID
  morbidity/mortality among children. I'm attaching that memo again here. John, have you gotten
  any feedback on the Qs Jeremy outlined in his memo?

These data could just be shared with us on background. We just want to make sure that in framing our argument, we're not misrepresenting the facts.

Warmly, Céline

--

Céline Gounder, MD, ScM, FIDSA she / her / hers

CEO/Founder, JUST HUMAN PRODUCTIONS

Host/Producer, AMERICAN DIAGNOSIS & EPIDEMIC podcasts

Medical Analyst, CNN

Clinical Assistant Professor of Medicine & Infectious Diseases, NYU School of Medicine & Bellevue

Hospital

Cell +1-917-275-2618

@celinegounder

From: Walke, Henry (CDC/DDID/NCEZID/DPEI)

**Sent:** Tue, 27 Apr 2021 14:33:40 +0000 **To:** Walensky, Rochelle (CDC/OD)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD)

Subject: FW: Myocarditis

#### See below

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Sent: Tuesday, April 27, 2021 10:22 AM

<acs1@cdc.gov>

Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc0@cdc.gov>; Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>; Fox, Kimberley (CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Cardo, Denise M. MD

(CDC/DDID/NCEZID/DHQP) < dbc0@cdc.gov>

Subject: Myocarditis

Henry

I think I sent this to you yesterday. Denise C and I discussed.

Hope this is what you need.

Best

Dana

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Monday, April 26, 2021 2:43 PM

To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov >; Cardo, Denise M. MD

(CDC/DDID/NCEZID/DHQP) < dbc0@cdc.gov>

Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov>; Tumpey, Abbigail

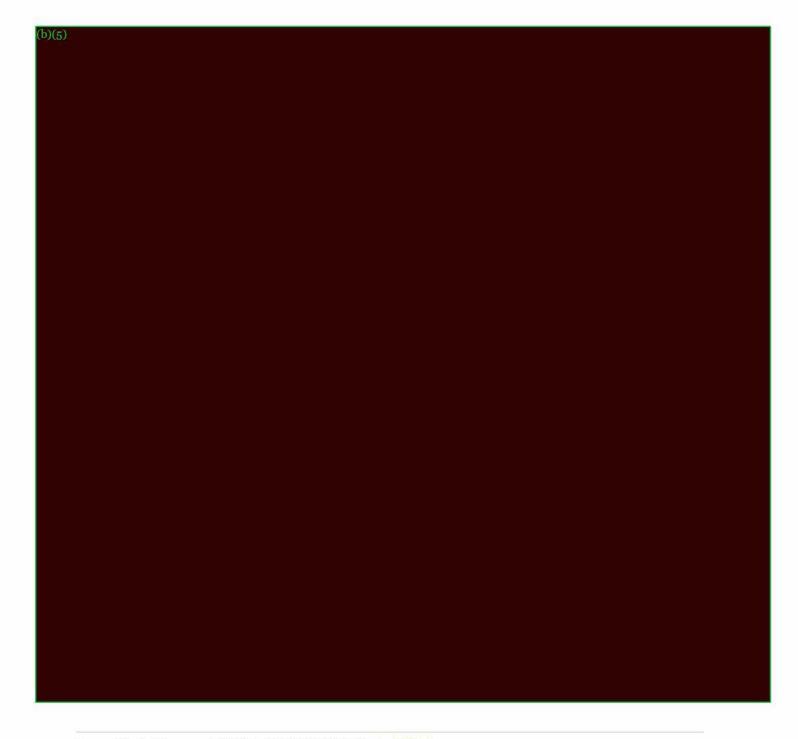
(CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

<vmo0@cdc.gov>

Subject: RE: Please read: Myocarditis

Here are some bullets (b)(5)

(b)(5)



From: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Sent: Monday, April 26, 2021 1:59 PM

To: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">dbc0@cdc.gov</a>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) <a y v 6 @ cdc.gov >

Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov >; Tumpey, Abbigail

(CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

<vmo0@cdc.gov>

Subject: RE: Please read: Myocarditis

Thanks, Denise. Asking Tom to add a few bullets about DoD findings.

tom

From: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < dbc0@cdc.gov>

Sent: Monday, April 26, 2021 1:42 PM

To: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>; Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov>

Cc: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov >; Tumpey, Abbigail

(CDC/DDPHSS/CSELS/OD) < aws8@cdc.gov >; Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

<vmo0@cdc.gov>

Subject: Please read: Myocarditis

Importance: High

Tom C and Tom S,

Please provide few bullets to CDC (as FYI) about the DoD info on myocarditis/pericarditis. I think it is

#### b)(5)

Thanks, Denise.

From: Coffin, Nicole (CDC/DDID/NCEZID/DHQP) < ndc3@cdc.gov>

Sent: Monday, April 26, 2021 1:13 PM

**To:** Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">dbc0@cdc.gov</a>; Kroop, Seth (CDC/DDID/NCEZID/DHQP) < <a href="mailto:wpw7@cdc.gov">wpw7@cdc.gov</a>; Moran, Kerri (CDC/DDID/NCEZID/DHQP)

<ytb5@cdc.gov>; Joshi, Cecilia (CDC/DDID/NCEZID/DHQP) <any9@cdc.gov>

Cc: Schindelar, Jessica (CDC/DDID/NCEZID/DHQP) < ghq1@cdc.gov >

Subject: FW: Myocarditis

FYSA, in case asked in other channels.

Below is cleared response from Tom and VEU that Abbigail Tumpey will use to respond to a question (b)(5)



https://www.cdc.gov/vaccines/acip/meetings/downloads/slides-2021-02/28-03-01/05-covid-Shimabukuro.pdf

https://www.cdc.gov/mmwr/volumes/70/wr/mm7008e3.htm

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

**Sent:** Fri, 14 May 2021 23:16:02 +0000

**To:** Walensky, Rochelle (CDC/OD); Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID); Walke, Henry (CDC/DDID/NCEZID/DPEI); Cohn, Amanda (CDC/DDID/NCIRD/OD); Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP); Wharton, Melinda

(CDC/DDID/NCIRD/ISD)

Cc: Nordlund, Kristen (CDC/DDID/NCIRD/OD)

**Subject:** Re: Language- ok?

Waiting to FDA to weigh in.

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Friday, May 14, 2021 7:12 PM

To: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID); Walke, Henry

(CDC/DDID/NCEZID/DPEI); Cohn, Amanda (CDC/DDID/NCIRD/OD); Shimabukuro, Tom

(CDC/DDID/NCEZID/DHQP); Wharton, Melinda (CDC/DDID/NCIRD/ISD)

Cc: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

Subject: RE: Language- ok?

Great...many thanks, when others are signed off, I am as well.

Thank you,

R

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Sent: Friday, May 14, 2021 7:10 PM

**To:** Walke, Henry (CDC/DDID/NCEZID/DPEI) <a href="mailto:know;">hfw3@cdc.gov>; Walensky, Rochelle (CDC/OD) <a href="mailto:know;">aux7@cdc.gov>; Cohn, Amanda (CDC/DDID/NCIRD/OD) <a href="mailto:know;">anc0@cdc.gov>; Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:know;">ayv6@cdc.gov>; Wharton, Melinda (CDC/DDID/NCIRD/ISD)</a>

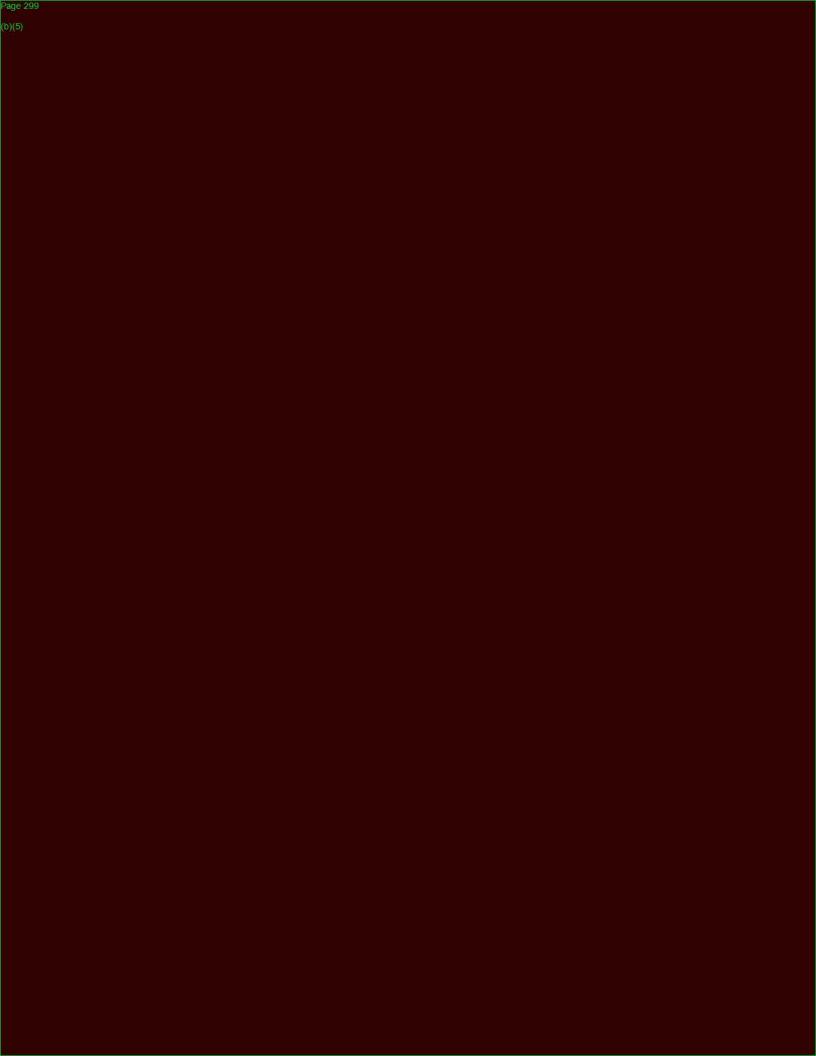
<mew2@cdc.gov>

Cc: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Subject: Language- ok?

Here is the latest- ok with everyone. Waiting on HHS approval and sent to FDA





From: Kwak, Grace EOP/WHO

Sent:Fri, 28 May 2021 14:00:29 +0000To:Berger, Sherri (CDC/OCOO/OD)Cc:Gershman, Lynn E. (CDC/OD/OCS)

Subject: RE: Myocarditis Materials

#### Thank you so much, Sherri!

From: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>

Sent: Friday, May 28, 2021 9:59 AM

To: Kwak, Grace EOP/WHO (b)(6)

Cc: Gershman, Lynn E. (CDC/OD/OCS) <veu4@cdc.gov>

**Subject:** Myocarditis Materials

Good morning, see below. Thanks

Public content: <a href="https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html">https://www.cdc.gov/coronavirus/2019-ncov/vaccines/safety/myocarditis.html</a>

Clinical Considerations: <a href="https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html">https://www.cdc.gov/vaccines/covid-19/clinical-considerations/myocarditis.html</a>

From: Walensky, Rochelle (CDC/OD)

Sent: Mon, 19 Apr 2021 13:55:42 +0000

To: Schuchat, Anne MD (CDC/OD)

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Subject: Re: Pericarditis and Mrna vaccines

Super helpful. Thank you!

Get Outlook for iOS

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Sent: Monday, April 19, 2021 9:49:34 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Subject: Fwd: Pericarditis and Mrna vaccines

#### Get Outlook for iOS

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Sent: Monday, April 19, 2021 9:48:31 AM

To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>; Walke, Henry (CDC/DDID/NCEZID/DPEI)

<hfw3@cdc.gov>

Subject: FW: Pericarditis and Mrna vaccines

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <ayv6@cdc.gov>

Sent: Monday, April 19, 2021 9:47 AM

To: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>; Clark, Thomas A.

(CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Cc: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) <dbc0@cdc.gov>; Fox, Kimberley

(CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>

Subject: RE: Pericarditis and Mrna vaccines

DoD and the Israeli MOH think they have a signal for myocarditis with mRNA vaccines, but there is potentially a lot of ascertainment bias in the DoD data. We don't have any evidence to suggest a signal or a safety problem for myocarditis or pericarditis with mRNA vaccines from VAERS and VSD surveillance and FDA and VA have not detected any signals in their monitoring.

DoD has submitted a case series of myocarditis following mRNA vaccines, so that might be published sometime in the future.

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov >

Sent: Monday, April 19, 2021 9:42 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a yo 6@cdc.gov>; Clark, Thomas A.

(CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Cc: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) <a href="mailto:cbc/dbc0@cdc.gov">dbc0@cdc.gov</a>; Fox, Kimberley

(CDC/DDID/NCIRD/DBD) < kaf6@cdc.gov >; Greco Kone, Rebecca (CDC/DDPHSIS/OD) < ftm1@cdc.gov > Subject: Pericarditis and Mrna vaccines

Anne S is on the deputies call with WH right now and is asking if there has been any signal with pericarditis and mRNA vaccines.

	20		-		100							
1	I am not	aware	of ar	nything	hut	inct	Wan	ted	to	chi	ock	
4	I GIII IIOL	avvale	UI al	IVUILIE	Dut	IUSL	vvall	LUU	LU	-111		٠.

Best

Dana

From: Walensky, Rochelle (CDC/OD) Sent: Sun, 23 May 2021 16:23:50 +0000

To: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Subject: Re: q

Great -

Get Outlook for iOS

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Sunday, May 23, 2021 12:00:24 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Subject: q

Can you take a look at these Oliver slides from before. Want to make sure we are synced.

(b)(5)

Henry Walke, MD, MPH Incident Manager CDC COVID-19 Response +1-404-639-3582 (office) +1-404-452-9624 (mobile) hwalke@cdc.gov

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

Fri, 14 May 2021 21:05:34 +0000 Sent:

Walensky, Rochelle (CDC/OD); Schuchat, Anne MD (CDC/OD) To:

McDonald, Jason (CDC/OD/OADC); Berger, Sherri (CDC/OCOO/OD); Goldstein, Cc:

Robert (CDC/OD/OADPS)

Subject: FYI: Myocarditis email

Per our discussion. Coordinating strategy.

From: Nordlund, Kristen (CDC/DDID/NCIRD/OD) <hok4@cdc.gov>

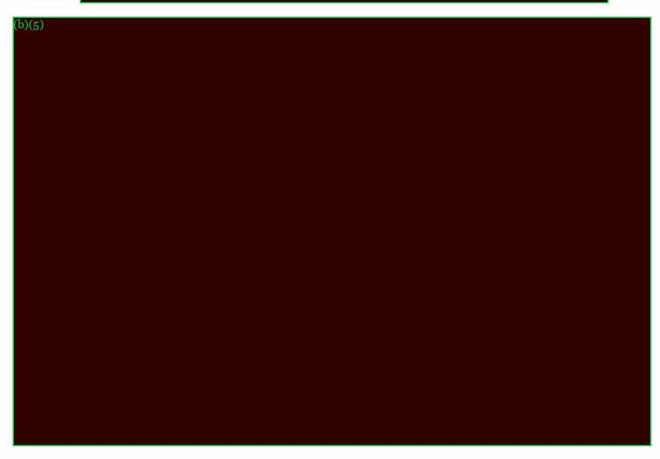
Sent: Friday, May 14, 2021 4:59 PM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

Cc: Cohn, Amanda (CDC/DDID/NCIRD/OD); Meaney Delman, Dana M.

(CDC/DDNID/NCBDDD/DBDID) Subject: Myocarditis email

CDC plans (b)(5)



 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Wed, 28 Apr 2021 19:43:13 +0000

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

Cc: McDonald, Jason (CDC/OD/OADC); Berger, Sherri (CDC/OCOO/OD); Goldstein,

Robert (CDC/OD/OADPS); Warner, Agnes (CDC/OD/OCS)

Subject: RE: Myocarditis TPs

Great – thanks, so (b)(5)

Thank you for running this down...

R

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Sent: Wednesday, April 28, 2021 3:13 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Warner, Agnes (CDC/OD/OCS)

<bli><bli>dc.gov>

Subject: RE: Myocarditis TPs

Rochelle,

The vaccine safety team is working (b)(

They are working with DoD on this now.

Re: Israel—they are doing continued surveillance.

(b)(5)

Please let me know if you need more.

Regards,

Abbigail

From: Walensky, Rochelle (CDC/OD) <a ux 7@cdc.gov>

Sent: Wednesday, April 28, 2021 1:59 PM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Cc: McDonald, Jason (CDC/OD/OADC) <gnf0@cdc.gov>; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Warner, Agnes (CDC/OD/OCS)

<bli><bli>dcdc.gov>

Subject: RE: Myocarditis TPs

Very helpful...so presumably (b)(5)

Do you have any update on what they are finding/doing in Israel?

Thank you!

R

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a ws8@cdc.gov>

Sent: Wednesday, April 28, 2021 1:49 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: McDonald, Jason (CDC/OD/OADC) < gnf0@cdc.gov >; Berger, Sherri (CDC/OCOO/OD)

<sob8@cdc.gov>; Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>; Warner, Agnes (CDC/OD/OCS)

<br/>bli8@cdc.gov>

Subject: RE: Myocarditis TPs

Rochelle,

Below is a response and at the bottom are internal notes from the discussions with DoD. Please let me know if you need more.





Notes from DoD discussion (not for public release, but for your awareness)

```
(b)(5)
```

Questions and discussion

(b)(5)	

Regards,

Abbigail

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Wednesday, April 28, 2021 9:56 AM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <a href="mailto:aws8@cdc.gov">aws8@cdc.gov</a>

**Subject:** Myocarditis TPs

We need this for the presser – we are we in running this down?



Thanks!

R

From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Mon, 19 Apr 2021 15:07:50 +0000

To: Walensky, Rochelle (CDC/OD); Schuchat, Anne MD (CDC/OD)

Cc: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

Subject: RE: Pericarditis and Mrna vaccines

Yep on it.

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Monday, April 19, 2021 11:06 AM

To: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>; Tumpey, Abbigail

(CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>
Subject: RE: Pericarditis and Mrna vaccines

Much – great – thank you!

Henry -(b)(5)

we should (b)(5)

Thank yoU!

R

From: Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

**Sent:** Monday, April 19, 2021 11:03 AM

To: Walensky, Rochelle (CDC/OD) < aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Subject: Fwd: Pericarditis and Mrna vaccines

More reassuring
Get Outlook for iOS

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Sent: Monday, April 19, 2021 11:01 AM

To: Schuchat, Anne MD (CDC/OD); Walke, Henry (CDC/DDID/NCEZID/DPEI)

Subject: FW: Pericarditis and Mrna vaccines

FYI

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Monday, April 19, 2021 10:28 AM

**To:** Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < <a href="mailto:vmo0@cdc.gov">vmo0@cdc.gov</a>; Cohn, Amanda (CDC/DDID/NCIRD/DD) < <a href="mailto:anco@cdc.gov">anco@cdc.gov</a>; Oliver, Sara Elizabeth (CDC/DDID/NCIRD/DVD)

<yxo4@cdc.gov>

Cc: Clark, Thomas A. (CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Subject: RE: Pericarditis and Mrna vaccines

We reviewed the VSD RCA data this morning and discussed the DoD data. We have substantial doses administered in younger age groups in VSD and don't have a hint of a signal; it's actually protective in the vaccinated concurrent comparator. We aren't really sure why DoD thinks they have a signal.

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Sent: Monday, April 19, 2021 9:52 AM

To: Cohn, Amanda (CDC/DDID/NCIRD/OD) <anc@cdc.gov>; Oliver, Sara Elizabeth

(CDC/DDID/NCIRD/DVD) <yxo4@cdc.gov>

Cc: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a y v 6 @cdc.gov >; Clark, Thomas A.

(CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov > Subject: FW: Pericarditis and Mrna vaccines

Anne thinks (b)(5)

From: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) <a href="mailto:ayv6@cdc.gov">ayv6@cdc.gov">ayv6@cdc.gov</a>

Sent: Monday, April 19, 2021 9:47 AM

To: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>; Clark, Thomas A.

(CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Cc: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < dbc0@cdc.gov>; Fox, Kimberley

(CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>

Subject: RE: Pericarditis and Mrna vaccines

DoD and the Israeli MOH think they have a signal for myocarditis with mRNA vaccines, but there is potentially a lot of ascertainment bias in the DoD data. We don't have any evidence to suggest a signal or a safety problem for myocarditis or pericarditis with mRNA vaccines from VAERS and VSD surveillance and FDA and VA have not detected any signals in their monitoring.

DoD has submitted a case series of myocarditis following mRNA vaccines, so that might be published sometime in the future.

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) vmo0@cdc.gov>

Sent: Monday, April 19, 2021 9:42 AM

To: Shimabukuro, Tom (CDC/DDID/NCEZID/DHQP) < ayv6@cdc.gov>; Clark, Thomas A.

(CDC/DDID/NCIRD/DVD) < tnc4@cdc.gov>

Cc: Cardo, Denise M. MD (CDC/DDID/NCEZID/DHQP) < <a href="mailto:dbc0@cdc.gov">dbc0@cdc.gov</a>; Fox, Kimberley

(CDC/DDID/NCIRD/DBD) <kaf6@cdc.gov>; Greco Kone, Rebecca (CDC/DDPHSIS/OD) <ftm1@cdc.gov>

Subject: Pericarditis and Mrna vaccines

Anne S is on the deputies call with WH right now and is asking if there has been any signal with pericarditis and mRNA vaccines.

I am not aware of anything but just wanted to check.

Best

Dana

 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Wed, 28 Apr 2021 16:01:34 +0000

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

**Subject:** RE: Myocarditis TPs

Super, thank you!

R

From: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

Sent: Wednesday, April 28, 2021 11:54 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Subject: RE: Myocarditis TPs

I am talking to the team now and will have something for you.

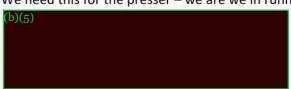
From: Walensky, Rochelle (CDC/OD) <a href="mailto:aux7@cdc.gov">aux7@cdc.gov</a>>

Sent: Wednesday, April 28, 2021 9:56 AM

To: Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD) <aws8@cdc.gov>

**Subject:** Myocarditis TPs

We need this for the presser – we are we in running this down?



Thanks!

R

From: Ohannessian, Dana (DPH)

**Sent:** Mon, 24 May 2021 11:47:03 +0000 **To:** Walensky, Rochelle (CDC/OD)

Subject: COVID-19 Vaccine Safety Message from CDC via Massachusetts Department of

**Public Health** 

URLs included to cut and paste into browsers should you choose to avoid clicking on embedded links.

MA DPH has received the following communication from CDC:

In recent weeks, there have been reports of myocarditis occurring after COVID-19 vaccination, including in Europe, where the EMA recently requested data from Pfizer and Moderna on reports of myocarditis and pericarditis after vaccination

- https://www.ema.europa.eu/en/news/meeting-highlights-pharmacovigilance-risk-assessment-commit tee-prac-3-6-may-2021

CDC is aware of these reports, which are rare given the number of vaccine doses administered and continues to monitor available data.

Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation of the lining outside the heart. In both cases, the body's immune system is causing inflammation in response to an infection or some other trigger. While myocarditis can be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart rhythms, shortness of breath, or chest pain.

As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the <u>Vaccine Adverse Event Reporting System (VAERS)</u> - <a href="https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vaers/index.html">https://www.cdc.gov/vaccinesafety/ensuringsafety/ensuringsafety/ensuringsafety/monitoring/vsd/index.html</a>. Datalink (VSD) - <a href="https://www.cdc.gov/vaccinesafety/ensuringsafety/monitoring/vsd/index.html">https://www.cdc.gov/vaccinesafety/ensuringsafety/ensuringsafety/monitoring/vsd/index.html</a>.

To date, there has not been a safety signal identified in either VAERS or VSD. CDC will continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19 vaccination and will share more information as it becomes available. Healthcare providers should consider myocarditis in an evaluation of chest pain after vaccination and report all cases to VAERS - https://vaers.hhs.gov/reportevent.html.

CDC continues to recommend COVID-19 vaccination for people 12 years and older.

From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Mon, 24 May 2021 00:15:14 +0000
To: Walensky, Rochelle (CDC/OD)

Subject: FW: Data by midweek question from RW

From: Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP) <yzq5@cdc.gov>

Sent: Sunday, May 23, 2021 8:12 PM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Subject: Data by midweek question from RW



#### Demetre C. Daskalakis, M.D., M.P.H.

Deputy Incident Manager and Senior Lead, Equity in COVID Data and Engagement

Director, Division of HIV/AIDS Prevention
National Center for HIV/AIDS, Viral Hepatitis, STD & TB Prevention
Centers for Disease Control and Prevention
1600 Clifton Road, NE (Mailstop US8-5)
Atlanta, GA 30329-4027

Tel: 404-639-0900 | Fax: 404-639-0897 Email: <u>ddaskalakis@cdc.gov</u> or <u>yzq5@cdc.gov</u>

Pronouns: He/His/Him

From: Walensky, Rochelle (CDC/OD)

Sent: Tue, 25 May 2021 01:04:30 +0000

To: Goldstein, Robert (CDC/OD/OADPS)

Cc: Berger, Sherri (CDC/OCOO/OD); Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

Subject: RE: Governors Call TPs

These look great...thanks much, Robbie and all.

We'll go with this.

Thank you!

Let's take a moment and celebrate the 50% mark...holy cow.

R

From: Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>

Sent: Monday, May 24, 2021 7:29 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Berger, Sherri (CDC/OCOO/OD) <sob8@cdc.gov>; Tumpey, Abbigail (CDC/DDPHSS/CSELS/OD)

<aws8@cdc.gov>

**Subject:** Governors Call TPs

Rochelle,

Attached are talking points for tomorrow's call with the Governors – starting with key metrics, talking briefly about breakthroughs (related to the MMWR for tomorrow), and then closing with myocarditis. I included the Q&As at the end in case you want them for reference.

One note – tomorrow we will document that 50% of adults are fully vaccinated in the country. Those numbers won't be released until after the call, but it will come out during the Press Briefing and thought you could foreshadow during this call, as well.

-Robbie

 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Wed, 28 Apr 2021 14:02:59 +0000

To: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID)

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Subject: RE: Myocarditis

Yes, thank you so much - I think

(b)(£

#### (b)(5

Thanks both,

R

From: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Sent: Wednesday, April 28, 2021 10:00 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Subject: RE: Myocarditis

Let me ask the safety team. You saw the summary from yesterday, right?

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Wednesday, April 28, 2021 9:58 AM

To: Meaney Delman, Dana M. (CDC/DDNID/NCBDDD/DBDID) < vmo0@cdc.gov>

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Subject: Myocarditis

Hi Dana,

On the deputies call there was

(b)(5)

#### (b)(5)

Thank you!

R

Walensky, Rochelle (CDC/OD) From: Sent: Sun, 23 May 2021 19:16:09 +0000

Walke, Henry (CDC/DDID/NCEZID/DPEI) To:

Subject: RE: DRAFT\_Myocarditis\_Advisory\_05232021\_1109

Great - sounds good...thank you!

R

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>

Sent: Sunday, May 23, 2021 1:33 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Subject: RE: DRAFT\_Myocarditis\_Advisory\_05232021\_1109

Perfect, will push it through.

I think Health advisory,

(b)(5)

From: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Sent: Sunday, May 23, 2021 1:17 PM

To: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov> Subject: RE: DRAFT\_Myocarditis\_Advisory\_05232021\_1109

Thank you - Will it be a full HAN -I'm fine with how this reads...grateful.

R

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Sunday, May 23, 2021 1:12 PM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov> Subject: DRAFT Myocarditis Advisory 05232021 1109

Latest HAN.

From: Walensky, Rochelle (CDC/OD)

Sent: Sat, 29 May 2021 13:35:15 +0000

To: Goldstein, Robert (CDC/OD/OADPS)

Subject: RE: JAMA Cardiology Article

Awesome...thank you!

R

From: Goldstein, Robert (CDC/OD/OADPS) <qyd2@cdc.gov>

Sent: Saturday, May 29, 2021 9:30 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Subject: JAMA Cardiology Article

Here's the article (link and attached):

Prevalence of Clinical and Subclinical Myocarditis in Competitive Athletes With Recent SARS-CoV-2
Infection: Results From the Big Ten COVID-19 Cardiac Registry | Cardiology | JAMA Cardiology | JAMA Network

From: Walensky, Rochelle (CDC/OD)

Sent: Wed, 28 Apr 2021 14:03:28 +0000

To: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Cc: Schuchat, Anne MD (CDC/OD)

Subject: RE: follow-up

#### Thanks much!

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) <hfw3@cdc.gov>

Sent: Wednesday, April 28, 2021 10:00 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>; Schuchat, Anne MD (CDC/OD) <acs1@cdc.gov>

Subject: follow-up

Will pull together talking points on myocarditis and share. Henry

Henry Walke, MD, MPH Incident Manager CDC COVID-19 Response +1-404-639-3582 (office) +1-404-452-9624 (mobile) hwalke@cdc.gov 
 From:
 Walensky, Rochelle (CDC/OD)

 Sent:
 Sun, 23 May 2021 15:13:01 +0000

To: Walke, Henry (CDC/DDID/NCEZID/DPEI)

Subject: RE: Myocarditis\_update deck 5232021\_FINAL (002)\_hw.pptx

#### Awesome...thank you!

From: Walke, Henry (CDC/DDID/NCEZID/DPEI) < hfw3@cdc.gov>

Sent: Sunday, May 23, 2021 11:07 AM

To: Walensky, Rochelle (CDC/OD) <aux7@cdc.gov>

Subject: Myocarditis\_update deck 5232021\_FINAL (002)\_hw.pptx

One slide with table if helpful

From: Walke, Henry (CDC/DDID/NCEZID/DPEI)
Sent: Sun, 23 May 2021 16:00:24 +0000
To: Walensky, Rochelle (CDC/OD)

Subject: c

Attachments: 06-COVID-Oliver-508.pdf

Can you take a look at these Oliver slides from before. Want to make sure we are synced.

For this afternoon we can make (b)(5)

(b)(5)

#### (b)(5)

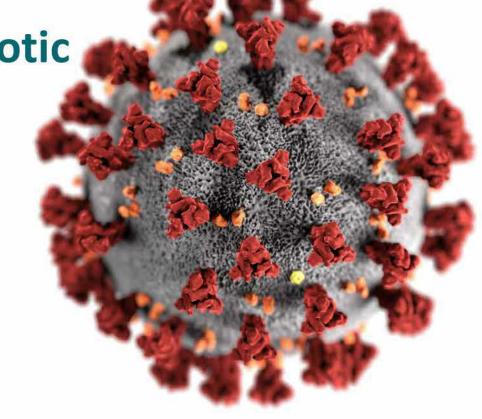
Henry Walke, MD, MPH Incident Manager CDC COVID-19 Response +1-404-639-3582 (office) +1-404-452-9624 (mobile) hwalke@cdc.gov



### **ACIP COVID-19 Vaccines**

Risk/Benefit assessment of thrombotic thrombocytopenic events after Janssen COVID-19 vaccines:

Applying Evidence to Recommendation Framework





Sara Oliver MD, MSPH ACIP Meeting April 23, 2021

## **Evidence to Recommendations Framework**



## **Evidence to Recommendations (EtR) Framework**

 Structure to describe information considered in moving from evidence to ACIP vaccine recommendations

 Provide transparency around the impact of additional factors on deliberations when considering a recommendation

# **Evidence to Recommendations (EtR) Framework**Policy Question

Should vaccination with the Janssen COVID-19 vaccine (1 dose) be recommended for persons 18 years of age and older under an Emergency Use Authorization?

## **Evidence to Recommendations (EtR) Framework:**

## Previous Janssen COVID-19 vaccine Recommendations

EtR Domain	Question					
Public Health Problem	Is the problem of public health importance?					
Benefits and Harms	<ul> <li>How substantial are the desirable anticipated effects?</li> <li>How substantial are the undesirable anticipated effects?</li> <li>Do the desirable effects outweigh the undesirable effects?</li> </ul>					
Values	<ul> <li>Does the target population feel the desirable effects are large relative to the undesirable effects?</li> <li>Is there important variability in how patients value the outcomes?</li> </ul>					
Acceptability	Is the intervention acceptable to key stakeholders?					
Feasibility	Is the intervention feasible to implement?					
Resource Use	Is the intervention a reasonable and efficient allocation of resources?					
Equity	What would be the impact of the intervention on health equity?					

#### **Evidence to Recommendations (EtR) Framework:**

Adaptation to Risk/Benefit assessment for Janssen COVID-19 vaccine recommendations

EtR Domain	Question
Public Health Problem	<ul> <li>Recent COVID-19 Epidemiology</li> <li>Thrombosis after COVID-19 Disease</li> <li>Cerebral Venous Sinus Thrombosis (CVST)</li> <li>Heparin Induced Thrombocytopenia (HIT)</li> <li>AstraZeneca COVID-19 vaccines: Available global data</li> </ul>
Benefits and Harms	<ul> <li>Benefits of Janssen COVID-19 vaccine</li> <li>Harms of Janssen COVID-19 vaccine:         <ul> <li>Estimated cases of TTS after Janssen COVID-19 vaccine</li> </ul> </li> <li>Benefit/Risk Assessment of COVID-19 vaccines</li> </ul>

#### **Evidence to Recommendations (EtR) Framework:**

Adaptation to Risk/Benefit assessment for Janssen COVID-19 vaccine recommendations

<b>EtR Domain</b>	Question
Values and Acceptability	<ul> <li>Intent to receive 1-dose COVID-19 vaccine</li> <li>Intent to receive Janssen COVID-19 vaccine over time</li> </ul>
Feasibility	<ul> <li>Jurisdictional use of Janssen COVID-19 vaccine</li> <li>Possible impact of Janssen COVID-19 vaccine policy options</li> </ul>
Equity	<ul> <li>Possible impact of Janssen COVID-19 vaccine policy options in disproportionately affected populations</li> </ul>
Resource Use	No information available

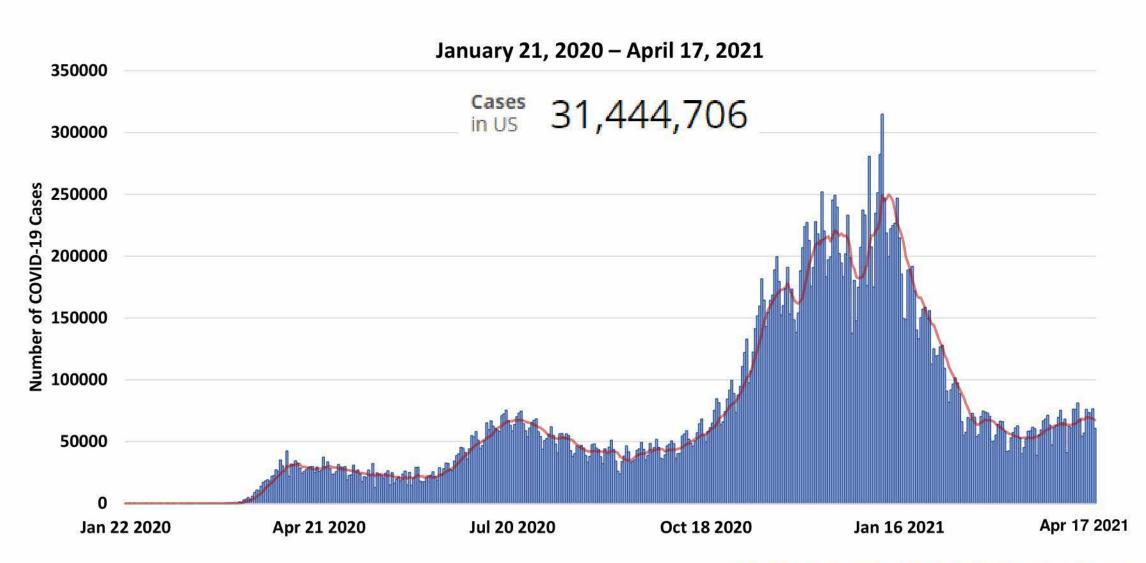
# **EtR Domain: Public Health Problem**



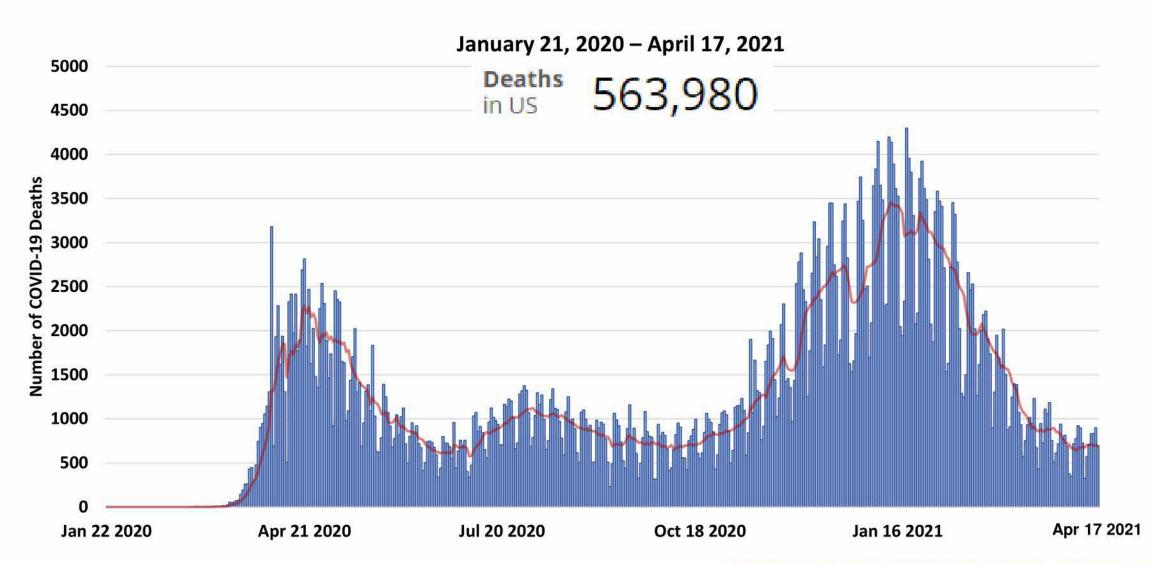
#### **Public Health Problem:**

- Recent COVID-19 Epidemiology
  - COVID-19 cases, hospitalization and deaths, stratified by age, sex, race and ethnicity
- Cerebral Venous Sinus Thrombosis (CVST)
- Heparin Induced Thrombocytopenia (HIT)
- Thrombosis after COVID-19 Disease
- AstraZeneca COVID-19 vaccines
  - Review of available global data

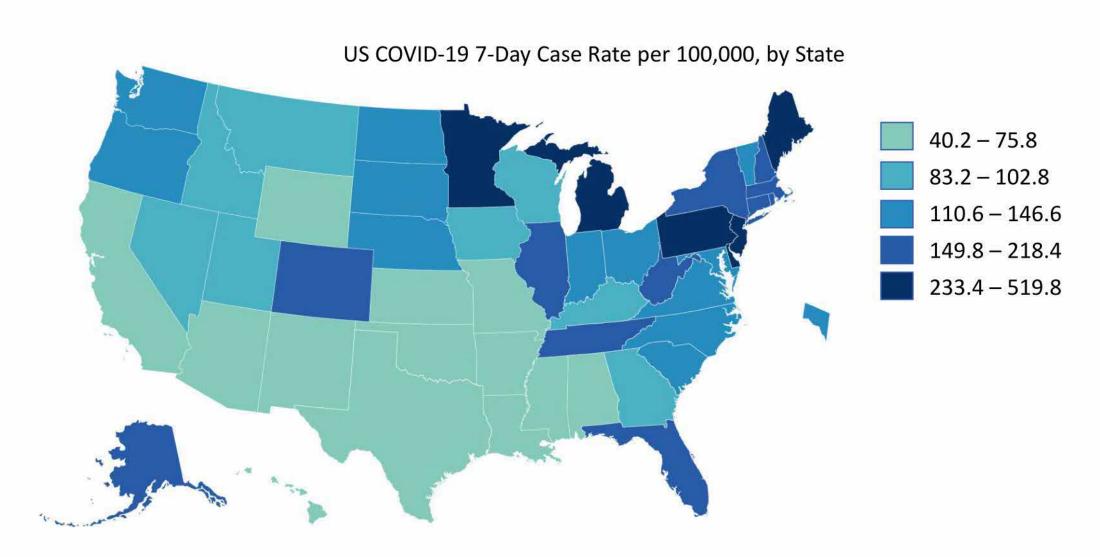
#### Trends in Number of COVID-19 Cases in the US



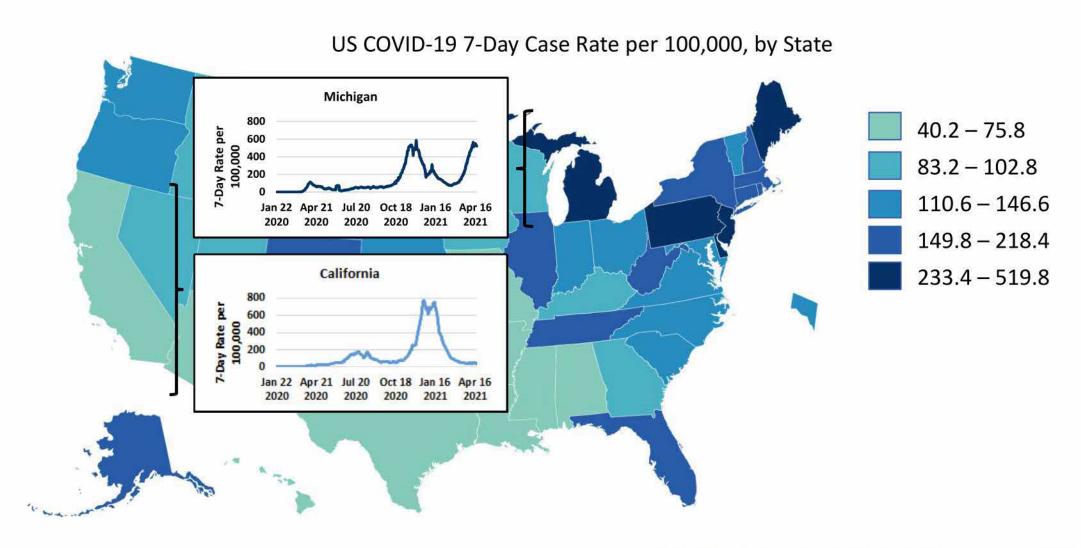
#### Trends in Number of COVID-19 Deaths in the US



# **COVID-19** Incidence Rates, by State

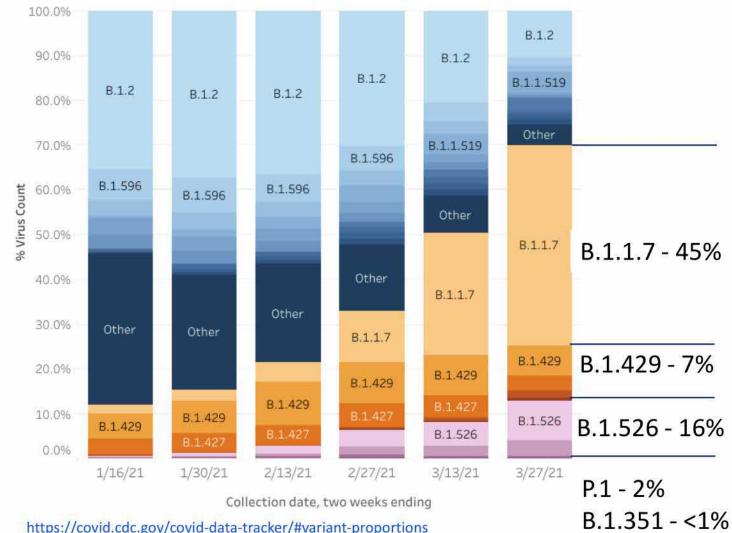


# **COVID-19** Incidence by State



### **SARS-CoV-2 Variants Circulating in the United States**

#### Variant Proportions, January 3 - March 27, 2021



	Lineage	% Total	95%CI	Type	
Most	B.1.1.7	44.7%	41.8-47.5%	VOC	-
common	B.1.2	10.5%	9.5-11.6%		
lineages	B.1.526	8.9%	6.9-11.4%	VOI	16
	B.1.429	6.9%	5.2-9.0%	VOC	
	B.1.1.519	4.5%	3.8-5.3%		
	B.1.526.1	3.6%	3.0-4.2%	VOI	
	B.1.526.2	3.2%	2.6-3.9%		
	B.1.427	3.1%	2.4-4.0%	VOC	
	B.1	1.6%	1.4-1.9%		
	B.1.596	1.6%	1.3-2.0%		
	P.1	1.5%	1.1-2.1%	VOC	
	R.1	1.1%	0.9-1.4%		
	B.1.575	1.1%	0.8-1.4%		
	B.1.243	0.7%	0.5-0.9%		
	B.1.1	0.7%	0.4-1.0%		
	B.1.234	0.5%	0.3-0.6%		
Additional	B.1.351	0.7%	0.5-1.1%	VOC	
VOI/VOC	P.2	0.3%	0.2-0.4%	VOI	
lineages	B.1.525	0.3%	0.2-0.4%	VOI	
Other*	Other	4.7%	4.0-5.5%		

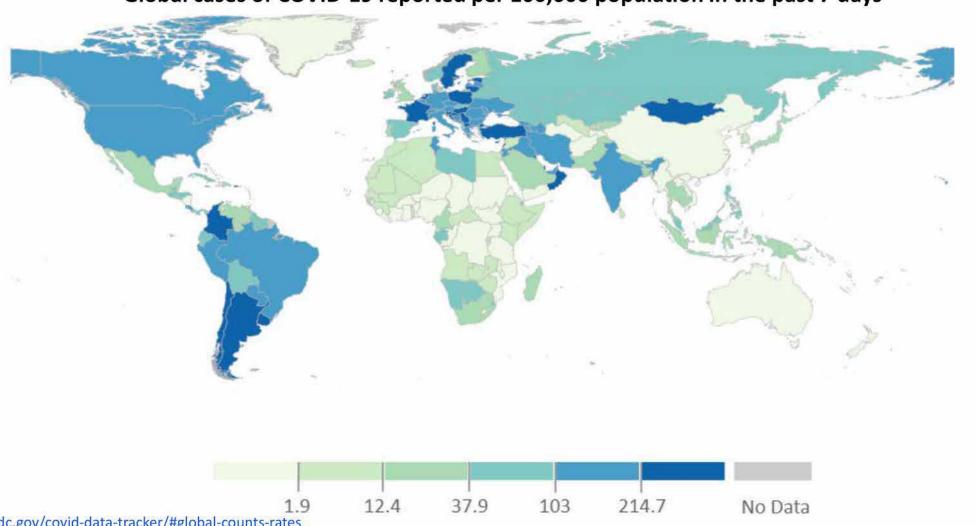
Summary data that appear in the table include specimen collection dates from March 14 through March 27, 2021.

<sup>\*</sup> Other represents >200 additional lineages, which are each circulating at <1% of viruses

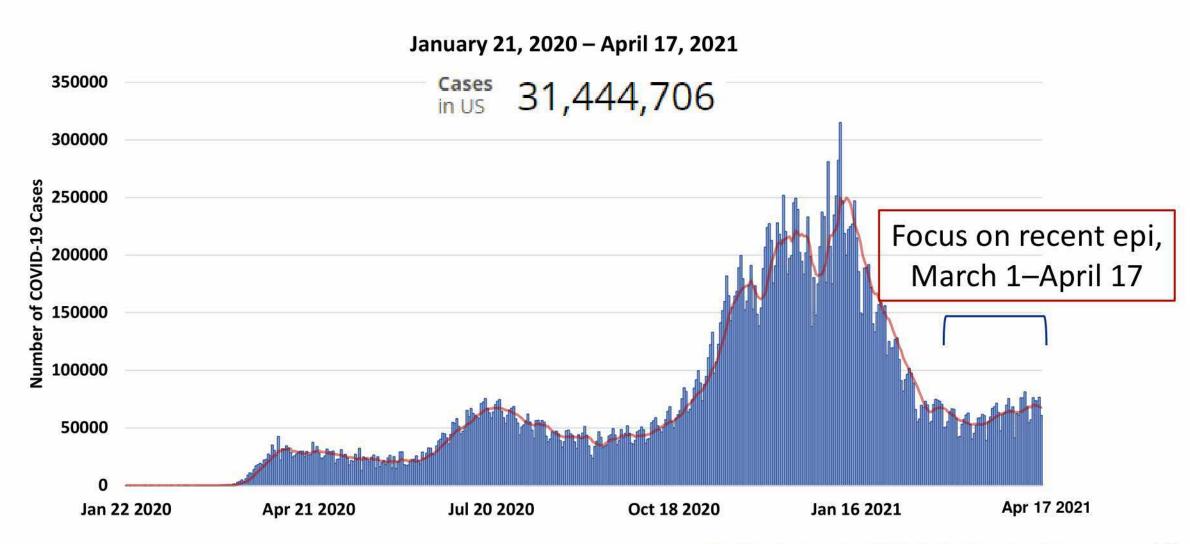
<sup>\*\*</sup> Most recent data are subject to change as samples from that period are still being processed.

#### **Global COVID-19 Incidence Rates**

Global cases of COVID-19 reported per 100,000 population in the past 7 days

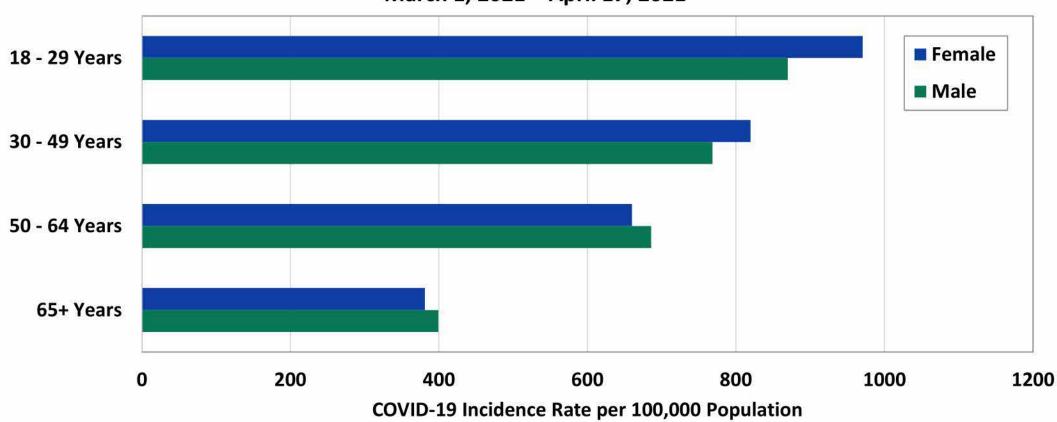


#### Trends in Number of COVID-19 Cases in the US



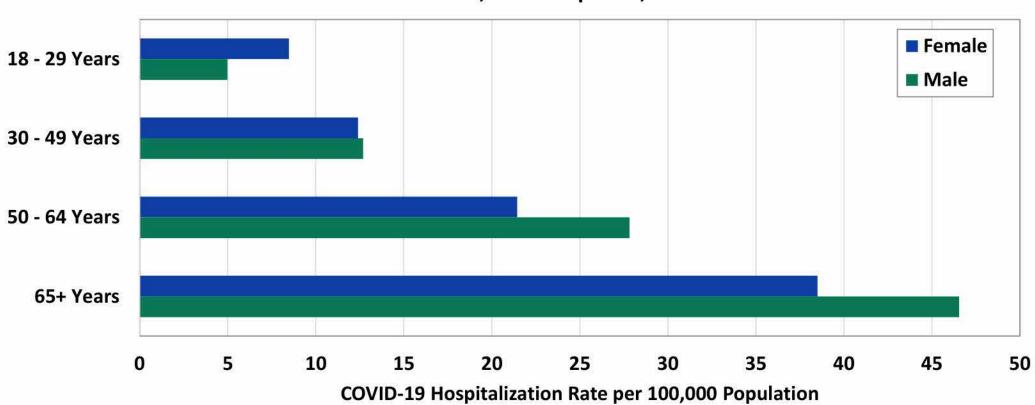
# **COVID-19 Incidence Rates, by Age Group and Sex**

COVID-19 Incidence Rate per 100,000 Population, by Age Group and Sex March 1, 2021 – April 17, 2021



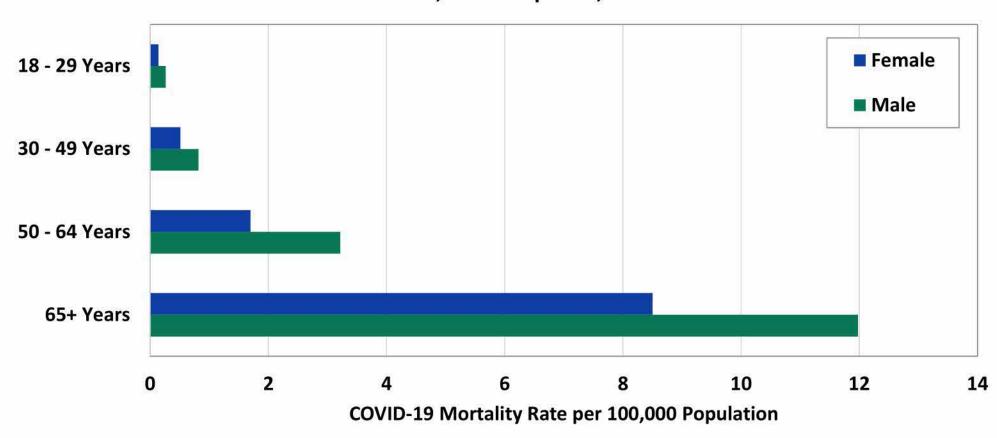
# **COVID-19 Hospitalization Rates, by Age Group and Sex**

COVID-19 Hospitalization Rate per 100,000 Population, by Age Group and Sex March 1, 2021 – April 17, 2021

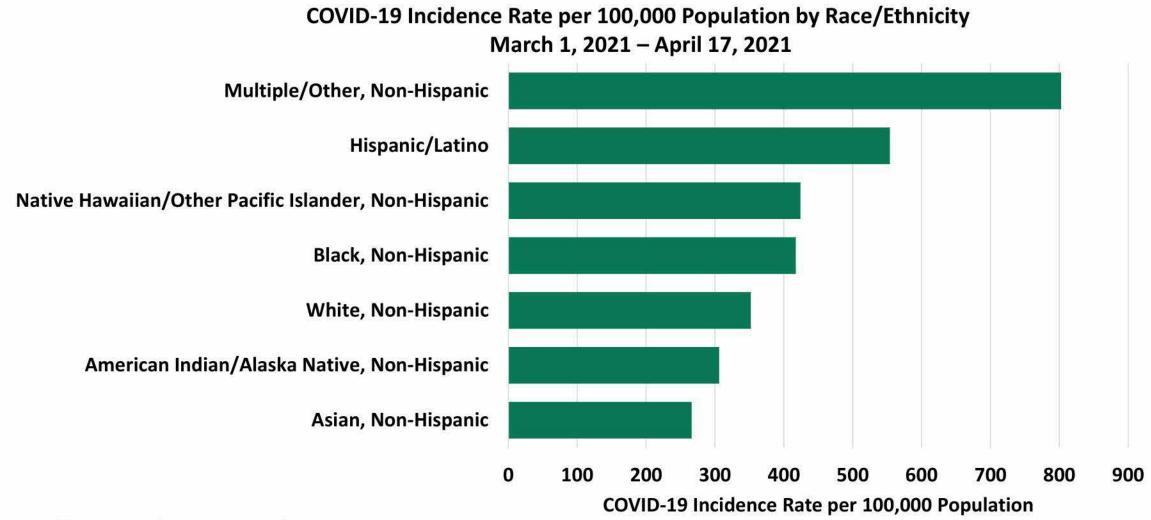


# **COVID-19 Mortality Rates, by Age Group and Sex**

COVID-19 Mortality Rate per 100,000 Population, by Age Group and Sex March 1, 2021 – April 17, 2021

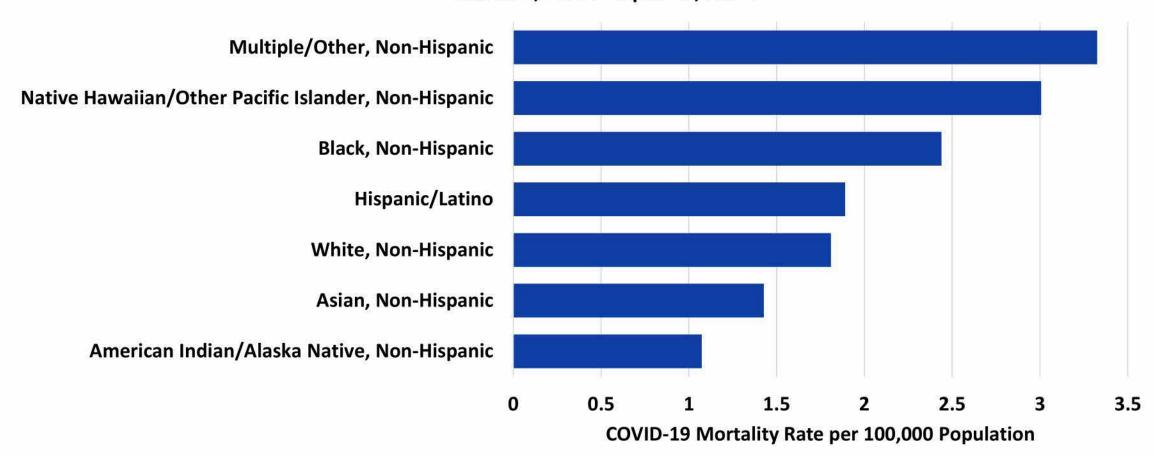


# **COVID-19 Incidence Rates, by Race/Ethnicity**



# **COVID-19 Mortality Rate, by Race/Ethnicity**

COVID-19 Mortality Rate per 100,000 Population by Race/Ethnicity March 1, 2021 – April 17, 2021



# **Summary of the COVID-19 Epidemiology**

#### March 1-April 17, 2021

#### Incidence

- Cumulative incidence rate for adults: 710.9 per 100,000 population
- Younger females (18-29 years) have the highest incidence of new infections

#### Hospitalization

- Cumulative hospitalization rate for adults: 20.6 per 100,000 population
- Most hospitalizations still occur in persons aged ≥ 65 years
  - Proportion of hospitalizations occurring in persons aged ≥65 years declining

#### Mortality

- Cumulative mortality rate: 3.0 per 100,000 population
- Most COVID-19 deaths still occur in persons aged ≥ 65 years
  - Proportion of deaths occurring in persons aged ≥65 years declining

# **Epidemiology of Cerebral Venous Sinus Thrombosis (CVST) and Splanchnic Vein Thrombosis (SVT)**

- Cerebral Venous Sinus Thrombosis (CVST) incidence: 14.5–28.5 per million U.S population
  - Incidence increasing in recent years (4% annually)
  - Higher in women aged 18-49 years
  - Risk factors (e.g. hereditary thrombophilia, oral contraceptives, obesity) identified in up to 85% of cases
  - Mortality ~5-10%
- Splanchnic Vein Thrombosis (SVT) incidence: 84–179 per million U.S. population
  - Incidence higher among men
  - Risk increases with age
- Incidence with thrombocytopenia much lower than without thrombocytopenia
  - CVST with thrombocytopenia: 0.7–1.6 per million U.S. population

# **Heparin-Induced Thrombocytopenia with Thrombosis (HITT)**

- Heparin-induced thrombocytopenia (HIT) occurs in 0.5% to 1% of patients exposed to unfractionated heparin for medical and surgical indications
  - Incidence: 23–45 per million total U.S. population\*
- Of patients with HIT, thrombosis occurs in about 20%–64% (called HITT)
- Immune mediated antibodies against platelet factor 4 (PF4) & heparin
- Risk factors for developing thrombosis
  - Genetic polymorphisms
  - Lower platelet count (and earlier fall in count)
  - Higher titer of anti-heparin/PF4 antibodies
  - Prior surgery (cardiac, orthopedic, trauma)
  - Cardiovascular disease
- Limited case series published on HIT occurring after COVID-19

<sup>\*</sup> Source: HCUP NIS 2018 and Marketscan (Continuously-enrolled Commercial Insurance and Medicaid) for 2019, unable to distinguish autoimmune HIT vs heparin-induced HIT Arepally et al. 2021. <a href="https://www.ahajournals.org/doi/epub/10.1161/ATVBAHA.120.315445">https://www.ahajournals.org/doi/epub/10.1161/ATVBAHA.120.315445</a>; Nand et al. 1998 <a href="https://doi.org/10.1002/(SICI)1096-8652(199709)56:1<12::AID-AJH3>3.0.CO;2-5">https://doi.org/10.1002/(SICI)1096-8652(199709)56:1<12::AID-AJH3>3.0.CO;2-5</a>; Fabris et al 2002. <a href="https://onlinelibrary.wiley.com/doi/epdf/10.1046/j.1365-2796.2002.01021.x">https://onlinelibrary.wiley.com/doi/epdf/10.1046/j.1365-2796.2002.01021.x</a>; Greinacher et al. 2005. <a href="https://www.thieme-connect.com/products/ejournals/abstract/10.1160/TH04-12-0825">https://www.thieme-connect.com/products/ejournals/abstract/10.1160/TH04-12-0825</a>

#### **CVST** associated with COVID-19

- Systematic review, meta-analysis of CVST among patients hospitalized for COVID-19
  - Estimates between 0.03% and 0.08% of hospitalized COVID-19 patients
- Estimated risk of 5–6 cases of CVST per million SARS-COV-2 infections\*
- CVST + thrombocytopenia in COVID-19 patients is extremely rare
- Pathology appears different than TTS after COVID-19 vaccines
  - PF4/heparin specific antibodies negative by ELISA or platelet functional assay for confirmed COVID-19 patients (n=222), including 10 with thromboembolic complications

<sup>\*</sup> Data source: Premier Healthcare Database, January 2020-January 2021

Acronyms: Cerebral Venous Sinus Thrombosis (CVST), Thrombosis with Thrombocytopenia Syndrome (TTS)

Katsanos et al. (2020) <a href="https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7753413/">https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7753413/</a>; Baldini et al. (2021) <a href="https://doi.org/10.1111/ene.14727">https://doi.org/10.1111/ene.14727</a>; Mowla et al. (2020) <a href="https://doi.org/10.1016/j.jns.2020.117183">https://doi.org/10.1016/j.jns.2020.117183</a>; Greinacher et al. Research Square preprint (Apr 9, 2021): <a href="https://www.researchsquare.com/article/rs-404769/v1">https://www.researchsquare.com/article/rs-404769/v1</a>

#### CVST associated with COVID-19

- Recent study using electronic health records (81m patients, mostly U.S.) to estimate CVST & portal vein thrombosis (PVT) incidence in 513,284 COVID-19 cases
  - Highest baseline CVST incidence observed over any 2-week period: 0.41 per million people
  - CVST incidence 2 weeks after COVID-19 diagnosis (among hospitalized): 39 per million
  - CVST incidence higher after COVID-19 diagnosis than after mRNA vaccines (4.1 per million) or after influenza disease (0.0 per million)
  - Mortality was 20% for CVST and 19% for PVT

#### Limitations

- Unable to assess incidence of CVST after adenovirus vector vaccines (Janssen, AstraZeneca)
- Did not provide rates of CVST + thrombocytopenia
  - Limited ability to directly compare to rates of CVST + thrombocytopenia after vaccines reported in US or Europe

# Thrombosis with Thrombocytopenia Syndrome (TTS) after AstraZeneca vaccine in Europe

- As of 4 April 2021, 169 cases of CVST & 53 cases of splanchnic vein thrombosis reported to EudraVigilance. ~34 million people vaccinated in EEA & UK by this date.
  - EU ~10 cases per million (1 case per 100,000) vaccinated adults
    - Higher in younger adults compared to older adults
  - Most of cases in women aged <60 years within 2 weeks of receiving 1<sup>st</sup> vaccine dose
- European Medicines Agency concluded benefit/risk ratio still favorable to use vaccine
  - Causal association plausible
  - Unable to identify definitive cause, but possibly similar to heparin-induced thrombocytopenia
  - No specific risk factors to date (epidemiology may be related to vaccine delivery)
  - Added unusual blood clots with low platelets to the label as very rare side effect

# UK decision on use of AstraZeneca vaccine — April 14, 2021

- Through April 14: 168 reports of blood clotting with low platelets
  - 77 CVST with thrombocytopenia; 91 in other major veins with thrombocytopenia
  - 93 women, 75 men, aged 18–93 years
  - 32 deaths
  - Most cases occurred after first vaccine dose; one case occurred after second dose
- Rate: 7.9 per million (21.2 million AZ doses given)
- Benefits continue to outweigh risks stronger evidence for a link of vaccine to extremely rare blood clots with lower platelets, but more work needed
  - Careful consideration be given to those at higher risk of blood clots because of medical conditions or pregnancy
  - Continue to give second doses, except to those with blood clots and low platelets after first dose
- Recommended ages 18–29 years at low risk of infections be offered other vaccines

# EMA's safety committee (PRAC) meeting on U.S. TTS cases after Janssen vaccine, April 20, 2021

- Reviewed evidence on 8 U.S. reports of serious cases of unusual blood clots with low levels of blood platelets, one of which had a fatal outcome. Over 7 million U.S. people had received Janssen vaccine, as of 13 April 2021
- Cases reviewed very similar to cases occurring with AstraZeneca COVID-19 vaccine
- Concluded that a warning about unusual blood clots with low blood platelets should be added to the product information for Janssen COVID-19 vaccine
- Very rare event, and the overall benefits of Janssen COVID-19 vaccine in preventing COVID-19 outweigh the risks of side effects
- Emphasized importance of healthcare provider awareness

#### **Public Health Problem:**

COVID-19

<u>Hospitalization</u>: 200 per million population

<u>Death</u>: 30 per million population

CVST after COVID-19

5-6 per million SARS-COV-2 infections

HIT

23–45 per million population

**CVST** 

14.5–28.5 per million population

CVST +
Thrombocytopenia

0.7–1.6 per million population

TTS after AZ vaccine

10 per million vaccinated population

EU:

<u>UK</u>:

7.9 per million vaccinated population

# **EtR Domain: Benefits and Harms**



#### **Benefits and Harms:**

- Benefits of Janssen COVID-19 vaccine
  - Prevention of COVID-19 cases, hospitalizations and deaths
- Harms of Janssen COVID-19 vaccine
  - Estimated cases of TTS after Janssen COVID-19 vaccine, by age and gender
- Benefit and Risk summary

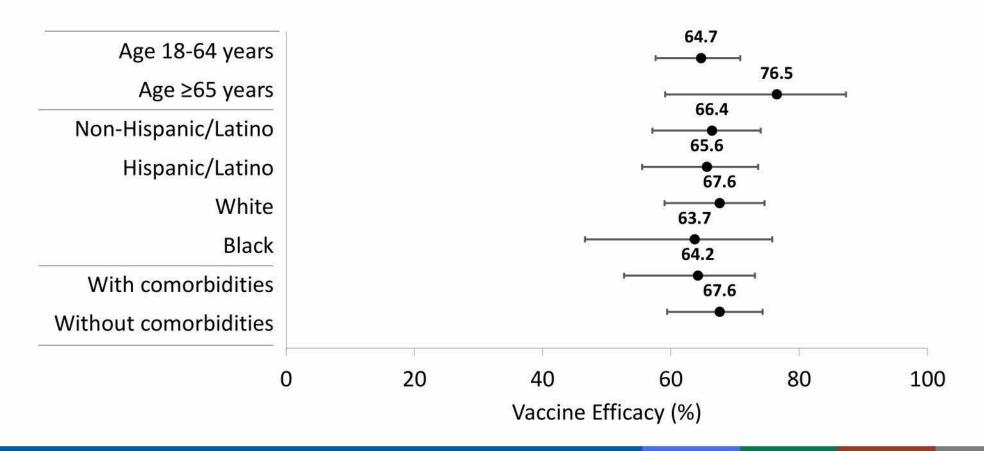
#### Benefits of the Janssen COVID-19 vaccine

- The clinical trial demonstrated efficacy against symptomatic, laboratory-confirmed COVID-19. The overall efficacy was 66.3% (95% CI: 59.9%, 71.8%)
- Vaccine efficacy against COVID-19 associated hospitalization was 93% (95% CI: 71%, 98%)
- Higher efficacy against severe outcomes than for any symptomatic COVID-19
  - VE against deaths due to COVID-19: 100%
- Efficacy against severe disease<sup>†</sup> remained high across world regions (73-82%\*), suggesting protection against severe illness with variant strains

†Definition: Respiratory Rate ≥ 30, Heart Rate ≥125, SpO2≤ 93% on room air at sea level or PaO2/FIO2< 300 mm Hg; OR respiratory failure or Acute Respiratory Distress Syndrome (ARDS), defined as needing high-flow oxygen, non-invasive or mechanical ventilation, or ECMO; OR evidence of shock (systolic blood pressure <90mmHg, diastolic BP<60mmHg or requiring vasopressors); OR significant acute renal, hepatic or neurologic dysfunction; OR admission to an intensive care unit or death \*Assessed ≥ 14 days post vaccination

#### Benefits of the Janssen COVID-19 vaccine

Similar efficacy for across age, sex, race, and ethnicity categories, and those with underlying medical conditions at ≥14 days post-vaccination



#### Benefits of the Janssen COVID-19 vaccine

- Vaccine shipment and storage (3 months) at refrigerator temperatures (2-8°C)\*
  - Refrigerator-stable vaccine could facilitate the availability of the Janssen COVID-19 vaccine in many community settings and mobile sites
- Single-dose series
- Easier to reach some disproportionately affected groups such as: homeless, rural residents, justice-involved, disabled, homebound, or with no/limited access to healthcare

\* Long-term storage at standard freezer temperatures (-20°C)

#### Potential Harms of the Janssen COVID-19 vaccine

- 7.98 million vaccine doses administered\*and 15 confirmed TTS cases as of April 21, 2021
  - Additional potential TTS cases under review, including potential male cases

	Females			Males		
Age group	Cases	Doses admin	Reporting rate <sup>†</sup>	Cases*	Doses admin	Reporting rate <sup>†</sup>
18-49 years old	13	1,866,294	7.0 per million	0	1,977,330	<b>0</b> per million
50+ years old	2	2,125,239	<b>0.9</b> per million	0	2,010,144	<b>0</b> per million

<sup>\*</sup> Source of doses administered: https://covid.cdc.gov/covid-data-tracker/#vaccinations; Some age- and sex-specific doses administered data were imputed

<sup>&</sup>lt;sup>†</sup> Reporting rate = TTS cases per 1 million Janssen COVID-19 vaccine doses administered

<sup>\*</sup> One TTS case occurred in the Phase 3 trial in a male aged 18-49 years.

# **Summary of Different Risk-Benefit Analyses**

#### **Population Level Risk-Benefit Analysis**

# Type of analysis Objective 1. Population (6-month period) Quantify COVID-19 infections, hospitalizations, and deaths averted under different assumptions about resumption of Janssen vaccination Quantify population-level, age-specific benefits and harms of resuming vaccination with Janssen COVID-19 vaccine

#### **Individual Level Risk-Benefit Analysis**

Type of analysis	Objective
2. Direct (1-month period)	<ul> <li>Quantify direct age and sex-specific benefits and harms, per million Janssen vaccine doses</li> </ul>

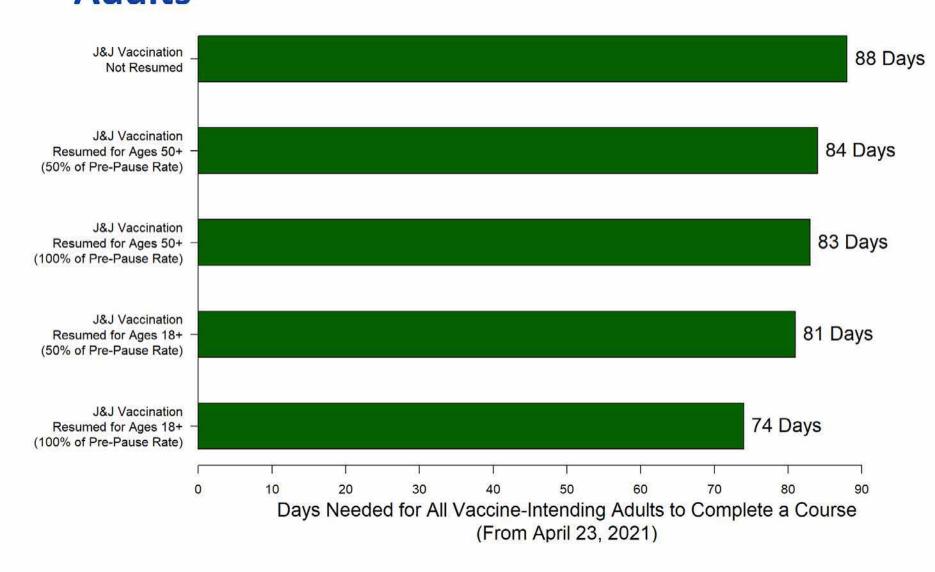
#### **Modeled Janssen COVID-19 Vaccine Scenarios**

- Objective: Quantify COVID-19 infections, hospitalizations, and deaths under different assumptions about resumption of Janssen vaccination
- In all scenarios we assume continued use of mRNA vaccines
- Evaluated the following scenarios:
  - Janssen vaccination not resumed
  - Janssen vaccination resumed on April 24th for all adults aged 18+ years
    - 50% of pre-pause J&J administration rate (in 18+ age group)
    - 100% of pre-pause J&J administration rate (in 18+ age group)
  - Janssen vaccination resumed on April 24th in adults aged 50+ years only
    - 50% of pre-pause J&J administration rate (in 50+ age group)
    - 100% of pre-pause J&J administration rate (in 50+ age group)

# **Model Overview & Assumptions**

- Compartmental model used to simulate incident infections, hospitalizations, and deaths over the course of the epidemic in the US
  - Stratified by age, essential-worker status, and underlying conditions
  - Calibrated to observations through Spring 2021. Future activity based on external scenarios.
- Two vaccine types: mRNA and Janssen (VE informed by RCTs)
  - Immunity develops 14 days after administration
  - 28 days between mRNA doses
- No loss to follow-up or delays in administration
- No waning of immunity over time

# Modeled Time to Complete Vaccination for All Intending Adults



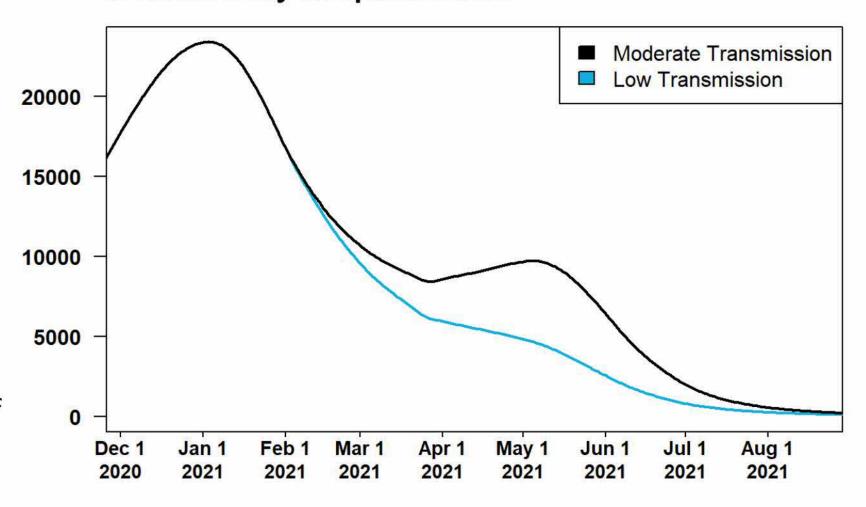
#### Multiple assumptions:

- Vaccine intent in each age group remains same
- Administration of mRNA vaccines continues at the same rate as before pause
- In practice, pace of administration may slow as those experiencing barriers to access and/or greater hesitancy comprise a greater share of the unvaccinated

# **Modeling Transmission Scenarios**

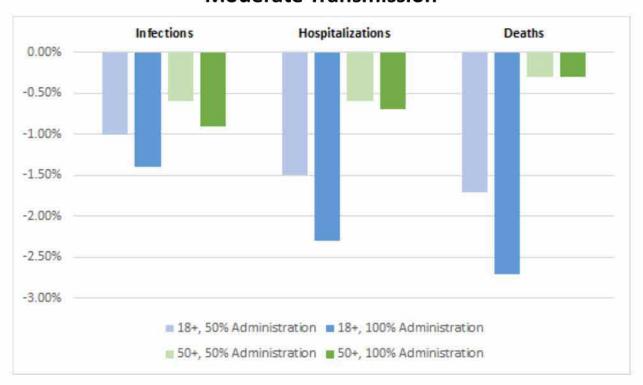
- Calibrated assuming no interruption of Janssen vaccination under two scenarios reflecting continued level of nonpharmaceutical interventions (i.e., low transmission and moderate transmission)
- Calibrated to Round 4 of the COVID-19 Scenario Hub

#### **Incident Daily Hospitalizations**



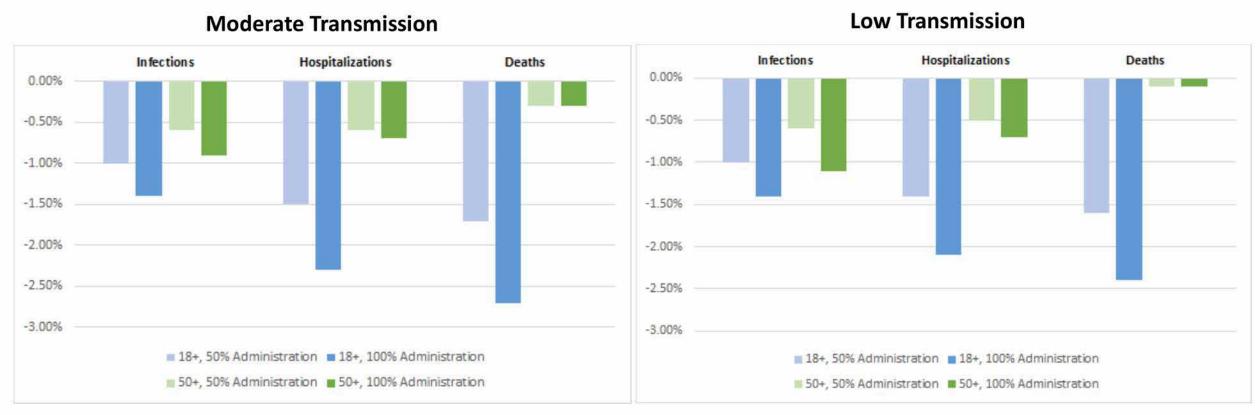
# Percent Change\* in Outcomes 6 Months Post-Pause, by Janssen Resumption Strategy

#### **Moderate Transmission**



<sup>\*</sup> compared to a scenario in which administration of the J&J vaccine does not resume

# Percent Change\* in Outcomes 6 Months Post-Pause, by Janssen Resumption Strategy



There is a benefit of resuming Janssen vaccination in terms of infections, hospitalizations and deaths prevented under different epidemiologic assumptions

<sup>\*</sup> Compared to a scenario in which administration of the J&J vaccine does not resume

### Population Risk-benefit assessment

- Quantify age-specific risks and benefits of resuming vaccination with Janssen COVID-19 vaccine
  - Risks: Number of TTS
  - Benefits: Prevention of COVID-19-related hospitalizations,
     ICU admissions, and deaths

### **Population Risk-Benefit Inputs**

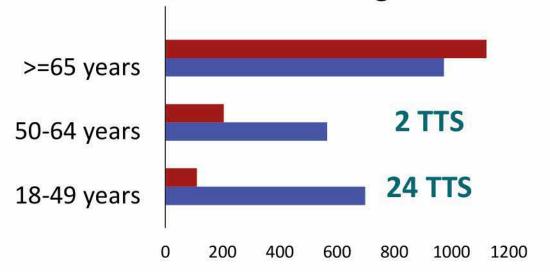
- Estimates from compartmental model
  - Numbers of hospitalizations and deaths due to COVID-19
  - Number of persons estimated to receive Janssen COVID-19 vaccine after pause
  - Conditions: Low and moderate transmission; 50% and 100% of prior vaccination rate; Resuming in ages 18+ and 50+, vs no resumption
  - 6-month time horizon
- ICU admissions per hospitalization (CDC Pandemic Planning Scenarios)
- Counts of TTS cases by age (CDC data)
- Numbers vaccinated with Janssen COVID-19 vaccine, by age, before pause (CDC data)

# Benefits and harms of resuming vaccination for ages ≥18 years vs. ≥50 years over 6-month period

Moderate transmission; Vaccination resumed at 50% of rate before pause



Resume vaccination: age 18+



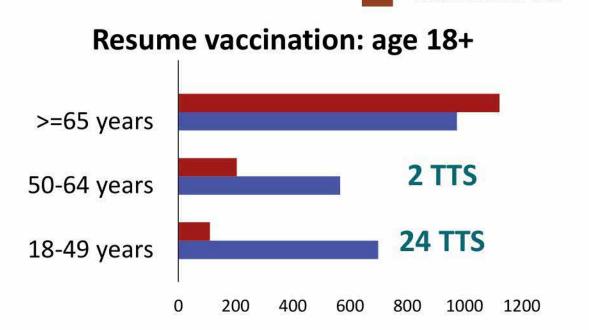
26 TTS in 9.8M vaccinations
Prevent 1,435 deaths, 2,236 ICU admissions

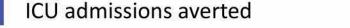
<sup>&</sup>lt;sup>1</sup> Based on observed cases adjudicated as of 4/21/2021 NOTE: in Phase III RCT, one male in 18-49 year age group experienced TTS; not included in this analysis Acronyms: Thrombosis with Thrombocytopenia Syndrome (TTS)

# Benefits and harms of resuming vaccination for ages ≥18 years vs. ≥50 years over 6-month period

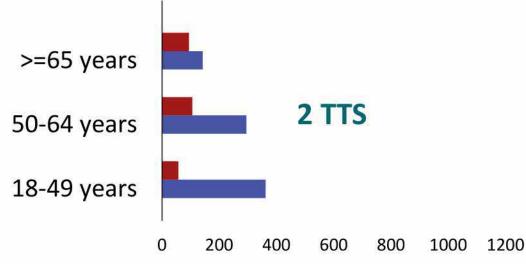
Moderate transmission; Vaccination resumed at 50% of rate before pause

Deaths averted









2 TTS in 3.6M vaccinations Prevent 257 deaths, 779 ICU admissions

NOTE: in Phase III RCT, one male in 18-49 year age group experienced TTS; not included in this analysis Acronyms: Thrombosis with Thrombocytopenia Syndrome (TTS)

<sup>26</sup> TTS in 9.8M vaccinations
Prevent 1,435 deaths, 2,236 ICU admissions

<sup>&</sup>lt;sup>1</sup> Based on observed cases adjudicated as of 4/21/2021

# Summary of population-level risks and benefits by recommendation, all scenarios

# Recommendation for all persons aged 18+

- Risks: Expect 26–45 TTS cases, depending on uptake
- Benefits: Depend on uptake, amount of transmission
  - 800–3,500 fewer ICU admissions
  - 600–1,400 fewer deaths

# Recommendation for all persons aged 50+

Risks: Expect2–3 TTScases, depending on uptake

**Benefits:** Depend on uptake, amount of transmission

300-1000 fewer ICU

admissions

40–250 fewer deaths

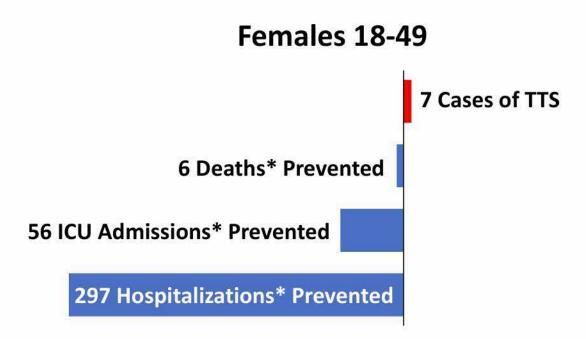
Note: Benefits of vaccination apply to the whole population over a 6-month period, and result from direct and indirect effects.

# Estimation of direct benefits and risks to vaccinated persons

- Evaluate direct benefits and risk, per million Janssen vaccine doses
- Used to visualize sex differences in risk and benefits
- Calculations based on recent hospitalization incidence, VE, Janssen vaccinations to date, number of persons already vaccinated
- 30-day period

### Risks and benefits by for females, by age group

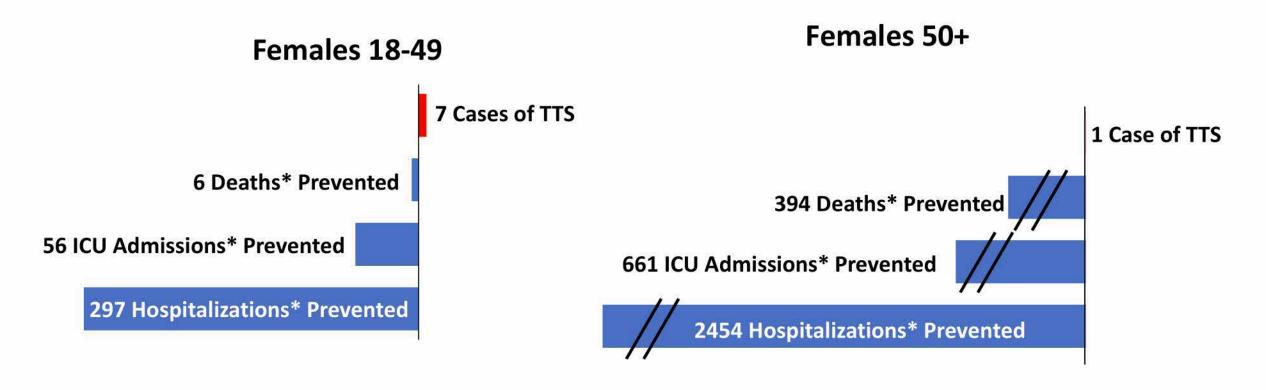
For every **1 million** doses of vaccine given with current US exposure risk<sup>1</sup>



<sup>\*</sup> Deaths, ICU admissions, and deaths due to COVID-19 Acronyms: Thrombosis with Thrombocytopenia Syndrome (TTS)

### Risks and benefits females, by age group

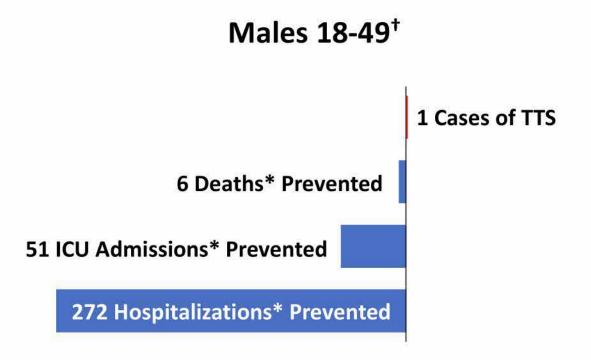
For every **1 million** doses of vaccine given with current US exposure risk<sup>1</sup>



<sup>\*</sup> Deaths, ICU admissions, and deaths due to COVID-19 Acronyms: Thrombosis with Thrombocytopenia Syndrome (TTS)

### Risks and benefits males, by age group

For every 1 million doses of vaccine given with current US exposure risk1



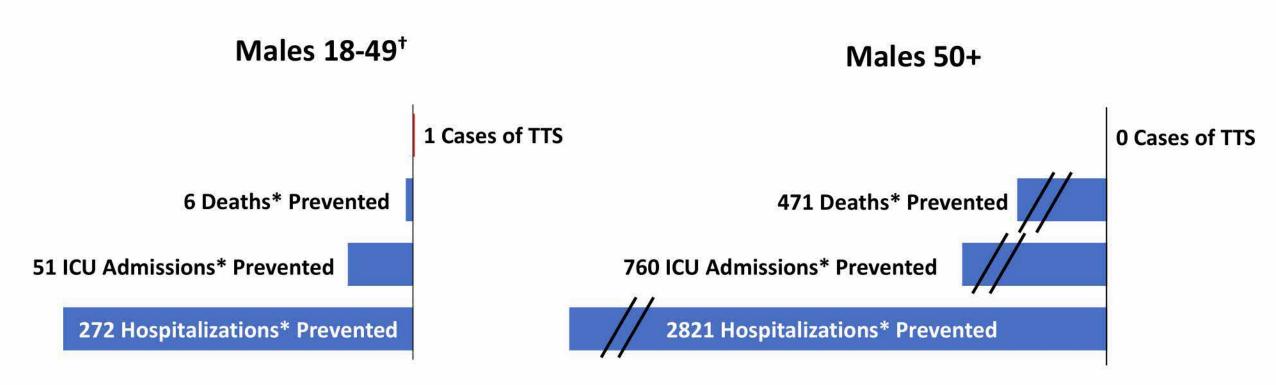
Acronyms: Thrombosis with Thrombocytopenia Syndrome (TTS)

<sup>†</sup>Analyses incorporated one TTS case that occurred in the Phase 3 trial in a male aged 18-49 years.

<sup>\*</sup>Deaths, ICU admissions, and deaths due to COVID-19

### Risks and benefits males, by age group

For every **1 million** doses of vaccine given with current US exposure risk<sup>1</sup>



<sup>†</sup>Analyses incorporated one TTS case that occurred in the Phase 3 trial in a male aged 18-49 years.

<sup>\*</sup>Deaths, ICU admissions, and deaths due to COVID-19

### **Risk-benefit interpretations**

- Population
  - Takes into account direct and indirect (herd) effects of vaccination
  - Incorporates availability of different vaccines
  - Simulates incidence, hospitalizations, and deaths over course of pandemic
  - 6-month time horizon
- Shows large population benefit of vaccination relative to rare TTS

#### Direct

- Considers individual benefits of vaccination vs. individual risks
- Only considers getting Janssen vaccine vs. not getting a vaccine
- Short, 1-month time horizon
- Shows positive balance for benefits vs. risks for all age and sex groups
- Balance of risks and benefits varies by age and sex

### **EtR Domains: Values and Acceptability**



### Values and Acceptability:

- Intent to receive 1-dose COVID-19 vaccine
  - Data stratified by age, sex, race/ethnicity and income
- Intent to receive Janssen COVID-19 vaccine over time
- Effect on overall vaccine confidence

# Values and Acceptability: Intent to receive 1-dose COVID-19 vaccine

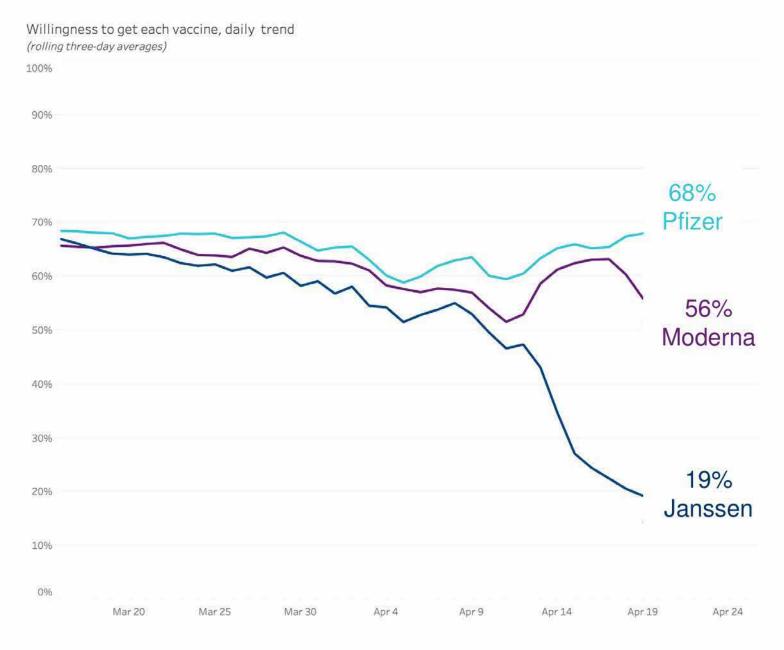
- Among unvaccinated respondents, if both a <u>2-dose and 1-dose</u> COVID-19 vaccine were available, which would you choose? Assume that both types of vaccines are safe.
  - Respondents could choose 1-dose, 2-dose, either, neither
  - Data collected February 2021
- Examined by age, sex, race/ethnicity, and income
  - Overall, 6% exclusively preferred 1-dose vaccine
  - No differences in proportion that preferred 1-dose by age, sex, or income
  - Significantly more Hispanic than White respondents (11%) preferred 1-dose

# Values and Acceptability: Intent to receive Janssen COVID-19 vaccine over time

- Only 37% of respondents called the Janssen COVID-19 vaccine safe after the pause was announced¹
  - Drop of 15% in two to three days
- Americans now much less likely to prefer the Janssen COVID-19 vaccine<sup>2</sup>
  - 13% decline in preference for the Janssen COVID-19 vaccine
  - Declined 9% to 25% across age and race categories

### Willingness to receive the J&J vaccine dropped immediately as a result of the pause

(Results among those who say "yes" they plan to get vaccinated but haven't yet)









### Values and Acceptability:

#### Effect on overall vaccine confidence

- Drop in vaccine confidence does not appear to extend to the Pfizer-BioNTech and Moderna COVID-19 vaccines<sup>1</sup>
  - 59% consider them safe
  - 19% feel they are unsafe
- Recent poll did not suggest reduction in intent to be vaccinated<sup>2</sup>
  - 40% more likely to receive COVID-19 vaccine compared to one month ago
  - 36% report no change in intent
- A different survey found half of the unvaccinated are less inclined to receive COVID-19 vaccine after the pause, regardless of brand<sup>3</sup>

<sup>1. &</sup>lt;a href="https://today.yougov.com/topics/politics/articles-reports/2021/04/15/johnson-johnson-vaccine-confidence">https://today.yougov.com/topics/politics/articles-reports/2021/04/15/johnson-johnson-vaccine-confidence</a>

<sup>2.</sup> deBeaumont Foundation Poll, April 15-16, 2021. Vaccine Confidence Grows Despite J&J Pause

<sup>3.</sup> CVS Health Survey- COVID-19 Vaccine Brand Preferences and Hesitancy Post J&J Pause

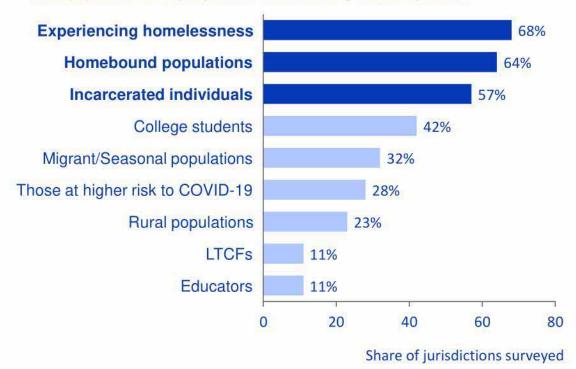
## **EtR Domain: Feasibility**



### Feasibility: Jurisdictions' pre-pause use of Janssen vaccine

**Populations:** Focus on reaching those experiencing homelessness, homebound or currently incarcerated

Q: Prior to the pause in administration of the Janssen vaccine, which populations had you focused on vaccinating with this product?



**Vaccination settings:** Three core settings used by jurisdictions to administer Janssen vaccine

#### Mobile vaccination

Temporary PODs and mobile vans able to reach transient, rural and

# homebound individuals

#### **Emergency departments**

- Provided at discharge from urgent care or ER departments
- Particularly for 'safety-net' hospitals reaching transient groups

#### Student health centers

 On-campus vaccination centers with ambition to vaccinate students unable or less likely to return for second dose at end of semester

# Feasibility: Impact if Janssen recommended <u>for specific</u> populations

Jurisdictions may need to reconfigure some vaccination sites, update scheduling tool, and have difficulty serving disproportionately affected populations



Changes to vaccination sites and schedulers might include...

Providers may need to carry multiple vaccines, if recommendation is restricted by sex.

Challenging to set-up dedicated community PODs if Janssen recommended for specific groups.

Would require IT systems update to internal scheduling and pre-screening tools.



Health depts. expressed concern about communicating change

Concerns about difficulty of communicating rationale for specific groups to public

Potential need to revise public-facing comms materials, provider training collateral, alongside re-training staff.

Expect low uptake on Janssen vaccine given negative publicity.



Greater difficulty serving disproportionately affected populations

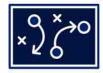
Likely to see drop in completed series for those "at risk of loss to follow-up" e.g., experiencing homelessness, seasonal workers.

More challenging to reduce gap in vaccine disparities for racial and ethnic minorities through mobile vaccination.

Would increase barriers to access in rural and hard-to-reach areas.

# Feasibility: Impact if Janssen were <u>no longer</u> recommended

Jurisdictions are particularly concerned about 2<sup>nd</sup> dose management and equity



### Janssen provided flexibility to jurisdictions to...

Avoid additional second dose management, particularly for transient and hard-to-reach populations

Run mobile vaccination clinics without need for return visits

Reduce administrative burden on providers

Fully vaccinate college students before end of school year



### Many individuals expressed a preference for Janssen

Convenience of single dose appeals to many recipients

Some individuals hesitant about receiving an mRNA vaccine

Possibility of second dose side effects causes some to favor Janssen

Some providers with lower volumes of patients have preference for single dose vaccine



# Greater difficulty serving disproportionately affected populations

Increased challenge to reach homebound, transient, and rural populations because of need to administer second dose

Less flexibility to use mobile vaccination units

Reduced ability to vaccinate upon ED/hospital discharge

Decreased vaccine supply from loss of Janssen could harm vaccine access

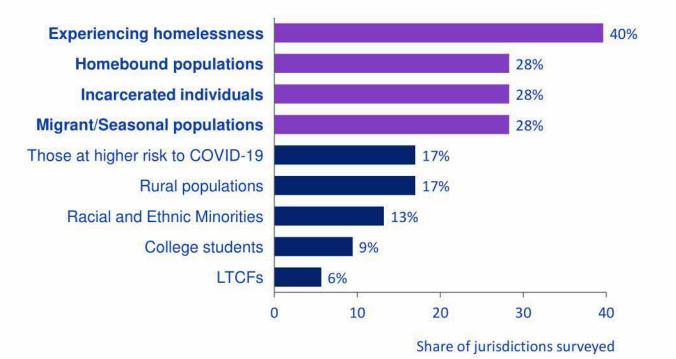
# **EtR Domain: Equity**



# Equity: Jurisdictions concerned revised recommendations would disproportionately affect several populations

Jurisdictions frequently raised four populations at risk of disproportionate impact

Q: Which, if any, populations would be disproportionally impacted if Janssen vaccine was no longer recommended or recommended for only a subset of the population?



#### Examples raised

**Region 6 jurisdiction:** "Most concerned about sub-populations that are difficult to reach e.g., people exp. homelessness, people who are working, as well as difficult geographic areas."

Region 2 jurisdiction: "The hardest to reach transient populations such as the homeless and those moving through substance use treatment programs, mental health treatment programs, etc. would be most impacted, given that they are among the most difficult individuals with whom to connect to provide second dose vaccination"

**Region 10 jurisdiction:** "...not having this vaccine would have an impact on trying to reduce the gap in vaccine disparities. We have community partners lined up to host events using the Janssen vaccine that are working with vulnerable populations in the state."

# **Policy Options**



### **Policy Options for Janssen Policy Recommendations**

Do **not** recommend use of Janssen vaccine

Recommend use of Janssen vaccine in **all adults**≥18 years of age

Recommend use of Janssen/J&J COVID-19 vaccine in **some** populations

### **Policy Options for Janssen Policy Recommendations**

- Recommend against use for all persons
- Reaffirm recommendations for all age and sex
  - FDA to include warning statement with EUA
- Recommend vaccination only for adults ≥50 years of age
- Reaffirm recommendations for use; women aged <50 years should be aware
  of the increased risk of TTS, and may choose another COVID-19 vaccine
  (i.e. mRNA vaccines)</li>

	Pros	Cons
Recommend <b>against use</b> in all persons	<ul> <li>No further cases of CVST/TTS after Janssen vaccine</li> </ul>	<ul> <li>Would remove choice from individuals</li> <li>Could lead to excess COVID-19 cases &amp; deaths</li> <li>Could disproportionately impact at-risk populations with barriers to access or difficulty returning for 2<sup>nd</sup> dose</li> </ul>
Reaffirm recommendation for <b>all</b> ages/sex *Setting of FDA warning	<ul> <li>Allow for flexibility/choice</li> <li>Allow for use of the vaccine in harder to reach populations</li> </ul>	<ul> <li>Burden on individual to understand risk; health dept/providers to convey risk</li> <li>May lead to more cases of TTS</li> <li>At-risk populations for COVID-19 likely at risk for barriers to TTS identification and treatment</li> </ul>

	Pros	Cons	
Recommend vaccination only for adults ≥50 years	<ul> <li>Would remove vaccine from most at-risk population (reduce TTS cases)</li> <li>Clear to communicate</li> </ul>	<ul> <li>Difficult to implement (vaccination sites could need stock two vaccines)</li> <li>Would remove an option in a population with lower risk (young men)</li> <li>Could disproportionately impact at-risk populations</li> </ul>	
Reaffirm recommendations for use; women <50 should be aware of increased risk, and may choose another COVID-19 vaccine	<ul> <li>Allow for flexibility/choice</li> <li>Allow for use of the vaccine in harder to reach populations, while still acknowledging risk in young women</li> </ul>	<ul> <li>Could be difficult to implement         (vaccination sites could need stock two vaccines)</li> <li>Could be difficult to communicate</li> </ul>	

# Policy Options for Janssen Policy Recommendations Work Group Summary

- Detailed discussion of risk/benefit balance difficult in many current vaccination settings
- Recommendations that require vaccination sites to require two types of vaccines would be difficult to implement
- Access to vaccines for hard-to-reach populations remains important
- Risk/benefit balance may change as the pandemic evolves and risk of COVID-19 disease changes

# Policy Options for Janssen Policy Recommendations Work Group Summary

- Work Group discussed benefits and concerns with all policy options for Janssen COVID-19 vaccine
- No single policy option as clear choice by Work Group
- However, many on Work Group appreciated flexibility of a broader recommendation for use, but acknowledgement of elevated risk in women <50 years of age</li>

#### Previous Janssen vote:

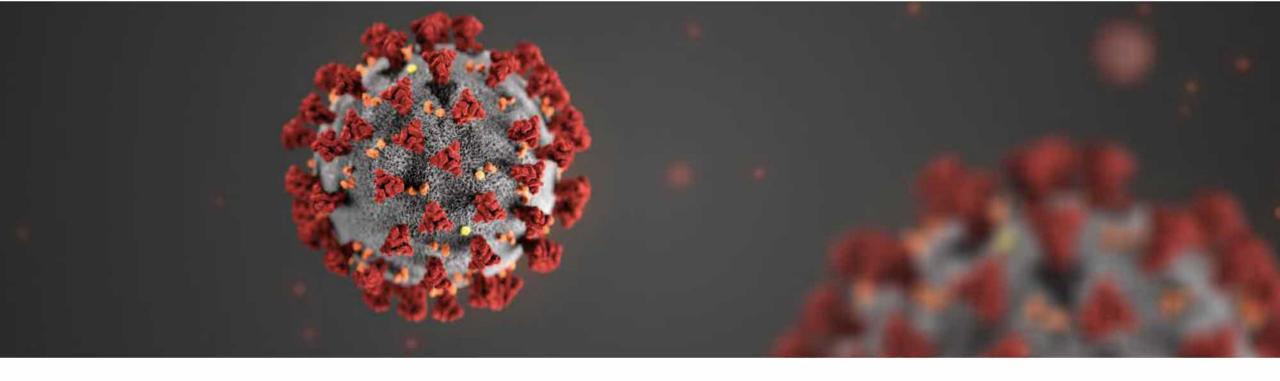
The Janssen COVID-19 vaccine is recommended for persons 18 years of age and older in the U.S. population under the FDA's Emergency Use Authorization

#### Question for ACIP to discuss:

• Given the review of the benefits and risks, what recommendation does ACIP feel is appropriate for use of the Janssen COVID-19 vaccine?

### **Policy Options for Janssen Policy Recommendations**

- Recommend against use for all persons
- Reaffirm recommendations for all age and sex
  - FDA to include warning statement with EUA
- Recommend vaccination only for adults ≥50 years of age
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For more information, contact CDC 1-800-CDC-INFO (232-4636)
TTY: 1-888-232-6348 www.cdc.gov

## Thank you

The findings and conclusions in this report are those of the authors and do not necessarily represent the official position of the Centers for Disease Control and Prevention.



 From:
 Walke, Henry (CDC/DDID/NCEZID/DPEI)

 Sent:
 Sun, 16 May 2021 11:32:15 +0000

To: Walensky, Rochelle (CDC/OD)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD); Daskalakis,

Demetre (CDC/DDID/NCHHSTP/DHP); Kimbrel, Alicia (CDC/OD/OCS)

Subject: DIRECTORS BRIEF 20210516

Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE - DIRECTORS BRIEF 20210516.pdf

#### Sunday, May 16, 2021

	Cumulative Total	Daily	7-Day Daily Average	Change from Prior 7-Day Period
Cases <sup>2</sup>	32,722,464	37,314	33,228	-22.8%
Hospital Admissions <sup>3</sup>	2,185,904	3,641	3,865	-13.6%
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Test Positivity <sup>4</sup>	8.1%	N/A	3.4%	-10.6%

Source: HHS Protect

#### COVID-19 Vaccinations in the United States<sup>5</sup>

	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Fully Vaccinated (% Population)
Overall US	442,630,185	344,503,395	270,832,342	156,217,367 (47.1)	121,768,268 (36.7)
Population ≥18 Years of Age <sup>6</sup>	N/A	N/A	N/A	153,374,769 (59.4)	120,313,236 (46.6)
Population ≥65 Years of Age	N/A	N/A	N/A	46,138,061 (84.4)	39,599,069 (72.4)

Data as of May 15, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID Tracker

(b)(5)

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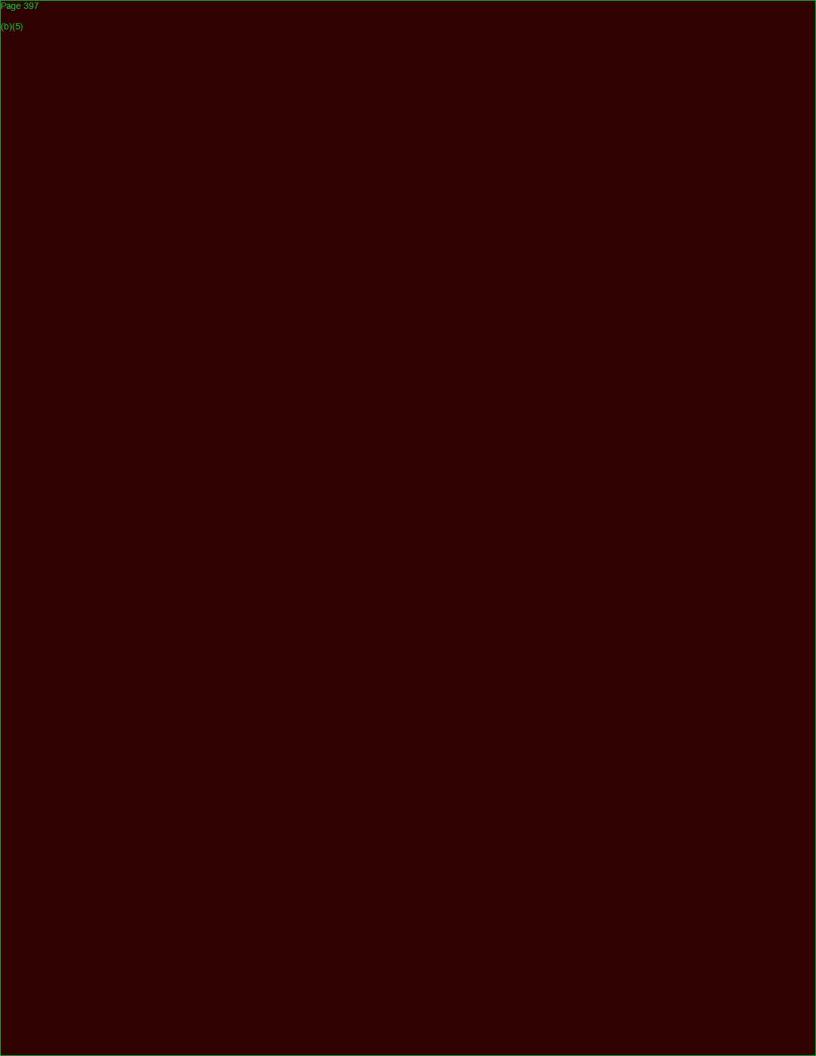
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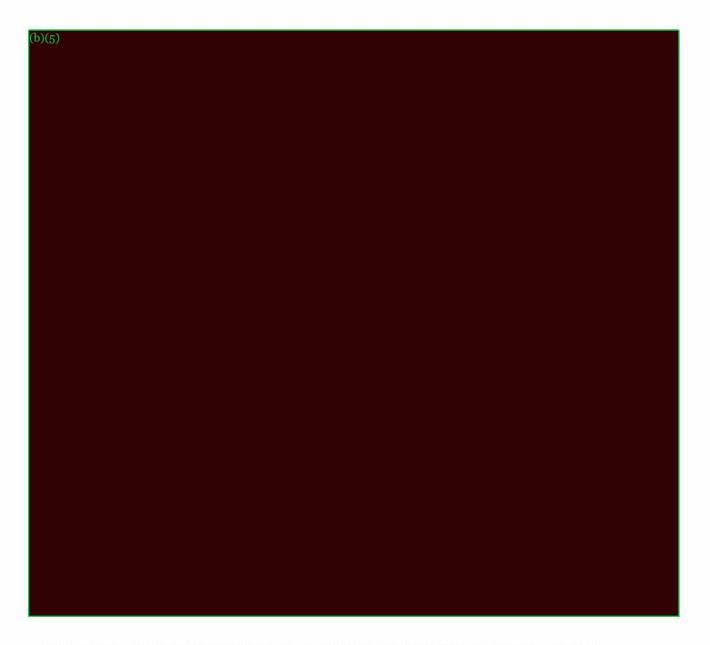
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<sup>5</sup> Includes data for US States, DC, US Territories, federal entities, and pharmacies (see table on last page for breakdown). Total doses allocated are through Jun 07, 2021

<sup>6</sup> Progress towards 70% coverage of adult (≥18 years) population with at least 1 dose by July 4, 2021: 50 days left until July 4.





- Deaths: The current 7-day moving average of new deaths (583) decreased 9.2% compared with the previous 7-day moving average (642).\*
  - 582,263 COVID-19 deaths reported as of May 14, 2021, including 690 new deaths reported by 57 jurisdictions.<sup>†</sup>

# COVID-19 Deaths: 7-Day Moving Average, Count, and Percent Change for the Last 21 Days

Date	7-Day Average	Number of	Percent Change in the
	Number	New Deaths	7-Day Moving Average

<sup>\*</sup>Historical deaths are excluded from the daily new deaths and 7-day average calculations until they are incorporated into the dataset by their applicable date. Of 14,476 historical deaths reported retroactively, none were reported on May 14, 2021; 125 were reported in the current week; and 250 were reported in the prior week. CDC is working with jurisdictions to obtain relevant dates and incorporate the data as soon as possible.

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	of New Deaths§		of New Deaths
8-May-21	628	566	-1.2%
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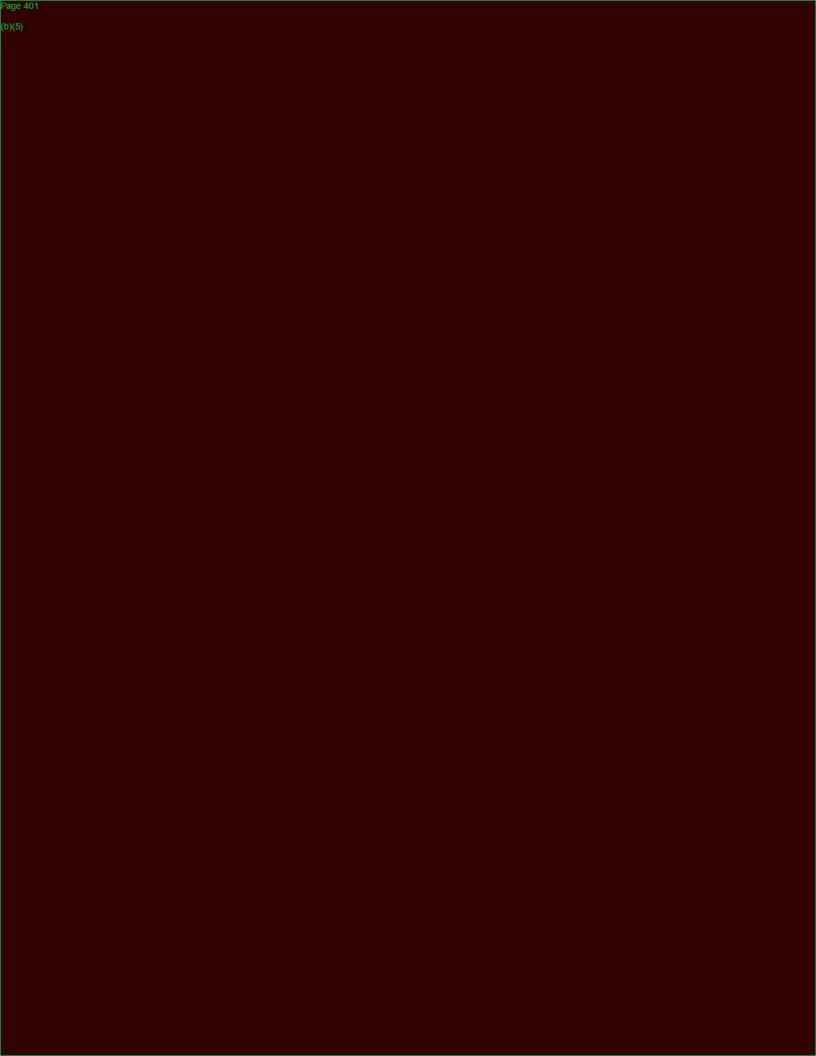
§The 7-day average values are updated as of May 14, 2021, and may differ from values presented on previous director's bullets due to ongoing incorporation of jurisdictions' historical data.

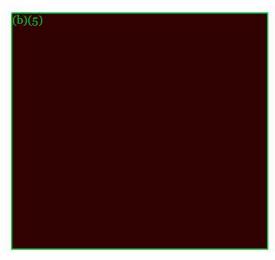


\*The nowcast estimates use a multinomial regression model of weighted sequencing data to estimate variant proportions and prediction intervals. The nowcast provides timely estimates while accounting for limited sequence data availability, as samples from that interval are still being processed. Nowcast estimates are projections and may differ from weighted estimates generated at later dates.

(b)(5)		
(b)(5)		

The tables below enumerate the point estimates and associated 95% prediction intervals of NOWCAST variant proportions of lineages that are circulating at or above 1% in the US, along with the current VOI and VOC proportions for the two-week period ending May 8, 2021.



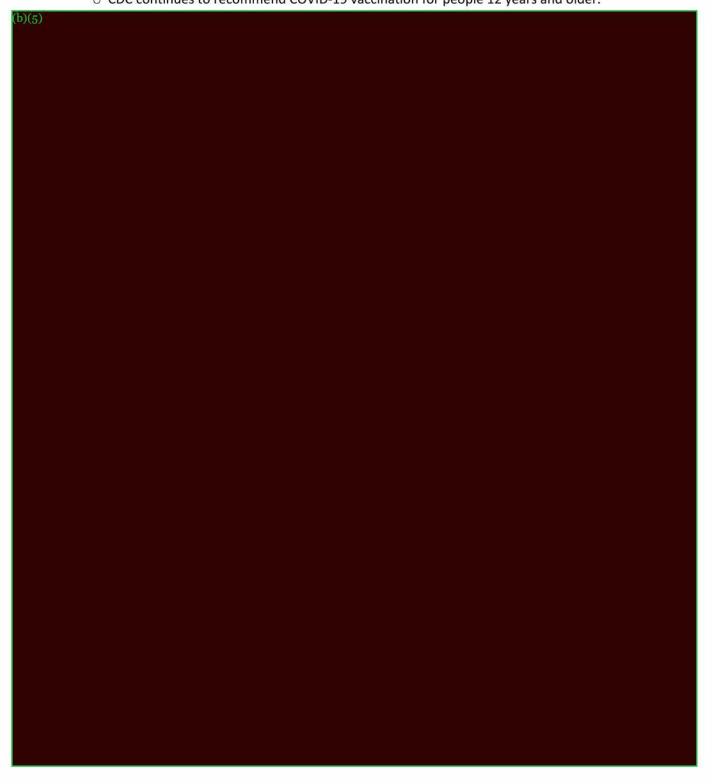




- Monitoring Reports of Myocarditis:
  - In recent weeks, there have been reports of myocarditis occurring after COVID-19
     vaccination, including in Europe, where the <u>EMA recently requested data from Pfizer</u>
     and <u>Moderna on reports of myocarditis and pericarditis after vaccination</u>. CDC is aware
     of these reports, which are rare given the number of vaccine doses administered, and
     continues to monitor available data.
  - Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation
    of the lining outside the heart. In both cases, the body's immune system is causing
    inflammation in response to an infection or some other trigger. While myocarditis can
    be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart
    rhythms, shortness of breath, or chest pain.
  - As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the <u>Vaccine Adverse Event</u> <u>Reporting System (VAERS)</u> and the <u>Vaccine Safety Datalink (VSD)</u>.
  - To date, there has not been a safety signal identified in either VAERS or VSD. CDC will
    continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19
    vaccination and will share more information as it becomes available. Healthcare

providers should consider myocarditis in an evaluation of chest pain after vaccination and report all cases to VAERS.

o CDC continues to recommend COVID-19 vaccination for people 12 years and older.



# • MMWR Releases

o No publications for May 16th

# CDC COVID-19 Response Update Report DIRECTOR'S BRIEF

# Sunday, May 16, 2021



US Department of Health and Human Services Centers for Disease Control and Prevention

### Preliminary COVID-19 COVID Case and Death Data1

Data Through	Total Cases	New Cases	Total Deaths	New Deaths
May 15, 2021	32,753,123	30,659	582,750	487

Source: State-level Aggregated Case and Death Counts (ACDC)

#### **COVID-19 Summary**

	Cumulative Total	Daily	7-Day Daily	Change from Prior
			Average	7-Day Period
Cases <sup>2</sup>	32,722,464	37,314	33,228	-22.8%
Hospital Admissions <sup>3</sup>	2,185,904	3,641	3,865	-13.6%
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Data as of May 15, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID Tracker

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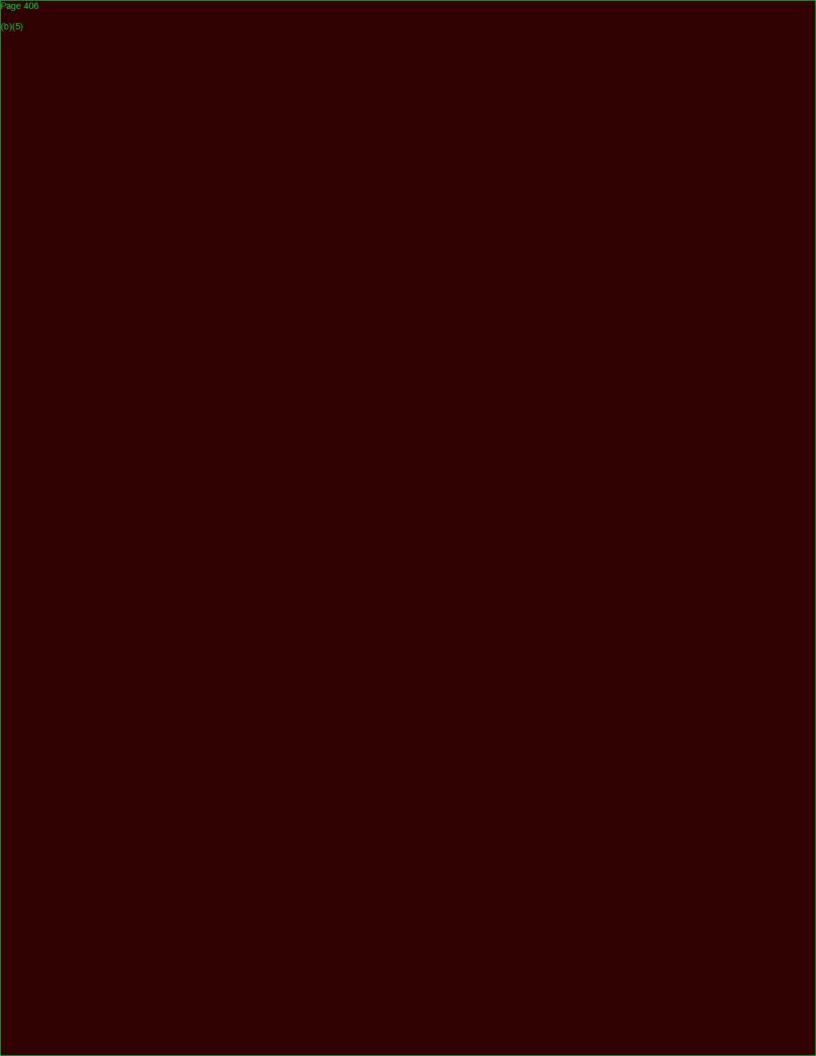
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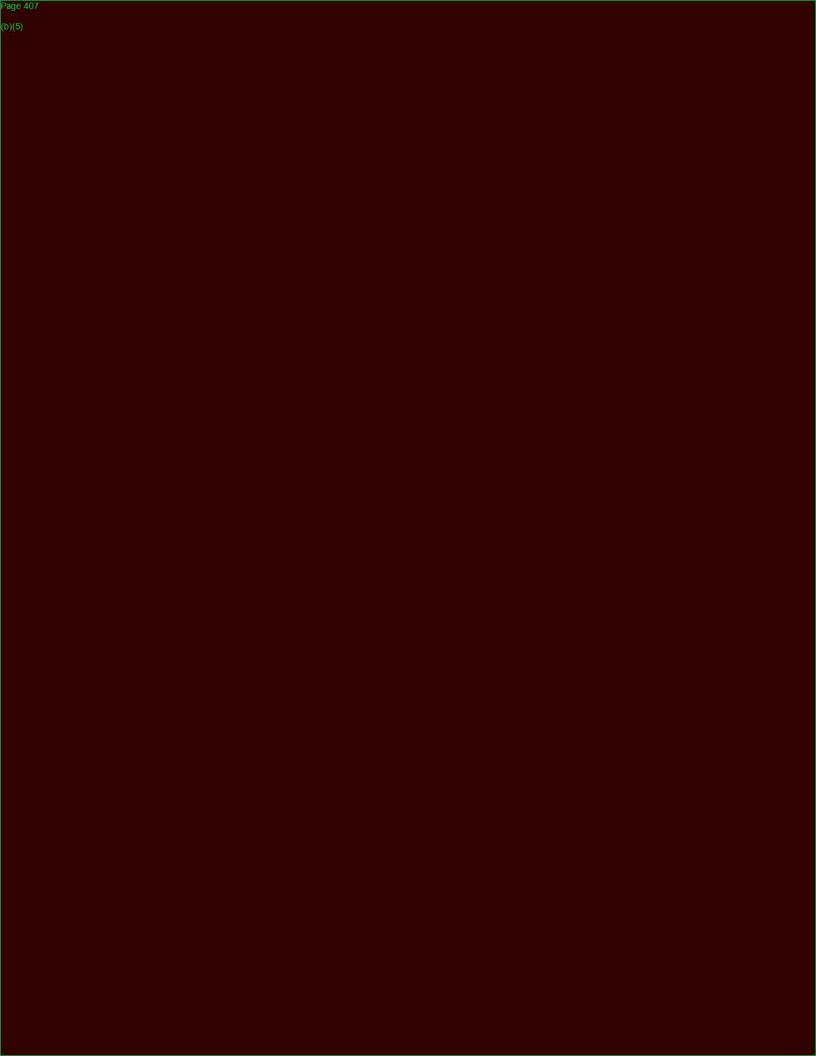
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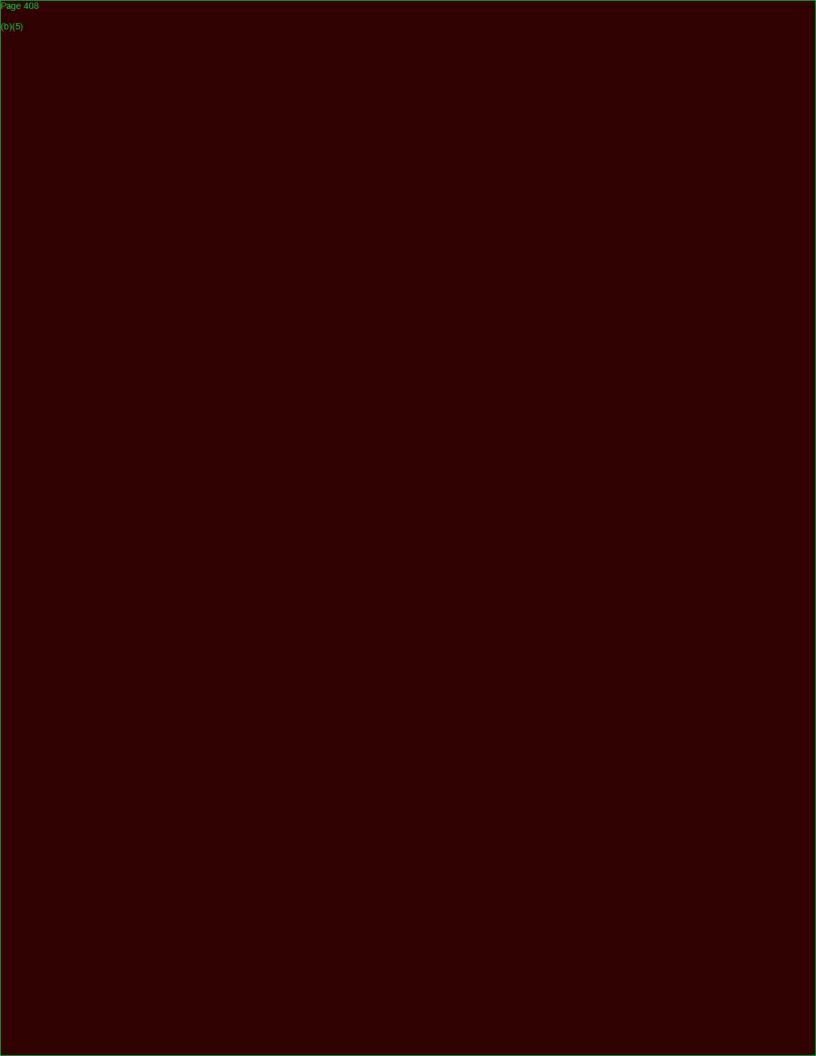
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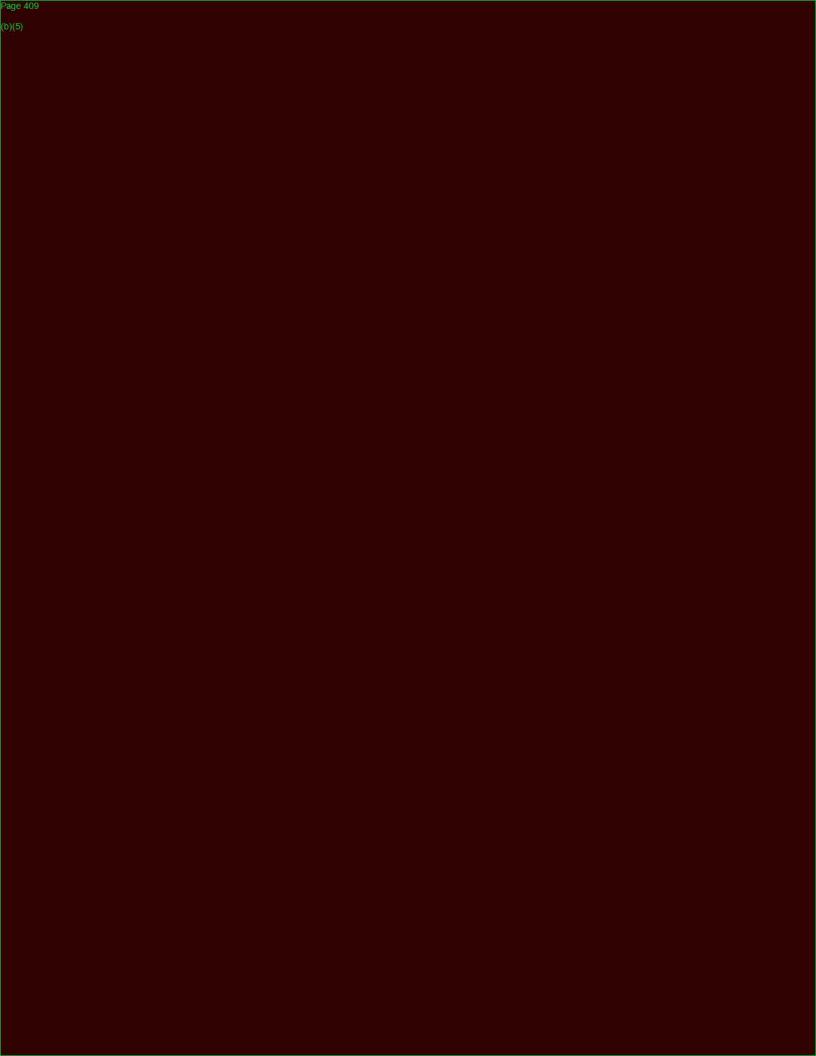
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From: Walke, Henry (CDC/DDID/NCEZID/DPEI)

**Sent:** Sat, 15 May 2021 23:42:15 +0000 **To:** Walensky, Rochelle (CDC/OD)

Cc: Schuchat, Anne MD (CDC/OD); Berger, Sherri (CDC/OCOO/OD); Daskalakis,

Demetre (CDC/DDID/NCHHSTP/DHP); Kimbrel, Alicia (CDC/OD/OCS)

Subject: DIRECTORS BRIEF 20210516

Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE - DIRECTORS BRIEF 20210516.pdf

# Will add prelim counts in AM

Sunday, May 16, 2021

	Cumulative Total	Daily	7-Day Daily	Change from Prior
			Average	7-Day Period
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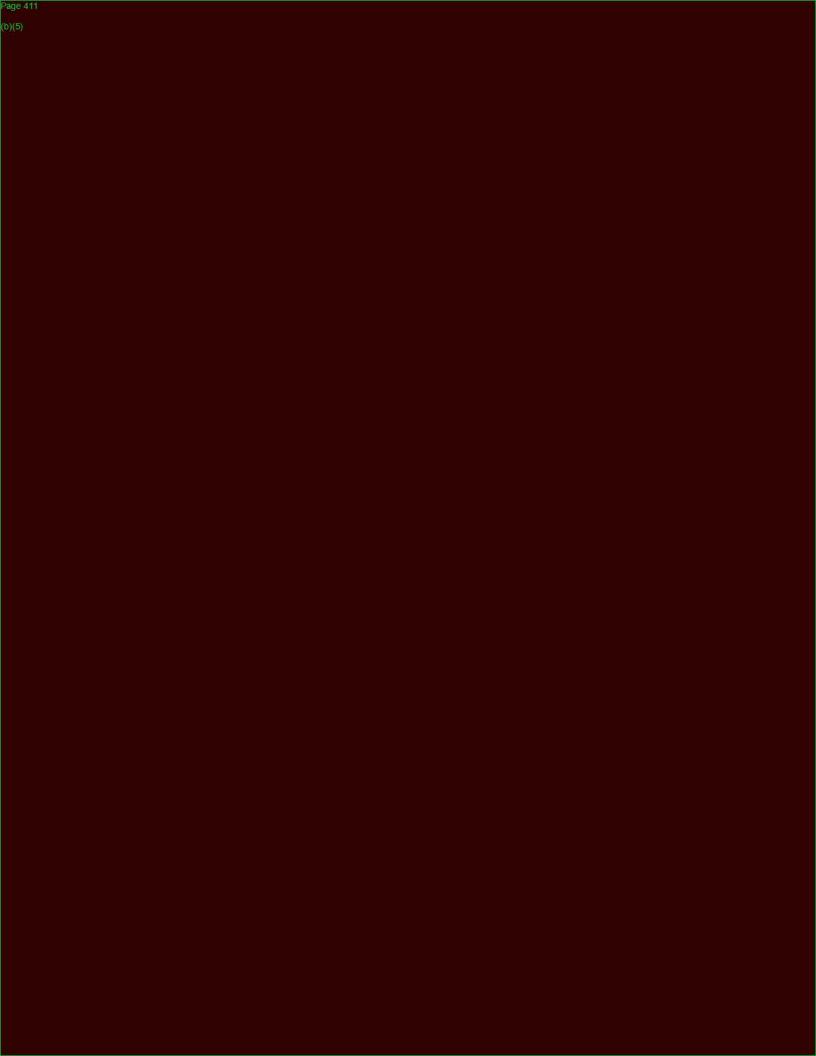
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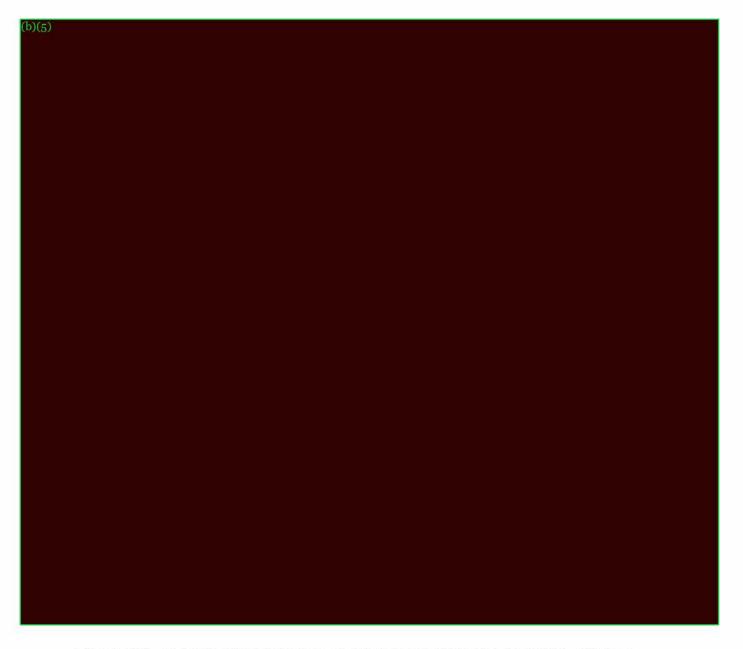
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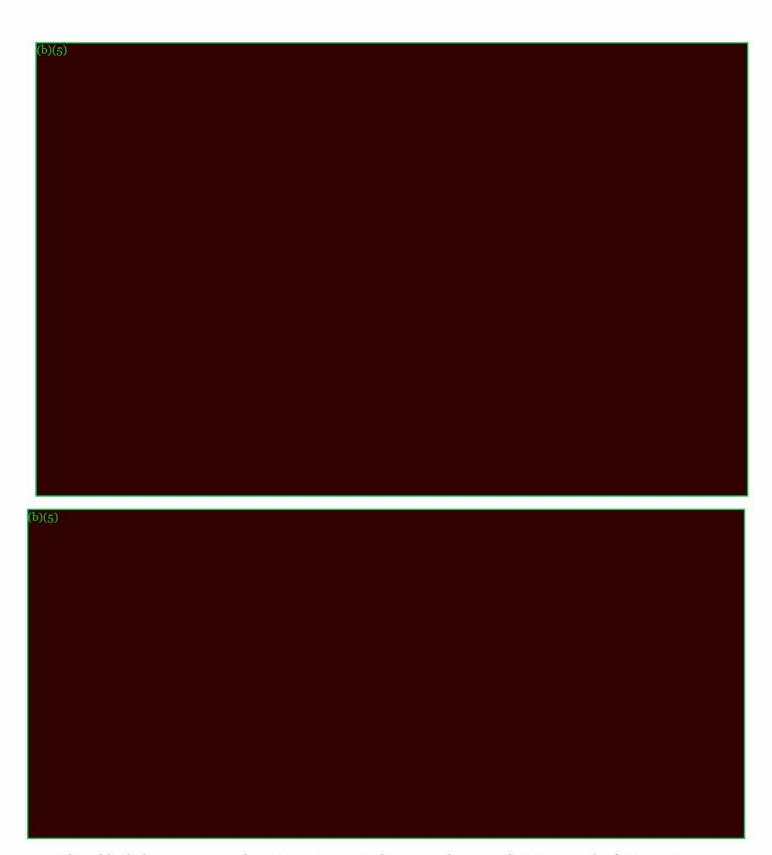
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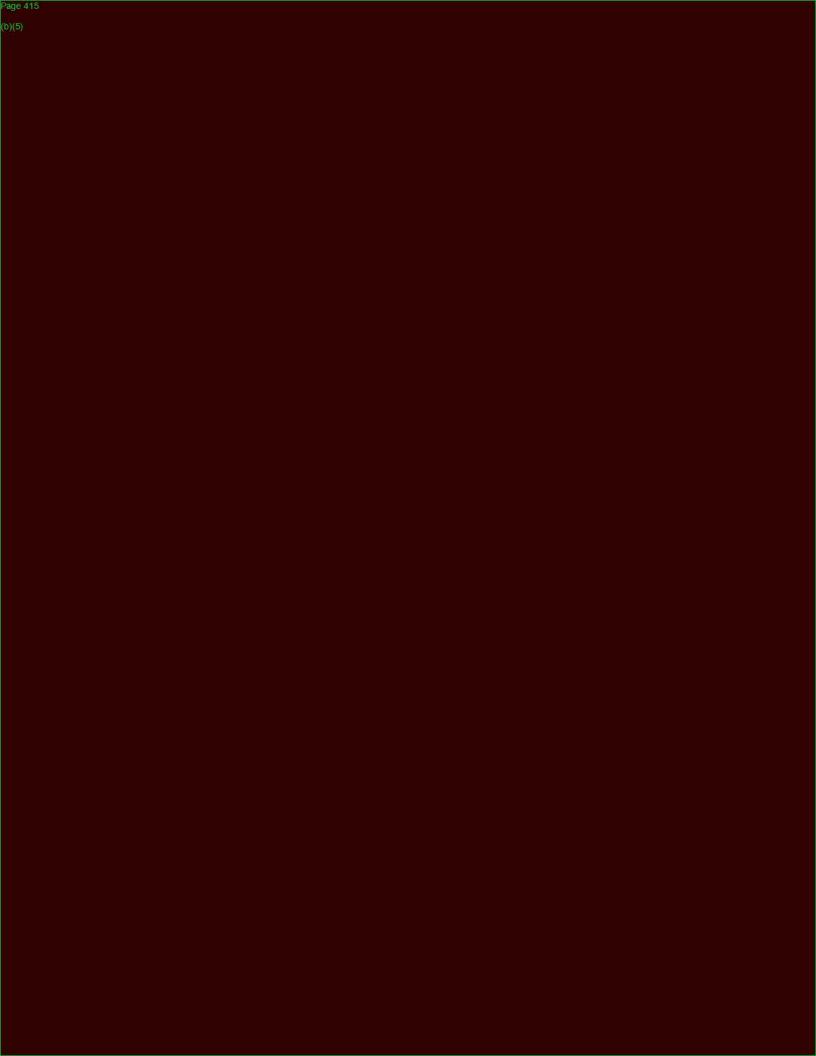
§The 7-day average values are updated as of May 14, 2021, and may differ from values presented on previous director's bullets due to ongoing incorporation of jurisdictions' historical data.



\*The nowcast estimates use a multinomial regression model of weighted sequencing data to estimate variant proportions and prediction intervals. The nowcast provides timely estimates while accounting for limited sequence data availability, as samples from that interval are still being processed. Nowcast estimates are projections and may differ from weighted estimates generated at later dates.



The tables below enumerate the point estimates and associated 95% prediction intervals of NOWCAST variant proportions of lineages that are circulating at or above 1% in the US, along with the current VOI and VOC proportions for the two-week period ending May 8, 2021.





- Monitoring Reports of Myocarditis:
  - In recent weeks, there have been reports of myocarditis occurring after COVID-19
    vaccination, including in Europe, where the <u>EMA recently requested data from Pfizer</u>
    and <u>Moderna on reports of myocarditis and pericarditis after vaccination</u>. CDC is aware
    of these reports, which are rare given the number of vaccine doses administered, and
    continues to monitor available data.
  - Myocarditis is the inflammation of the heart muscle and pericarditis is the inflammation
    of the lining outside the heart. In both cases, the body's immune system is causing
    inflammation in response to an infection or some other trigger. While myocarditis can
    be serious, it is frequently mild and self-limited. Symptoms can include abnormal heart
    rhythms, shortness of breath, or chest pain.
  - As part of COVID-19 vaccine safety efforts, we have been closely monitoring myocarditis/pericarditis in multiple safety systems, including the <u>Vaccine Adverse Event</u> <u>Reporting System (VAERS)</u> and the <u>Vaccine Safety Datalink (VSD)</u>.
  - To date, there has not been a safety signal identified in either VAERS or VSD. CDC will
    continue to evaluate reports of myocarditis/pericarditis occurring after COVID-19
    vaccination and will share more information as it becomes available. Healthcare

providers should consider myocarditis in an evaluation of chest pain after vaccination and report all cases to VAERS.

 $\circ\,$  CDC continues to recommend COVID-19 vaccination for people 12 years and older. (b)(5)

# • MMWR Releases

o No publications for May 16th

# CDC COVID-19 Response Update Report DIRECTOR'S BRIEF

# Sunday, May 16, 2021



US Department of Health and Human Services Centers for Disease Control and Prevention

# Preliminary COVID-19 COVID Case and Death Data<sup>1</sup>

Data Through	Total Cases	New Cases	Total Deaths	New Deaths
May 15, 2021	NA 302 303 1103 303 304 304 305 305			

Source: State-level Aggregated Case and Death Counts (ACDC)

#### **COVID-19 Summary**

Source: HHS Protect

	Cumulative Total	Daily	7-Day Daily	Change from Prior
			Average	7-Day Period
Cases <sup>2</sup>	32,722,464	37,314	33,228	-22.8%
Hospital Admissions <sup>3</sup>	2,185,904	3,641	3,865	-13.6%
Deaths <sup>2</sup>	582,263	690	583	-9.2%
Test Volume <sup>4</sup>	431,912,678	N/A	1,065,621	-9.5%
Test Positivity <sup>4</sup>	8.1%	N/A	3.4%	-10.6%

# COVID-19 Vaccinations in the United States<sup>5</sup>

	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Fully Vaccinated (% Population)
Overall US	442,630,185	344,503,395	270,832,342	156,217,367 (47.1)	121,768,268 (36.7)
Population ≥18 Years of Age <sup>6</sup>	N/A	N/A	N/A	153,374,769 (59.4)	120,313,236 (46.6)
Population ≥65 Years of Age	N/A	N/A	N/A	46,138,061 (84.4)	39,599,069 (72.4)

Data as of May 15, 2021, 06:00 ET

Sources: Data Monitoring and Reporting Section, Vaccine Task Force; CDC COVID Tracker

<sup>&</sup>lt;sup>1</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

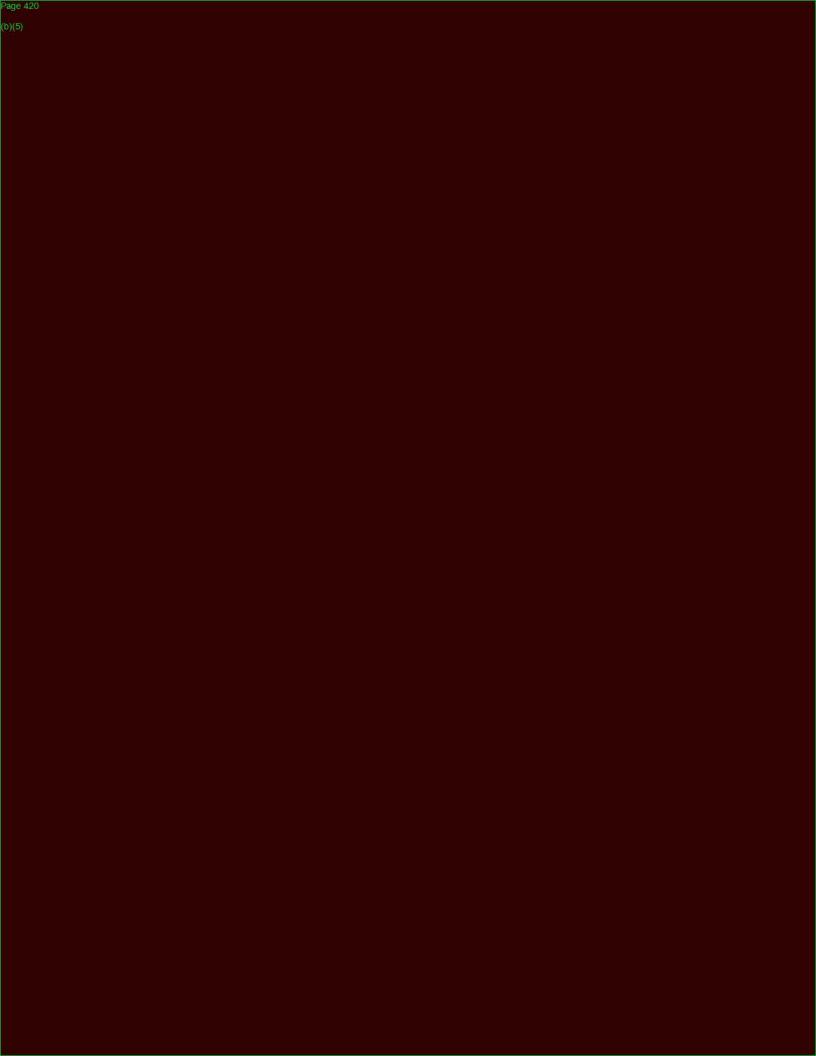
<sup>&</sup>lt;sup>2</sup> Time Period: Jan 22, 2020 – May 14, 2021; confirmed and probable cases and deaths. The total of new cases/deaths in the last 24 hours and 7-day averages do not include historical cases/deaths reported retroactively. Of 93,645 historical cases reported retroactively, 3,180 were reported on the most recent submission date; 4,694 in the current week; and 1,514 in the prior week. Of 14,476 historical deaths reported retroactively, none were reported on the most recent submission date; 125 in the current week; and 250 in the prior week.

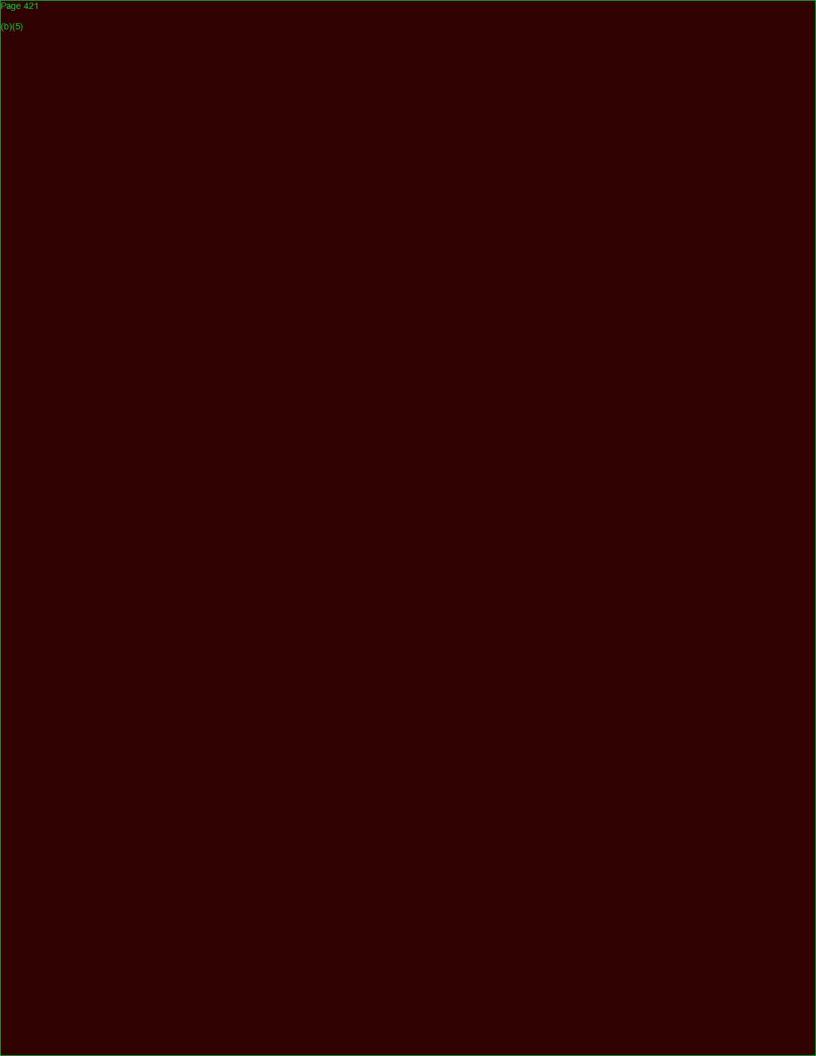
<sup>&</sup>lt;sup>3</sup> Time period: Aug 01, 2020 - May 13, 2021.

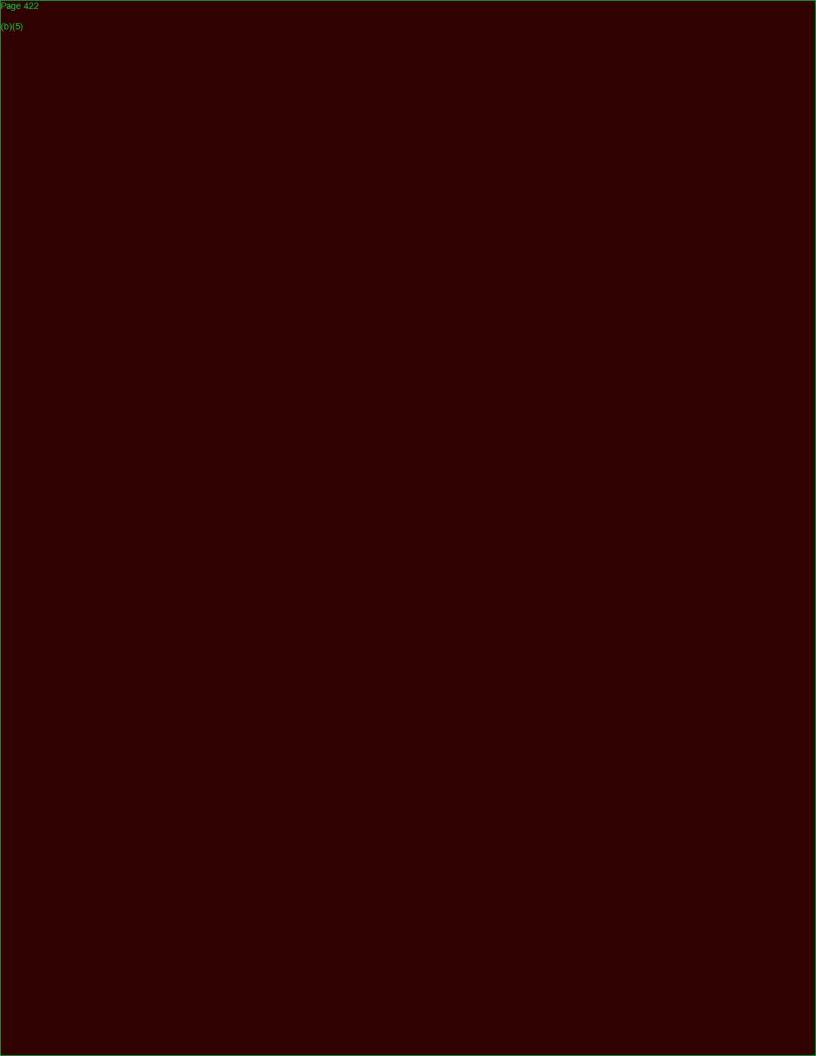
<sup>&</sup>lt;sup>4</sup> Time period: Mar 01, 2020 – May 12, 2021; Time period for test volume 7-day average and percent change: Apr 25, 2021 – May 08, 2021.

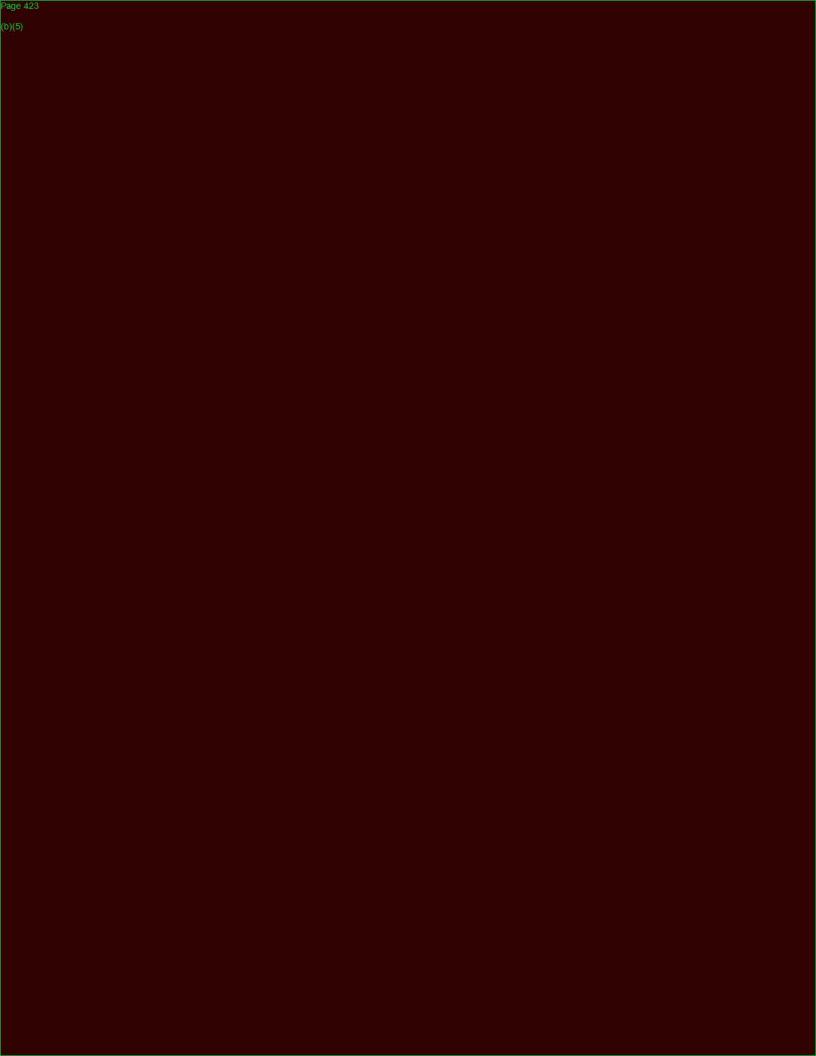
<sup>&</sup>lt;sup>5</sup> Includes data for US States, DC, US Territories, federal entities, and pharmacies (see table on last page for breakdown). Total doses allocated are through Jun 07, 2021.

<sup>&</sup>lt;sup>6</sup> Progress towards 70% coverage of adult (≥18 years) population with at least 1 dose by July 4, 2021: 50 days left until July 4.









From: (b)(6)

**Sent:** Sat, 22 May 2021 16:12:05 -0700 **To:** Walensky, Rochelle (CDC/OD)

**Subject:** Fwd: Myocarditis //// This is the right attachment

Attachments: APPENDIX 3.7 SAFETY EVALUATION OF MYOCARDITIS AND PERICARDITIS.pdf

The attachment has the Israeli data included. It has all been sent to your team.

Sent from my iPhone

Begin forwarded message:

From: "Caubel, Patrick" < Patrick. Caubel@pfizer.com>

Date: May 22, 2021 at 4:02:35 PM PDT

To: (b)(6)

Subject: Myocarditis //// This is the right attachment

Larry,

This is the data for MYOCARDITIS (excluding pericarditis). Cut-off date is today.



Number of valid Adverse Events cases reported to Pfizer as of today is myocarditis cases).

(b)(4)

Attached our latest monthly aggregate analysis.

Patrick

Month	# cases received
Jan 2021	(b)(4)
Feb 2021	
Mar 2021	

Apr 2021	(b)(4)	2
 May 2021		

Country	# cases
Austria	(b)(4)
Belgium	
Canada	
Czech Republic	
Denmark	
Finland	
France	
Germany	
Greece	
Ireland	
Israel	
Italy	
Japan	
Poland	
Portugal	
Serbia	
Spain	
Sweden	
Switzerland	
UK	
US	

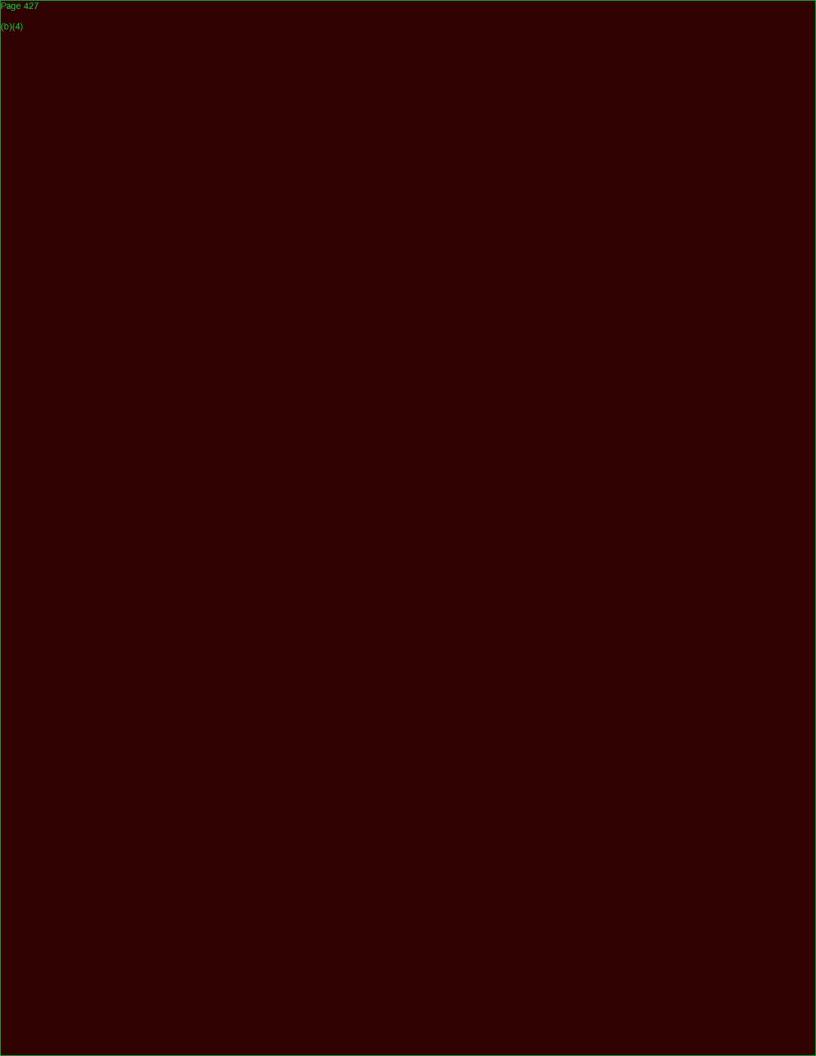
# Pfizer-BioNTech COVID-19 Vaccine

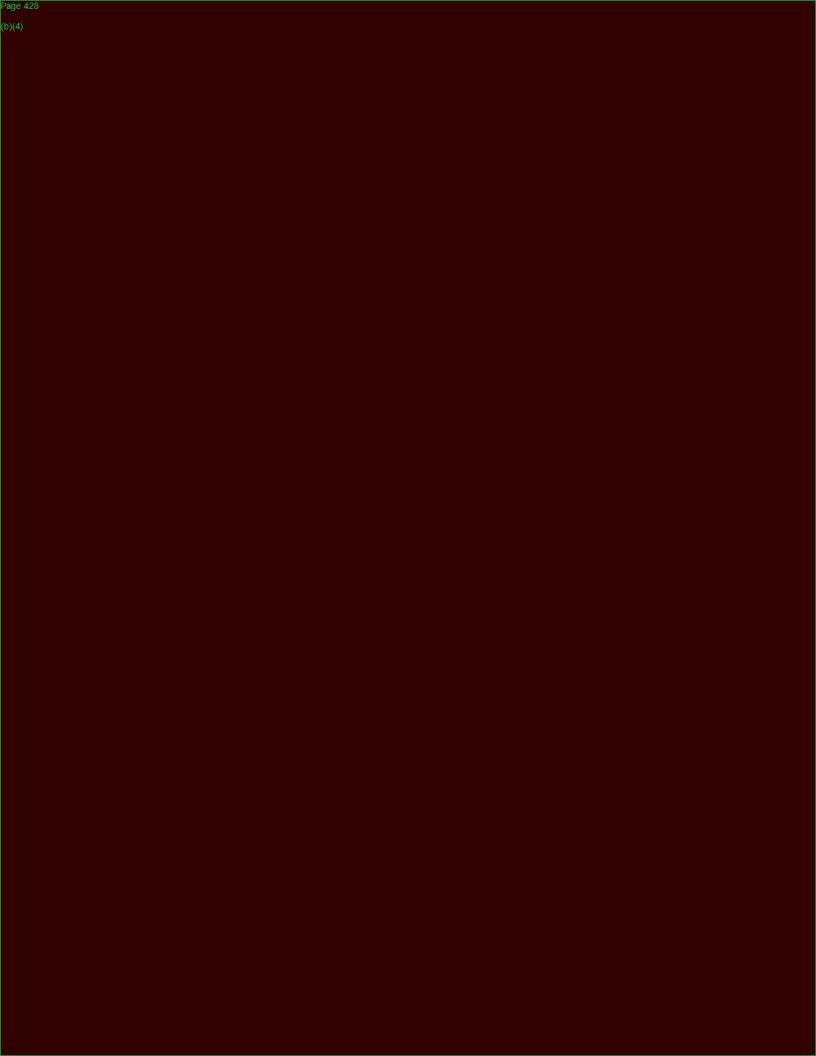
**Myocarditis and Pericarditis** 

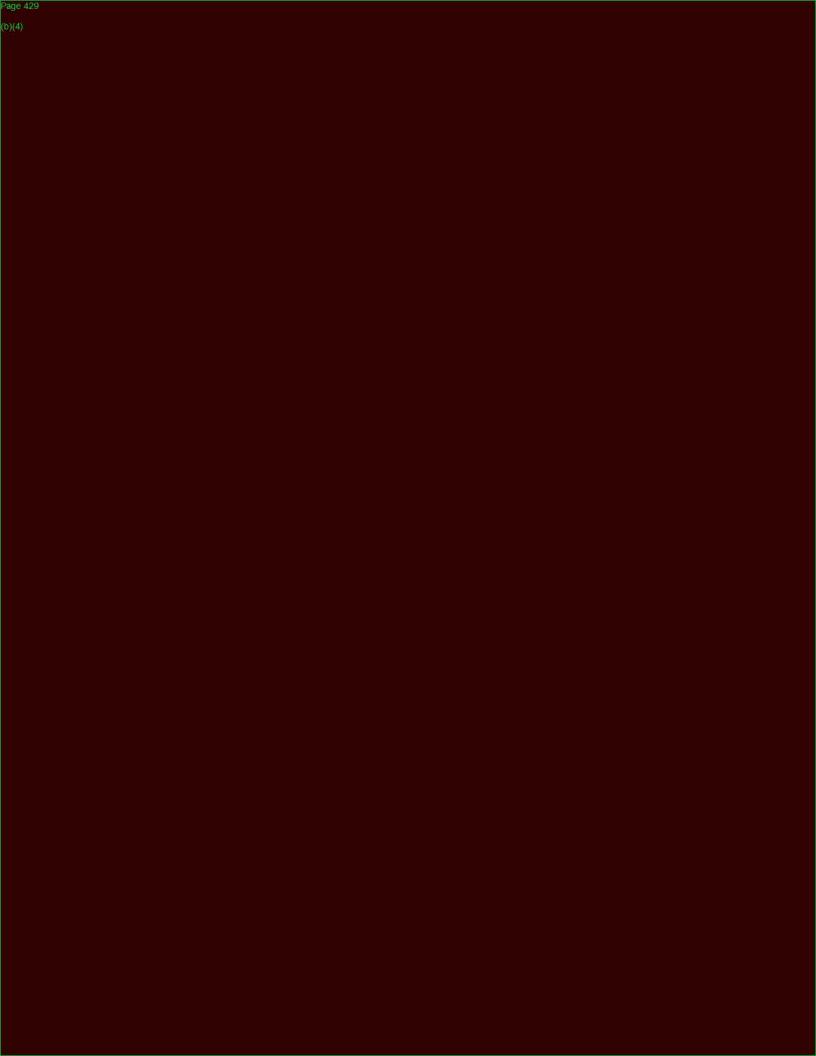
# Report Prepared by:

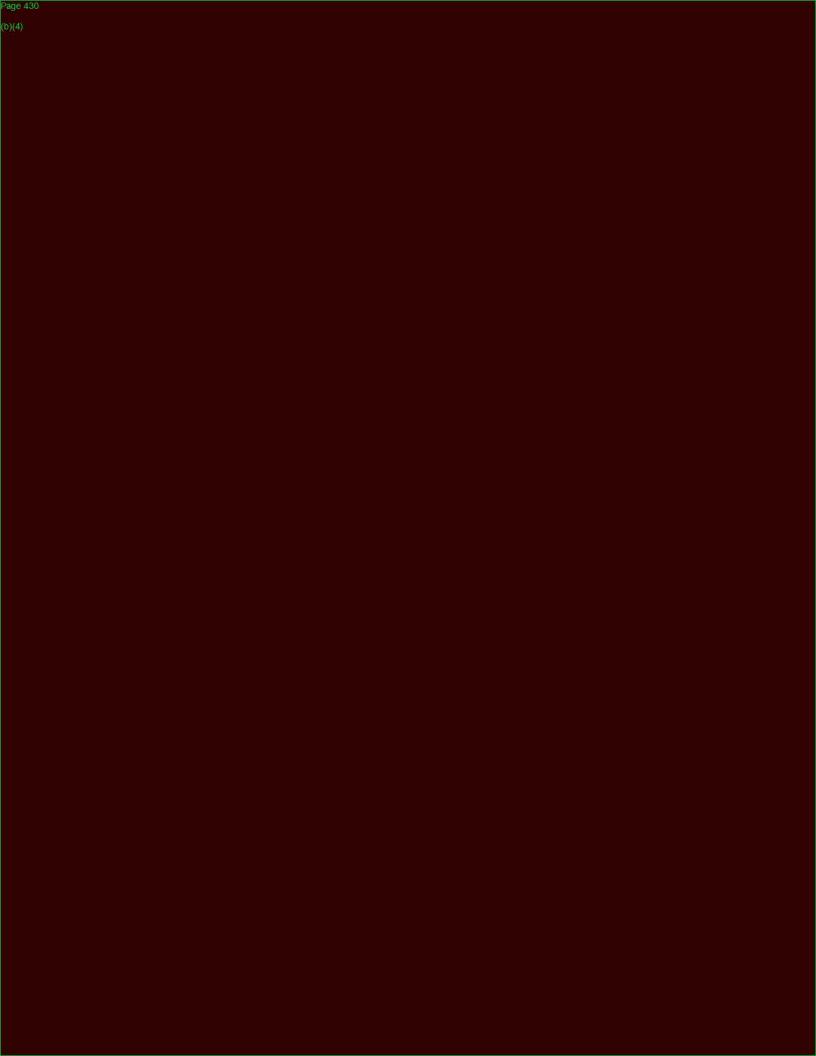
# **BioNTech-Pfizer**

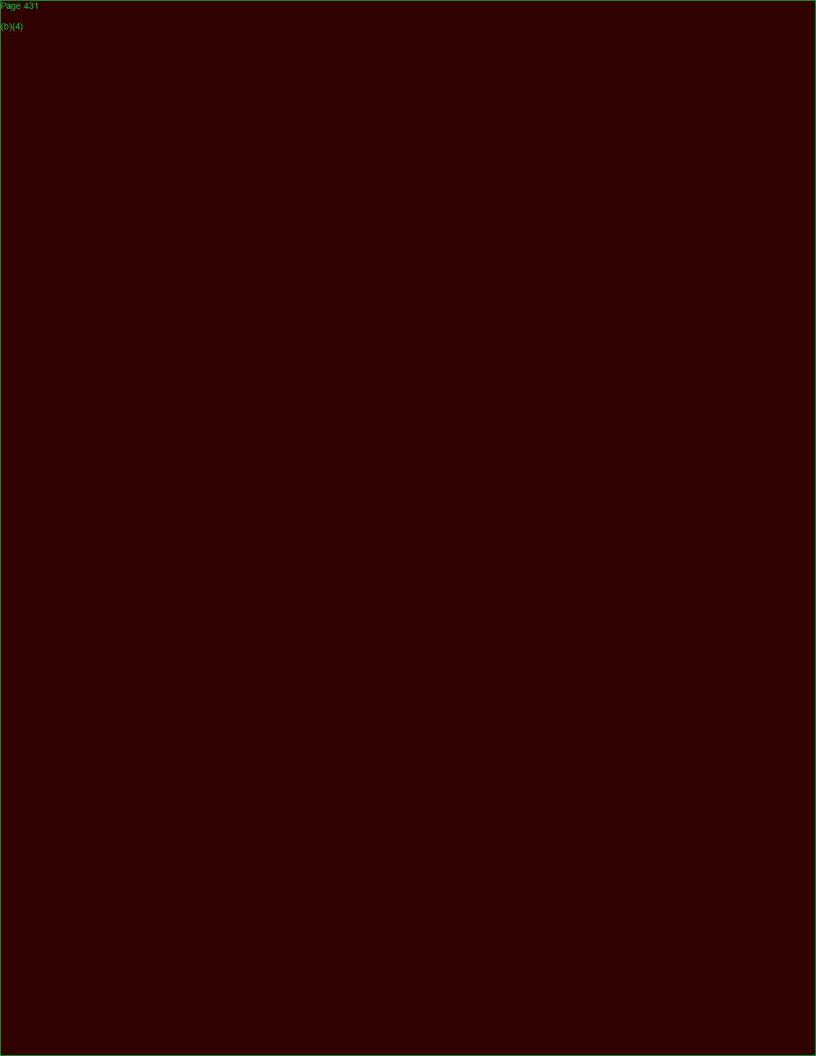
The information contained in this document is proprietary and confidential. Any disclosure, reproduction, distribution, or other dissemination of this information outside of BioNTech and Pfizer, its Affiliates, its Licensees, or Regulatory Agencies is strictly prohibited. Except as may be otherwise agreed to in writing, by accepting or reviewing these materials, you agree to hold such information in confidence and not to disclose it to others (except where required by applicable law), nor to use it for unauthorized purposes.

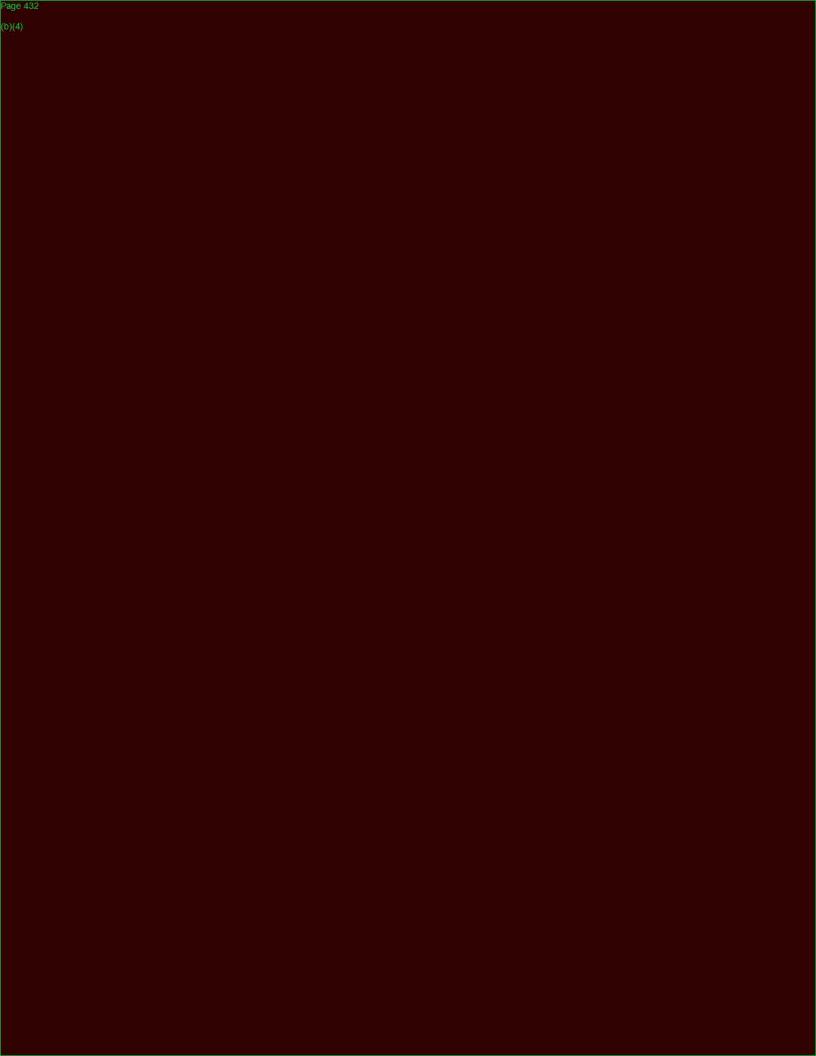


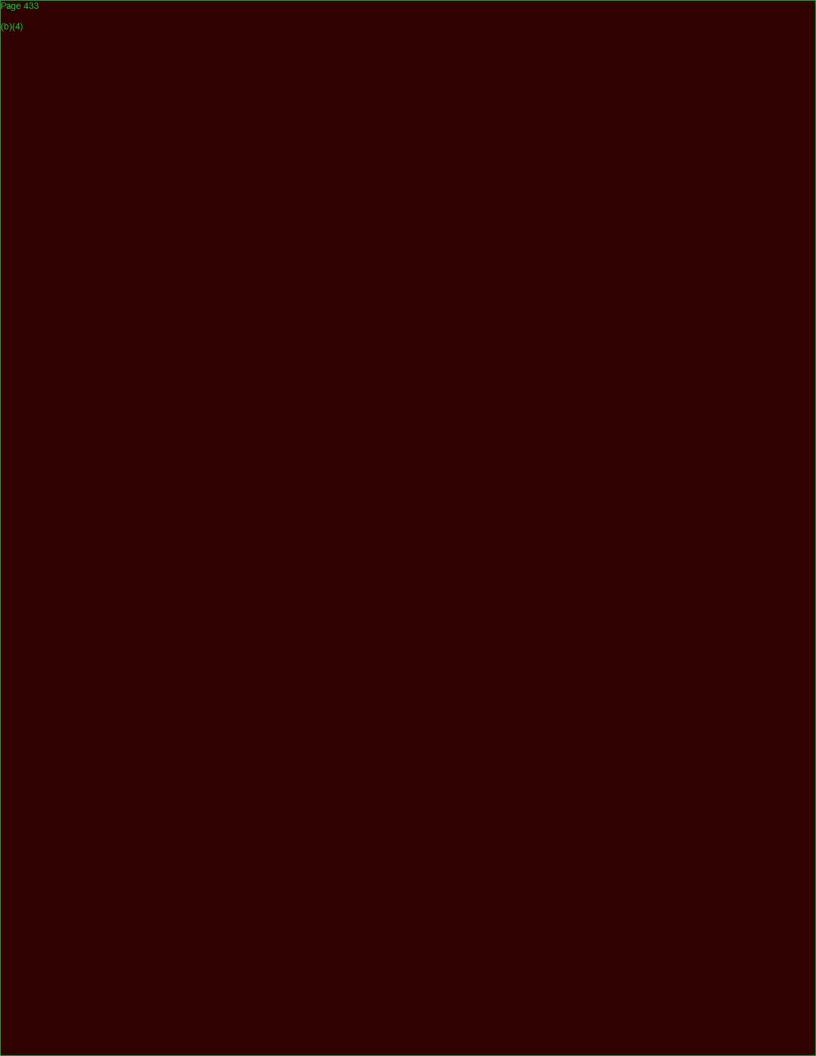


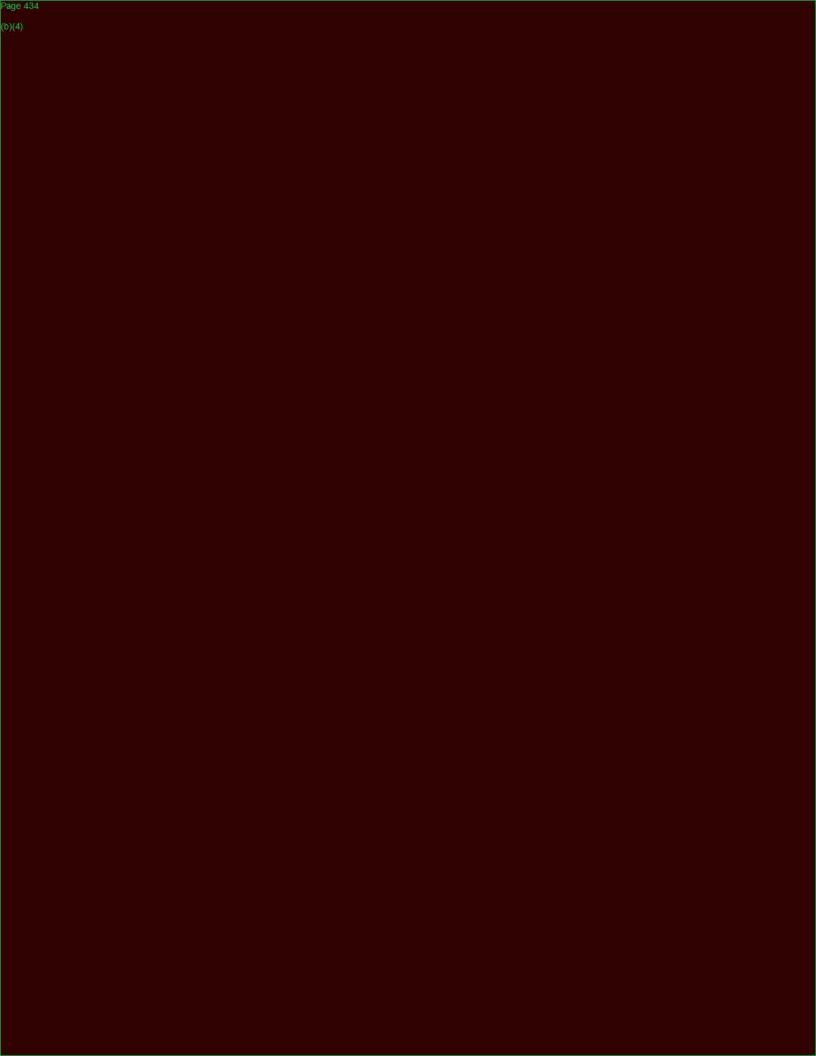


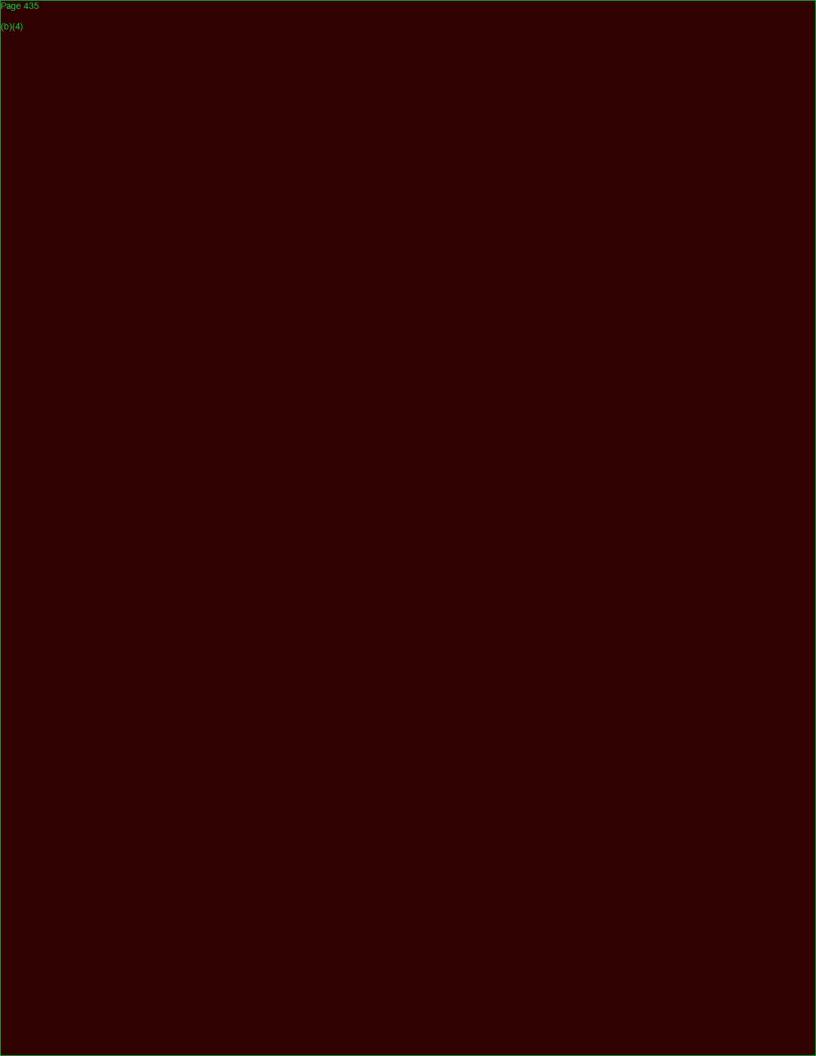


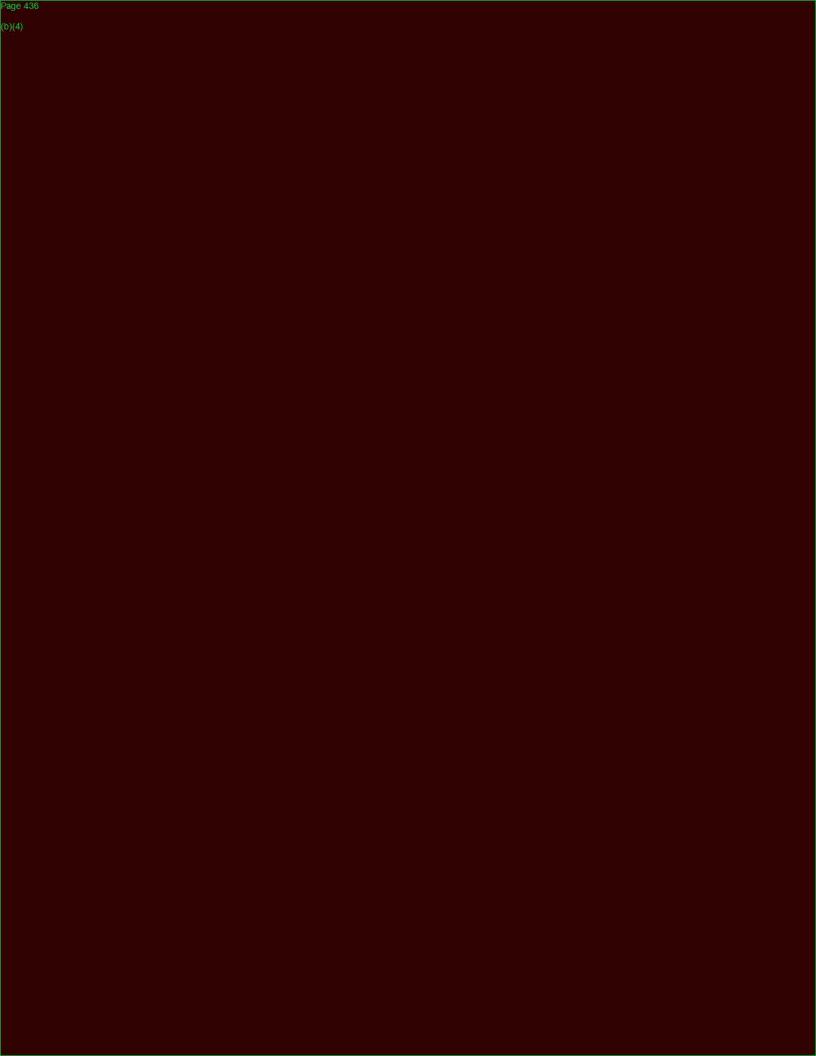


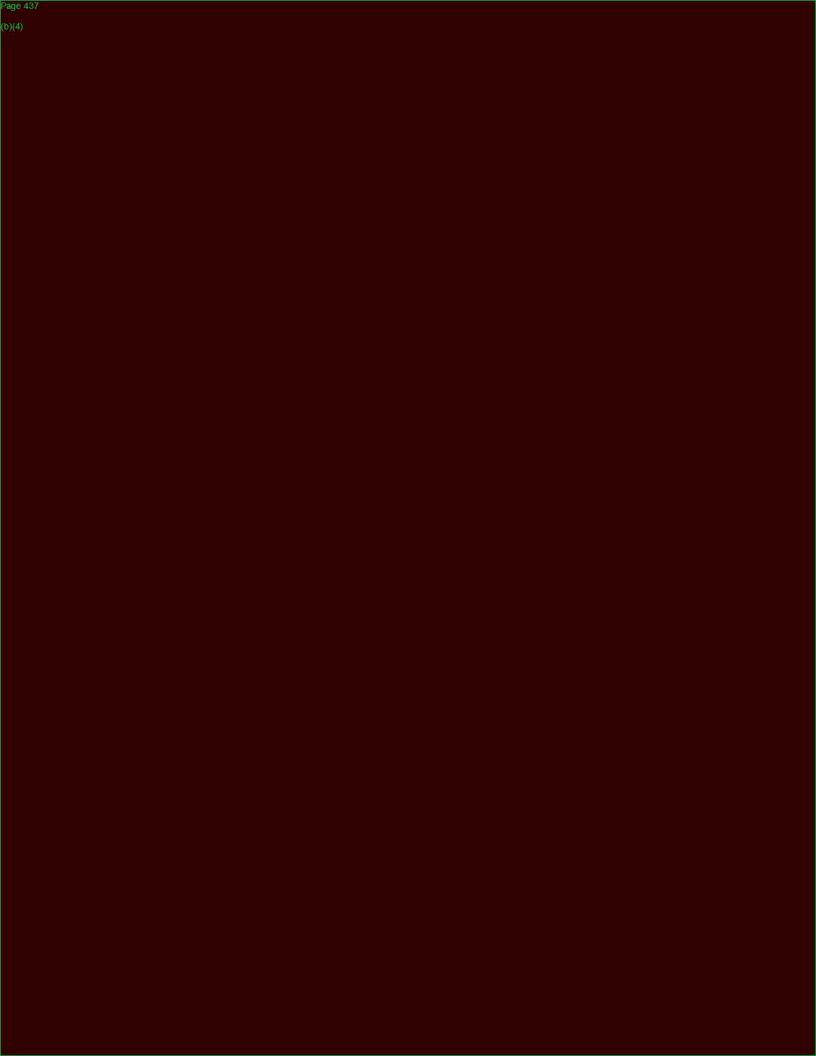


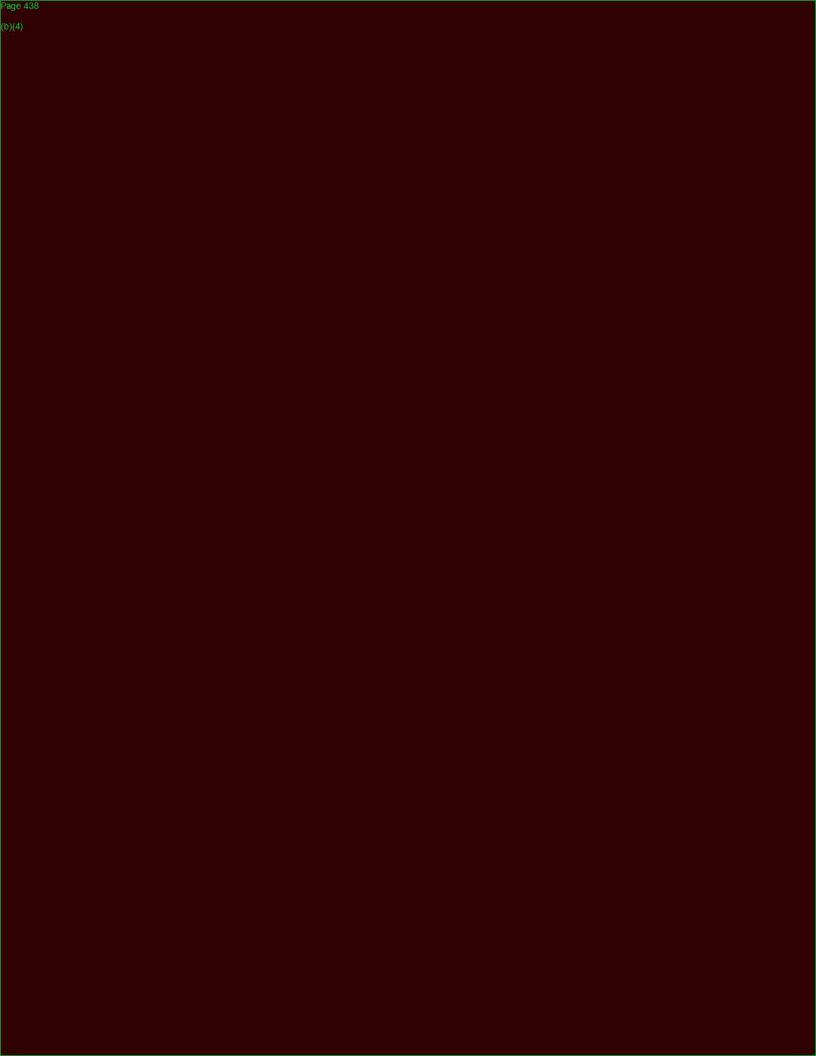


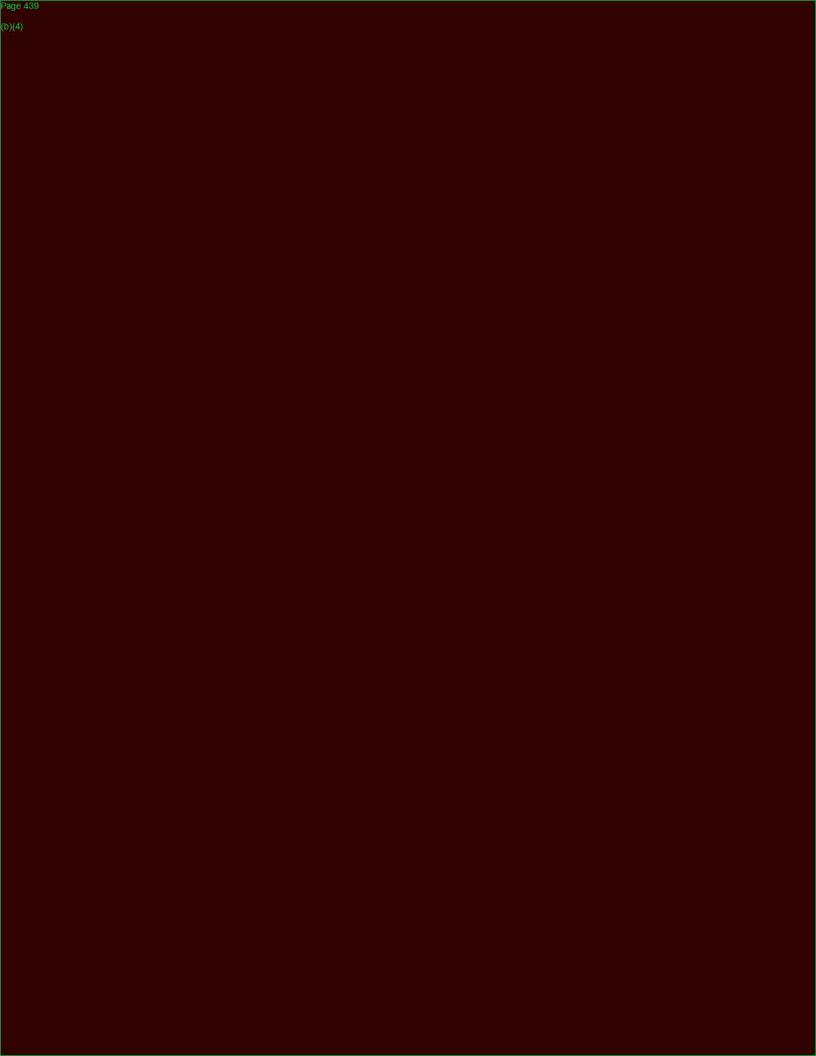


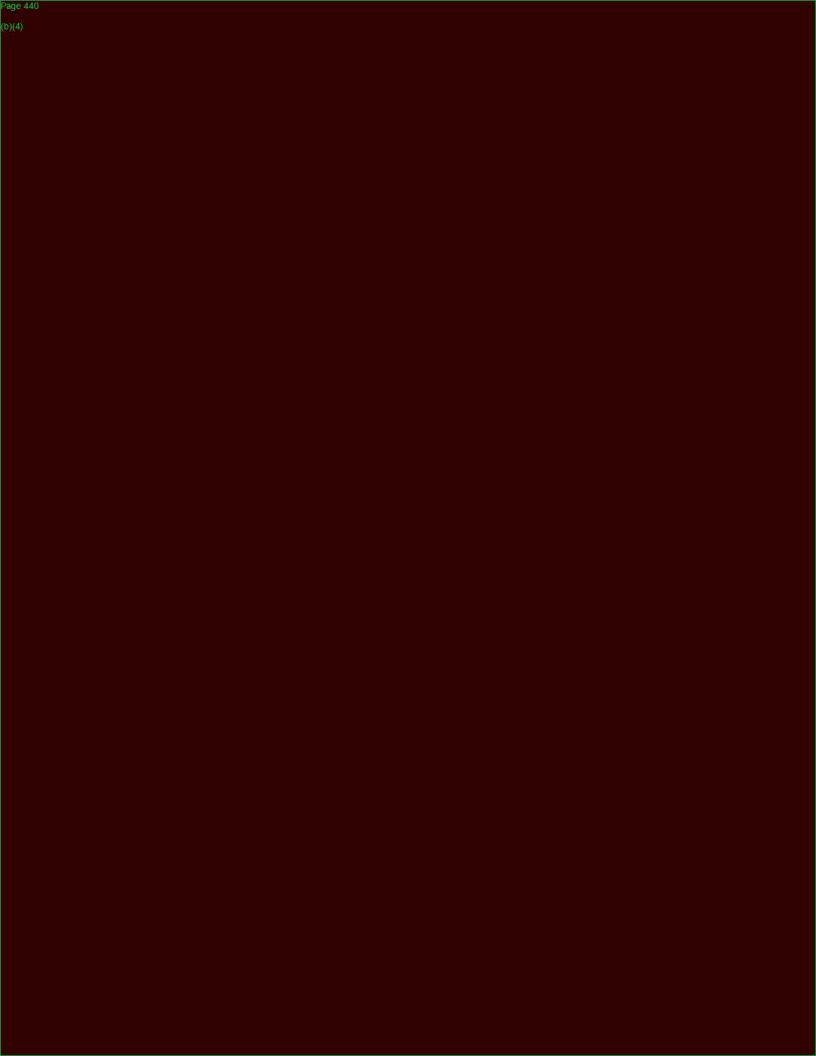












From: Beach, Michael J. (CDC/DDID/NCEZID/DFWED)

**Sent:** Thu, 27 May 2021 00:10:57 +0000 **To:** Walensky, Rochelle (CDC/OD)

Cc: Walke, Henry (CDC/DDPHSIS/CPR/OD); Beach, Michael J. (CDC/DDID/NCEZID/DFWED); Schuchat, Anne MD (CDC/OD); Daskalakis, Demetre

(CDC/DDID/NCHHSTP/DHP); Butler, Jay C. (CDC/DDID/OD); Berger, Sherri (CDC/OD/OCS)

Subject: DIRECTORS BRIEF: Thursday May 27, 2021

Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE - DIRECTORS BRIEF 20210527.pdf

Just FYI—as of today, all adult age strata within "fully vaccinated" are >30% coverage. As of last week, all adult age strata within "at least 1 dose" are >40% coverage (vaccination by age trends at CDC COVID Data Tracker)

### Thursday, May 27, 2021

COVID-19 Summary				
	Cumulative Total	Daily	7-Day Daily Average	Change from Prior 7-Day Period
Cases <sup>2</sup>	32,994,369	20,956	22,139	-23.0%
Hospital Admissions <sup>3</sup>	2,221,407	2,688	3,146	-11.4%
Deaths <sup>2</sup>	588,421	545	436	-17.7%
Test Volume <sup>4</sup>	443,001,047	N/A	933,745	-9.8%
Test Positivity <sup>4</sup>	8.0%	N/A	2.6%	-14.0%

Source: HHS Protect

COVID-19 Vaccinations in the United States <sup>5</sup>					
	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Fully Vaccinated (% Population)
Overall US	493,339,485	359,849,035	289,212,304	165,074,907 (49.7)	131,850,089 (39.7)
Population ≥18 Years of Age <sup>6</sup>	N/A	N/A	N/A	159,488,319 (61.8)	129,784,042 (50.3)
Population ≥65 Years of Age	N/A	N/A	N/A	46,742,786 (85.5)	40,532,730 (74.1)

Data as of May 26, 2021, 06:00 ET

<sup>&</sup>lt;sup>1</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

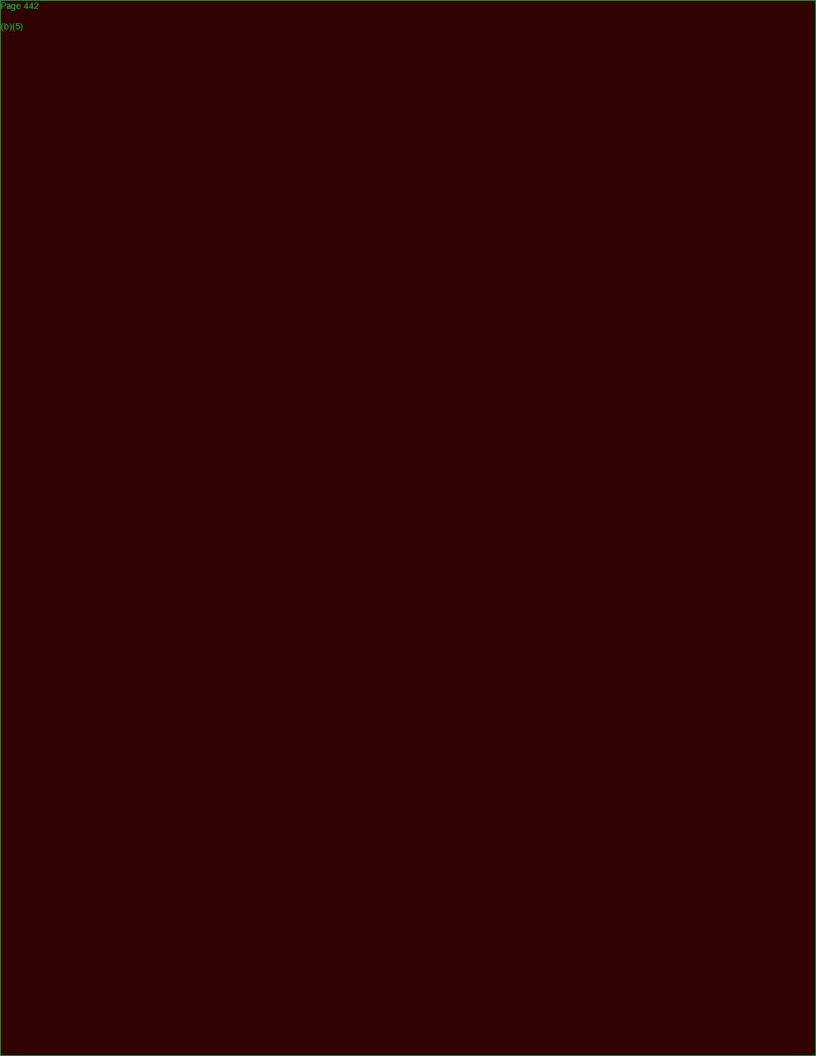
<sup>&</sup>lt;sup>3</sup> Time Period: Jan 22, 2020 – May 25, 2021; confirmed and probable cases and deaths. The total of new cases/deaths in the last 24 hours and 7-day averages do not include historical cases/deaths reported retroactively. Of 88,420 historical cases reported retroactively, 1,502 were reported on the most recent submission date; 2,486 in the current week; and 1,947 in the prior week. Of 11,331 historical deaths reported retroactively, 32 were reported on the most recent submission date; 375 in the current week; and 15 in the prior week.

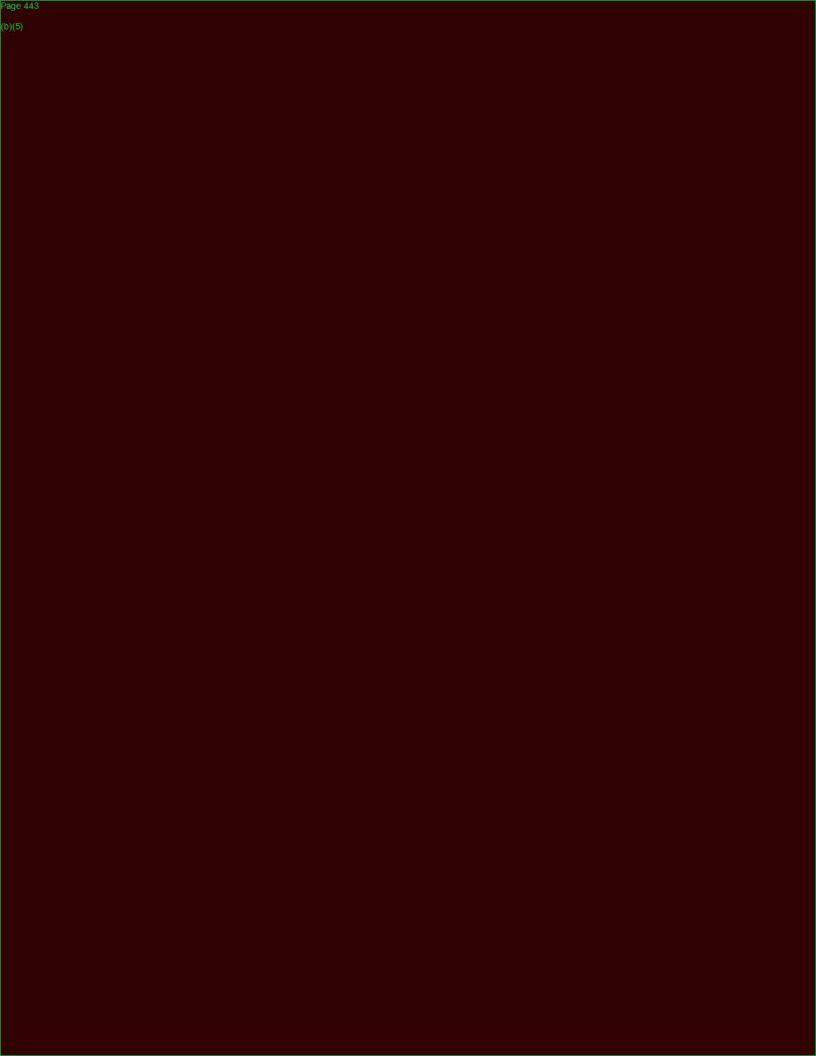
<sup>&</sup>lt;sup>3</sup> Time period: Aug 01, 2020 – May 24, 2021.

<sup>&</sup>lt;sup>4</sup> Time period: Mar 01, 2020 – May 23, 2021; Time period for test volume 7-day average and percent change: May 06, 2021 – May 19, 2021.

<sup>&</sup>lt;sup>5</sup> Includes data for US States, DC, US Territories, federal entities, and pharmacies (see table on last page for breakdown). Total doses allocated are through Jun 14, 2021.

<sup>&</sup>lt;sup>6</sup> Progress towards 70% coverage of adult (≥18 years) population with at least 1 dose by July 4, 2021: 39 days left until July 4.





- Deaths: The current 7-day moving average of new deaths (436) has decreased 17.7% compared with the previous 7-day moving average (529).\*
  - 588,421 COVID-19 deaths reported as of May 25, 2021, including 545 new deaths reported by 56 jurisdictions.<sup>†</sup>

\*Historical deaths are excluded from the daily new deaths and 7-day average calculations until they are incorporated into the dataset by their applicable date. Of 11,331 historical deaths reported retroactively, 32 were reported on May 25,2021; 375 were reported in the current week; and 15 were reported in the prior week. CDC is working with jurisdictions to obtain relevant dates and incorporate the data as soon as possible.

COVID-19 Deaths: 7-Day Moving Average, Count, and Percent Change for the Last 21 Days

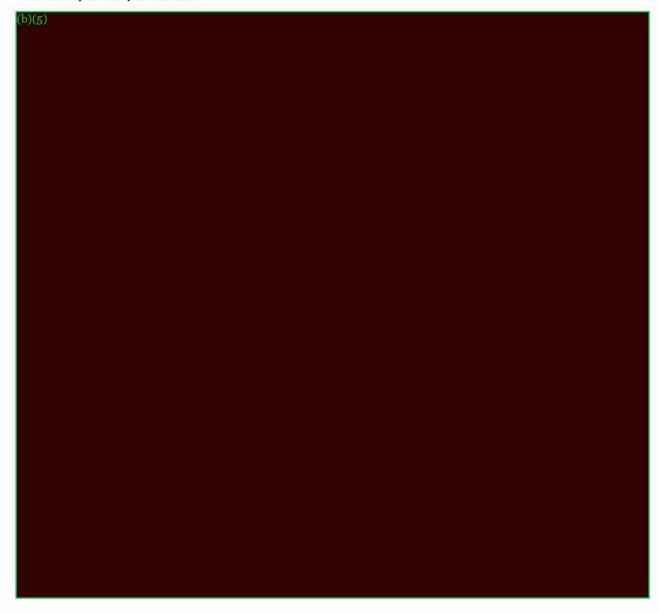
Date	7-Day Average Number of New Deaths <sup>8</sup>		Percent Change in the 7-Day Moving Average of New Deaths
5/19/2021	504	564	-11.4%
5/20/2021	489	504	-13.2%
5/21/2021	483	613	-11.6%

<sup>&</sup>lt;sup>†</sup>Four jurisdictions did not report data for May 25, 2021 (FSM, KS, MD, NC).

5/22/2021	478	323	-9.5%
5/23/2021	460	154	-12.8%
5/24/2021	450	347	-14.9%
5/25/2021	436	545	-17.7%

§The 7-day average values are updated as of May 25, 2021, and may differ from values presented on previous director's bullets due to ongoing incorporation of jurisdictions' historical data.

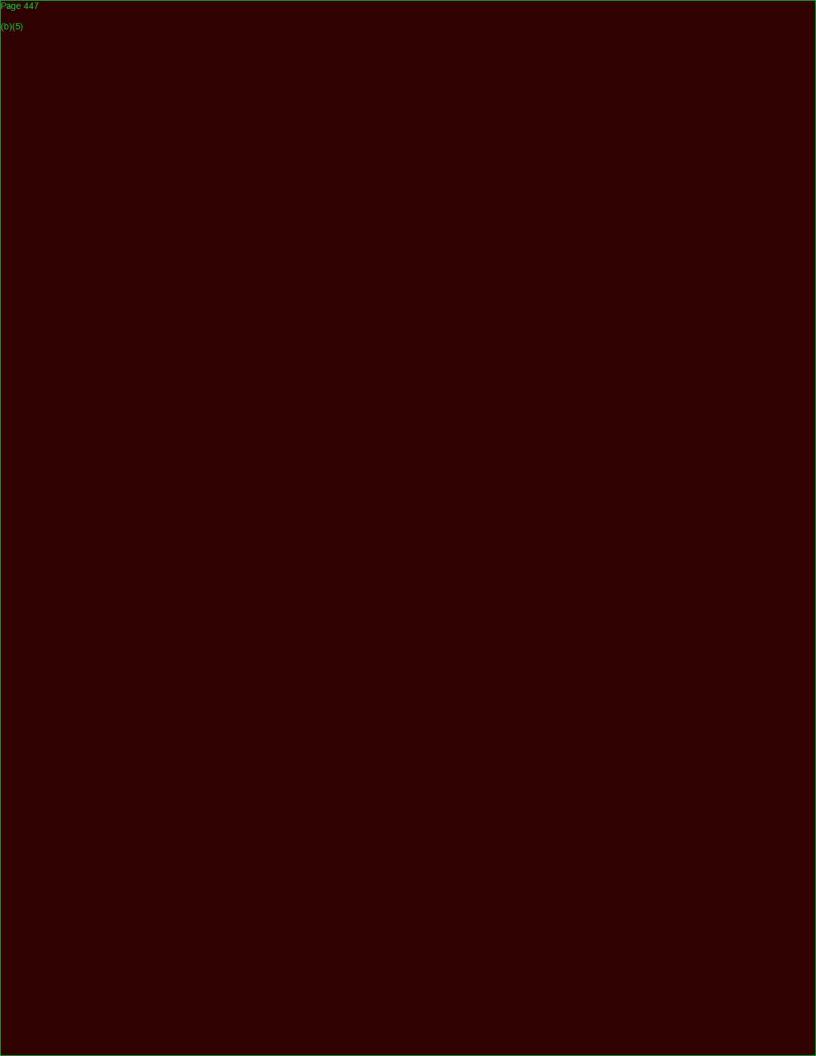
SARS-CoV-2 National and Regional Variant Proportions: The data below show weighted
estimates for specimens collected through May 8, 2021 and NOWCAST\*\* predictions for
specimens collected during the two-week period ending May 22, 2021. The proportions
corresponding to the bar on the far right and are enumerated in the table. Below is a
summary of the predictions.

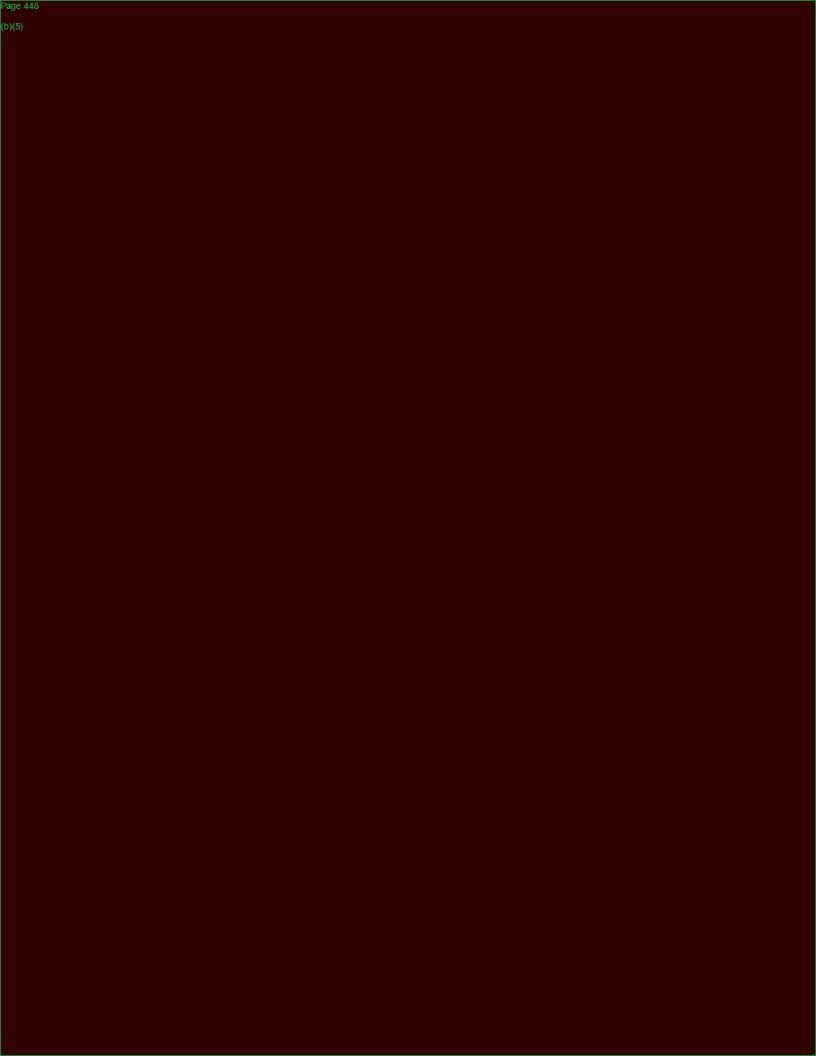


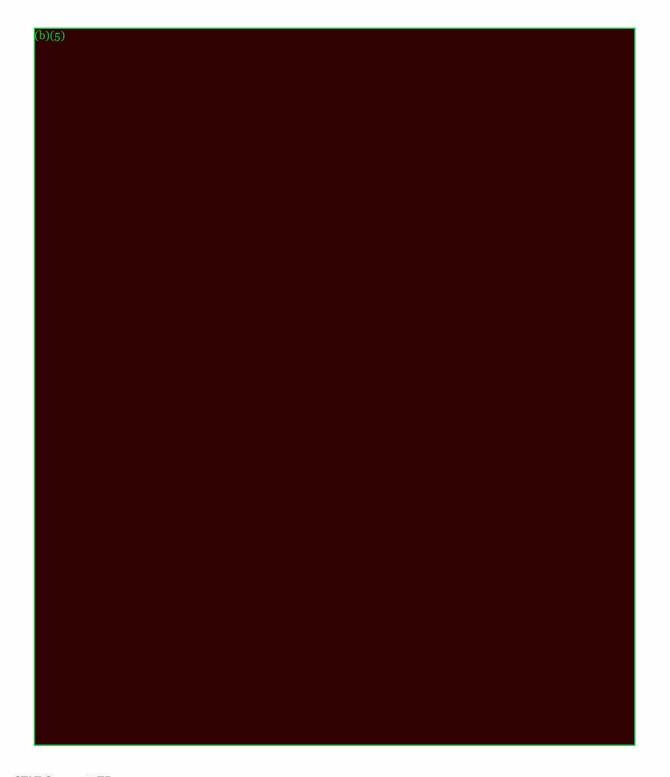


\*\* The Nowcast estimates use a multinomial regression model of weighted sequencing data to estimate variant proportions and prediction intervals. The nowcast provides timely estimates while accounting for limited sequence data availability, as samples from that interval are still being processed. Nowcast estimates are projections and may differ from weighted estimates generated at later dates.









### • STLT Support TF

 STLT's Health Department and Deployment Sections are working quickly to mobilize support for Washington State's Department of Health (WA DOH) and the 27 cases of Myocarditis/Pericarditis identified as potentially associated with COVID-19 mRNA vaccination. STLT responded to WA's request for assistance and held two calls this week, including with Vaccine TF, to plan an epidemiologic investigation of these cases. WA

- plans to start collecting medical records in a standardized format as early as 5/28 and will have a CDC epidemiologist deployed to WA to assist.
- The STLT School Field Work Section is providing technical assistance to the Lake County Health Department (Illinois) in evaluating the impact of modified quarantine on secondary transmission of SARS-CoV-2 in 33 K-12 schools. Individuals within 3-6 ft. of a COVID-19 case can be exempted from quarantine and continue in-person learning if mitigation strategies were in place at time of exposure. Exempted contacts get tested 5-7 days following exposure. Data from these schools will be compared with data on cases and contacts from 15 K-12 schools who will not implement modified quarantine.

#### MMWR Releases

One MMWR report related to the COVID-19 Response is scheduled as part of the <u>regular issue</u> of the Weekly, with the embargo lifting Thursday, May 27<sup>th</sup> at 1:00 PM. Please note that the title, content, and timing might change.

# Notes from the Field: Impact of the COVID-19 Response on Scale-up of HIV Viral Load Testing — PEPFAR-Supported Countries, January—June 2020

 BLUF: Routinely reported data from all PEPFAR-supported countries was reviewed for viral load testing coverage of ART patients and rates of viral load suppression since the COVID-19 pandemic began. Viral load testing coverage decreased during January–March 2020. After routine services were reinstated (April–June 2020), viral load testing coverage increased, and viral suppression remained stable.

### Key Points:

- Viral load coverage for all PEPFAR-supported countries was stable at 78% during September—December 2019.
- Viral load testing coverage decreased to 71% during January—March 2020, likely the result of limited access to clinical and laboratory services during the pandemic.
- After routine services were reinstated (April–June 2020), viral load testing coverage increased to 75%.
- Among ART patients who received viral load testing, the percentage who were virally suppressed remained stable at 91% during October 2019–March 2020, and increased to 92% during April–June 2020
- Summary/abstract: CDC and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) are committed to maintaining an international response to the HIV epidemic, even as countries face the challenge of controlling the COVID-19 pandemic. The Joint United Nations Programme on HIV/AIDS has set the following 95-95-95 targets for HIV infection control by 2030: 1) ensure that 95% of HIV-positive persons are aware of their HIV status, 2) ensure that 95% of these persons receive antiretroviral treatment (ART) and 3) facilitate viral load testing and suppression (viral load ≤1,000 HIV RNA copies per mL of blood) among 95% of persons with HIV infection. Because the limited availability of skilled laboratorians and restricted ART access could decrease viral load testing, the

effects of the COVID-19 pandemic on viral load testing were examined. The period reviewed was September 2019 through June 2020. Viral load testing coverage for all PEPFAR-supported countries was stable during September—December 2019. However, viral load testing coverage decreased during January—March 2020, likely the result of limited access to clinical and laboratory services during the pandemic. After routine services were reinstated (April—June 2020), viral load testing coverage increased. Despite the challenges of controlling the COVID-19 pandemic, PEPFAR-supported countries should continue advancing toward the 95-95-95 by 2030 goals with expansion of viral load testing for all persons with HIV infection who are receiving ART.

# CDC COVID-19 Response Update Report DIRECTOR'S BRIEF

## **Thursday, May 27, 2021**



US Department of Health and Human Services Centers for Disease Control and Prevention

#### Preliminary COVID-19 COVID Case and Death Data<sup>1</sup>

Data Through	Total Cases	New Cases	Total Deaths	New Deaths
May 26, 2021				

Source: State-level Aggregated Case and Death Counts (ACDC)

#### **COVID-19 Summary**

Source: HHS Protect

	<b>Cumulative Total</b>	Daily	7-Day Daily	<b>Change from Prior</b>
			Average	7-Day Period
Cases <sup>2</sup>	32,994,369	20,956	22,139	-23.0%
Hospital Admissions <sup>3</sup>	2,221,407	2,688	3,146	-11.4%
Deaths <sup>2</sup>	588,421	545	436	-17.7%
Test Volume <sup>4</sup>	443,001,047	N/A	933,745	-9.8%
Test Positivity <sup>4</sup>	8.0%	N/A	2.6%	-14.0%

COVID-19 Vaccinations in the United States<sup>5</sup>

	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Fully Vaccinated (% Population)
Overall US	493,339,485	359,849,035	289,212,304	165,074,907 (49.7)	131,850,089 (39.7)
Population ≥18 Years of Age <sup>6</sup>	N/A	N/A	N/A	159,488,319 (61.8)	129,784,042 (50.3)
Population ≥65 Years of Age	N/A	N/A	N/A	46,742,786 (85.5)	40,532,730 (74.1)

Data as of May 26, 2021, 06:00 ET

<sup>&</sup>lt;sup>1</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

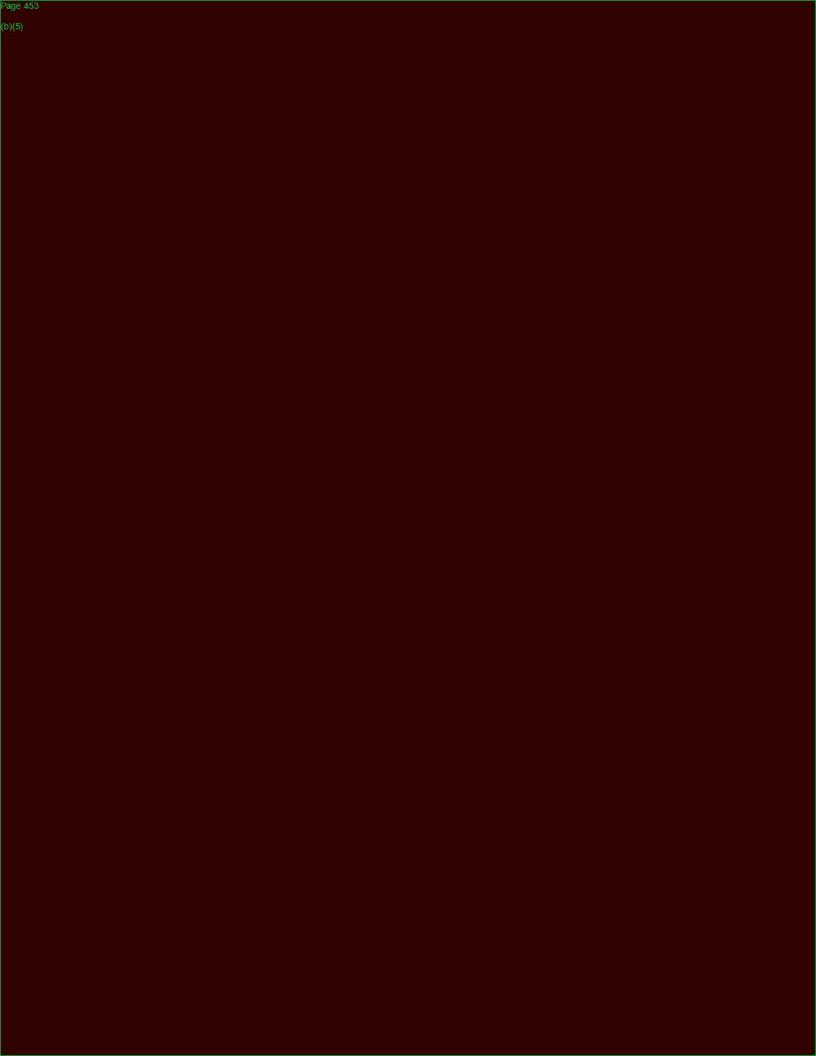
<sup>&</sup>lt;sup>2</sup> Time Period: Jan 22, 2020 – May 25, 2021; confirmed and probable cases and deaths. The total of new cases/deaths in the last 24 hours and 7-day averages do not include historical cases/deaths reported retroactively. Of 88,420 historical cases reported retroactively, 1,502 were reported on the most recent submission date; 2,486 in the current week; and 1,947 in the prior week. Of 11,331 historical deaths reported retroactively, 32 were reported on the most recent submission date; 375 in the current week; and 15 in the prior week.

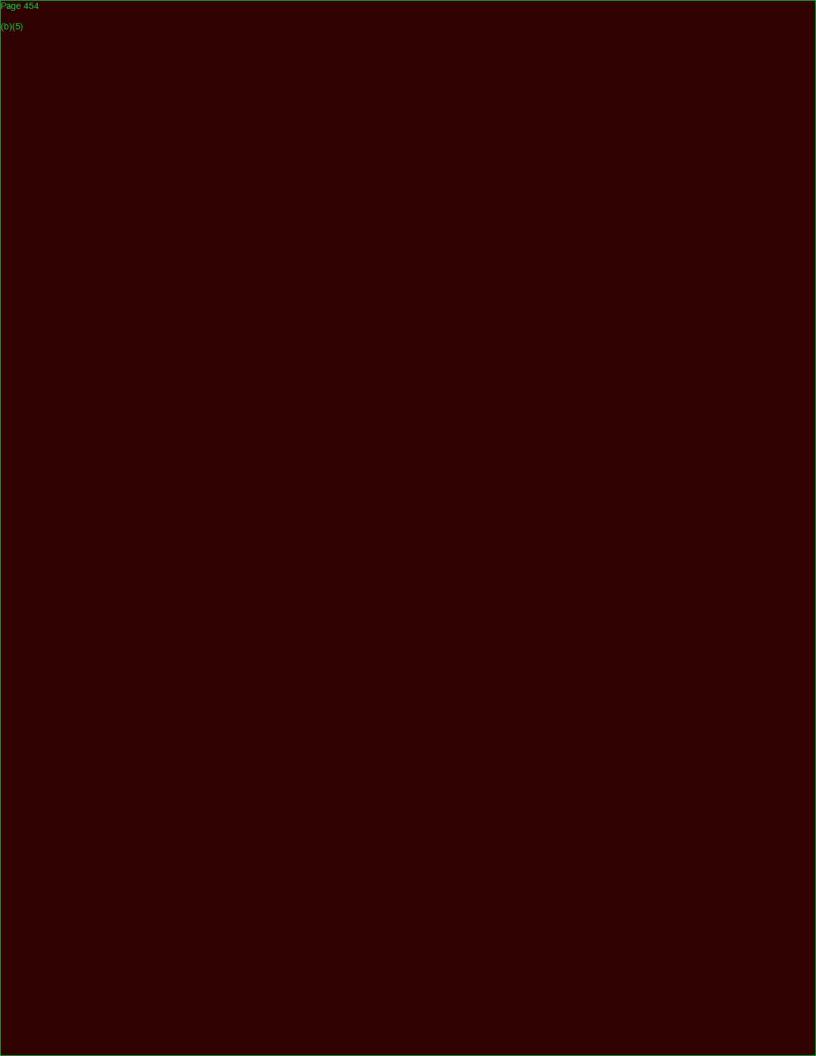
<sup>&</sup>lt;sup>3</sup> Time period: Aug 01, 2020 – May 24, 2021.

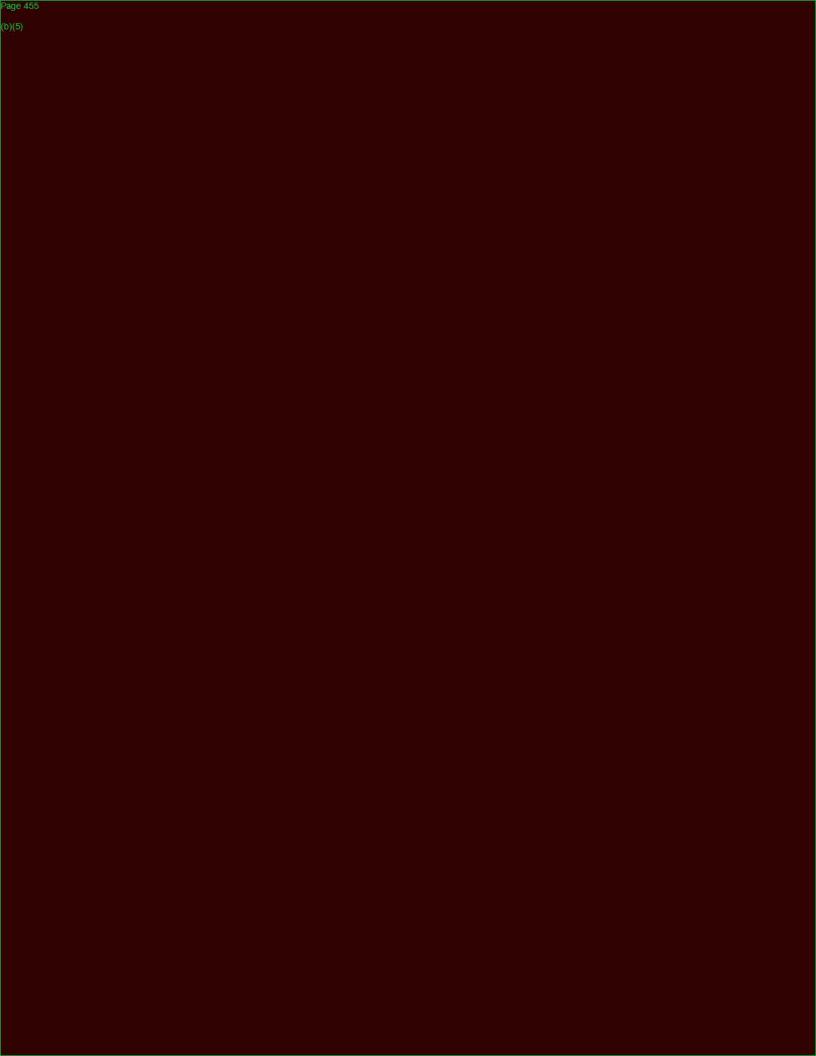
<sup>&</sup>lt;sup>4</sup> Time period: Mar 01, 2020 – May 23, 2021; Time period for test volume 7-day average and percent change: May 06, 2021 – May 19, 2021.

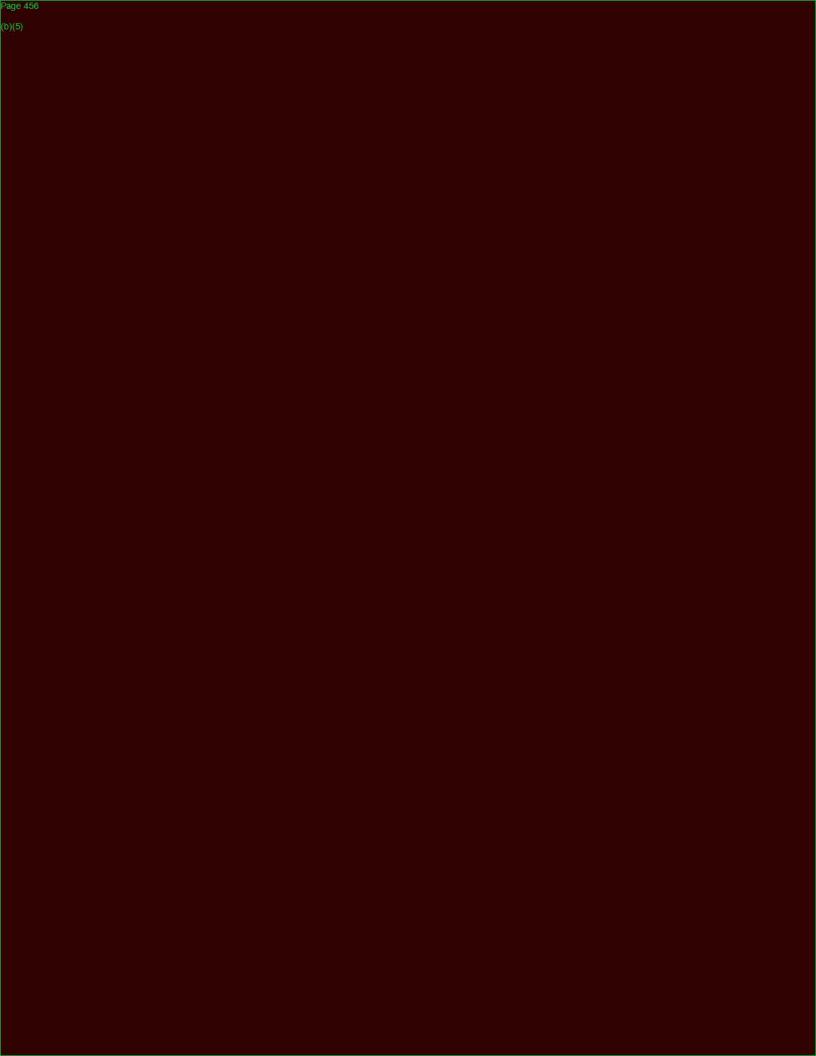
<sup>&</sup>lt;sup>5</sup> Includes data for US States, DC, US Territories, federal entities, and pharmacies (see table on last page for breakdown). Total doses allocated are through Jun 14, 2021.

<sup>6</sup> Progress towards 70% coverage of adult (≥18 years) population with at least 1 dose by July 4, 2021: 39 days left until July 4.









From: Beach, Michael J. (CDC/DDID/NCEZID/DFWED)

**Sent:** Thu, 27 May 2021 10:37:42 +0000 **To:** Walensky, Rochelle (CDC/OD)

Cc: Walke, Henry (CDC/DDID/NCEZID/DPEI); Schuchat, Anne MD (CDC/OD); Daskalakis, Demetre (CDC/DDID/NCHHSTP/DHP); Butler, Jay C. (CDC/DDID/OD); Berger, Sherri

(CDC/OCOO/OD); Beach, Michael J. (CDC/DDID/NCEZID/DFWED) **Subject:** DIRECTORS BRIEF: Thursday May 27, 2021

Attachments: (FOUO) CDC COVID-19 RESPONSE UPDATE - DIRECTORS BRIEF 20210527.pdf

### **Thursday, May 27, 2021**

OVID-19 Summary				
	Cumulative Total	Daily	7-Day Daily Average	Change from Prior 7-Day Period
Cases <sup>2</sup>	32,994,369	20,956	22,139	-23.0%
Hospital Admissions <sup>3</sup>	2,221,407	2,688	3,146	-11.4%
Deaths <sup>2</sup>	588,421	545	436	-17.7%
Test Volume <sup>4</sup>	443,001,047	N/A	933,745	-9.8%
Test Positivity <sup>4</sup>	8.0%	N/A	2.6%	-14.0%

Source: HHS Protect

COVID-19 Vaccinations in the U	is in the United States <sup>3</sup>				
	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Fully Vaccinated (% Population)
Overall US	493,339,485	359,849,035	289,212,304	165,074,907 (49.7)	131,850,089 (39.7)
Population ≥18 Years of Age <sup>6</sup>	N/A	N/A	N/A	159,488,319 (61.8)	129,784,042 (50.3)
Population ≥65 Years of Age	N/A	N/A	N/A	46,742,786 (85.5)	40,532,730 (74.1)

Data as of May 26, 2021, 06:00 ET

<sup>&</sup>lt;sup>1</sup> These data were generated through an externally supported web-scraping process and have not been validated by CDC. Data are provisional and subject to change. Not all jurisdictions have necessarily updated their websites from which data were collected as of 06:00 ET today.

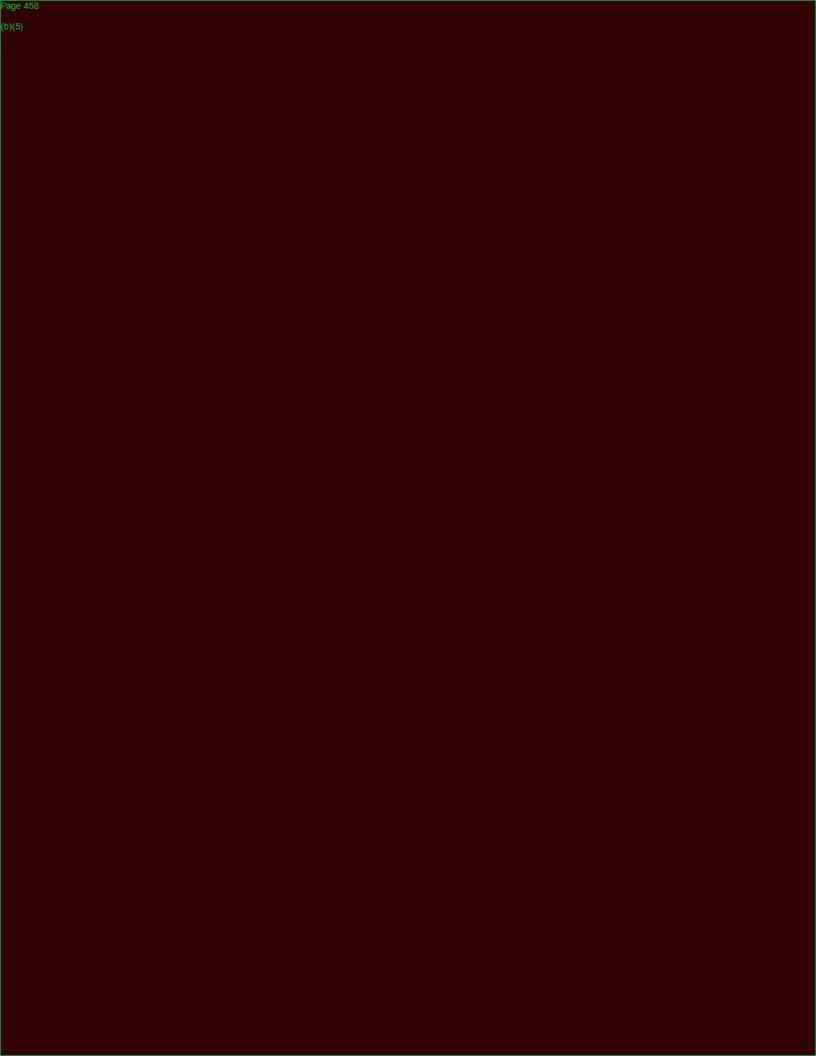
<sup>&</sup>lt;sup>2</sup> Time Period: Jan 22, 2020 – May 25, 2021; confirmed and probable cases and deaths. The total of new cases/deaths in the last 24 hours and 7-day averages do not include historical cases/deaths reported retroactively. Of 88,420 historical cases reported retroactively, 1,502 were reported on the most recent submission date; 2,486 in the current week; and 1,947 in the prior week. Of 11,331 historical deaths reported retroactively, 32 were reported on the most recent submission date; 375 in the current week; and 15 in the prior week.

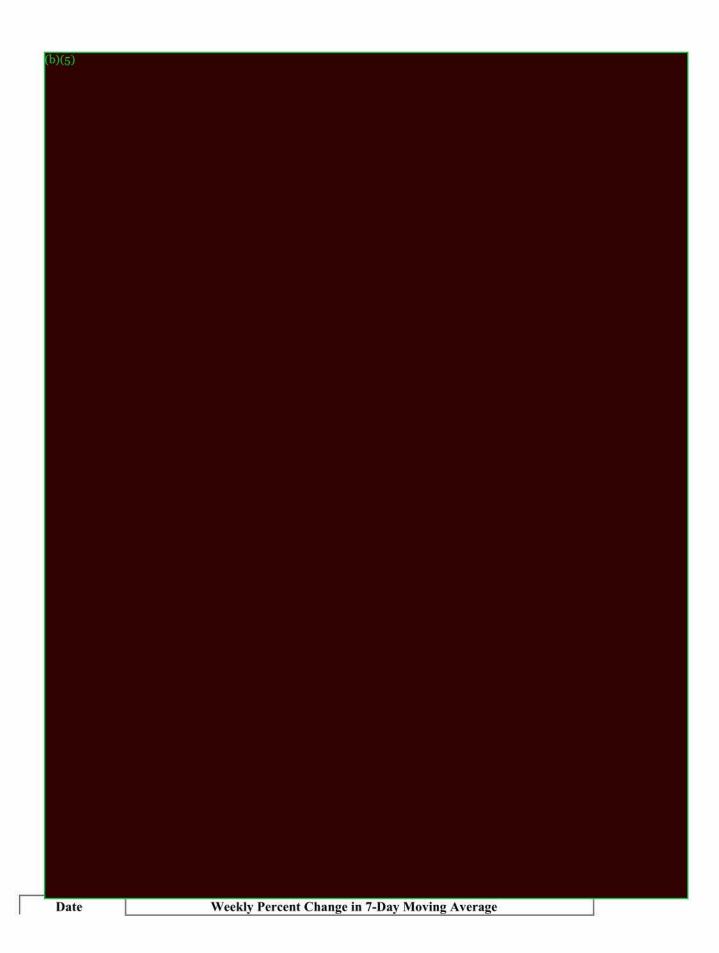
<sup>&</sup>lt;sup>3</sup> Time period: Aug 01, 2020 - May 24, 2021.

<sup>&</sup>lt;sup>4</sup> Time period: Mar 01, 2020 – May 23, 2021; Time period for test volume 7-day average and percent change: May 06, 2021 – May 19, 2021.

Includes data for US States, DC, US Territories, federal entities, and pharmacies (see table on last page for breakdown). Total doses allocated are through Jun 14, 2021

<sup>&</sup>lt;sup>6</sup> Progress towards 70% coverage of adult (≥18 years) population with at least 1 dose by July 4, 2021: 39 days left until July 4.







\*The 7-day moving average for ED visits has been generally decreasing since April 21, 2021.

<sup>†</sup>The 7-day moving average for **new admissions** has been consistently decreasing since April 19, 2021.

§The 7-day moving average for **current hospitalizations** has been consistently decreasing since April 23, 2021.

**Note:** ED visits, admissions, and current hospitalizations are pulled from a 10 am EST snapshot of the HHS Unified Hospital Timeseries Dataset. Due to potential reporting delays, data from the most recent 7 days should be interpreted with caution. Small shifts in historic data may also occur due to changes in the CMS Provider of Services file, which is used to identify the cohort of included hospitals.

- Deaths: The current 7-day moving average of new deaths (436) has decreased 17.7% compared with the previous 7-day moving average (529).\*
  - 588,421 COVID-19 deaths reported as of May 25, 2021, including 545 new deaths reported by 56 jurisdictions.<sup>†</sup>

\*Historical deaths are excluded from the daily new deaths and 7-day average calculations until they are incorporated into the dataset by their applicable date. Of 11,331 historical deaths reported retroactively, 32 were reported on May 25,2021; 375 were reported in the current week; and 15 were reported in the prior week. CDC is working with jurisdictions to obtain relevant dates and incorporate the data as soon as possible.

**COVID-19 Deaths: 7-Day Moving Average, Count, and Percent Change for the Last 21 Days** 

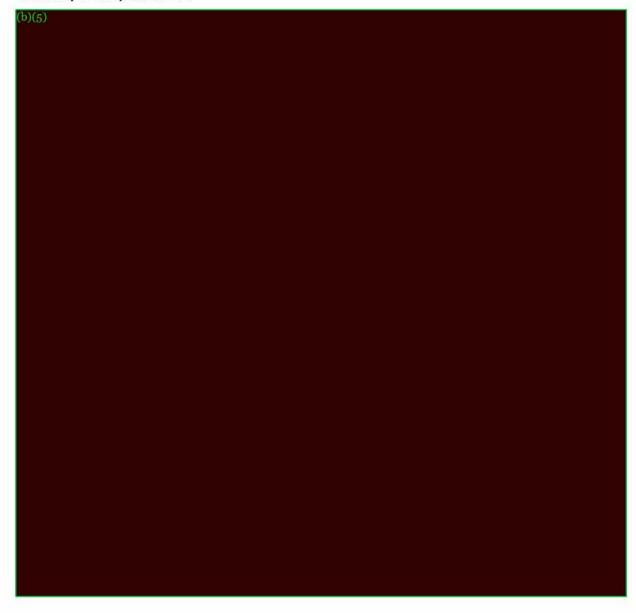
Date	7-Day Average Number of New Deaths§		Percent Change in the 7-Day Moving Average of New Deaths
5/19/2021	504	564	-11.4%
5/20/2021	489	504	-13.2%
5/21/2021	483	613	-11.6%

<sup>†</sup>Four jurisdictions did not report data for May 25, 2021 (FSM, KS, MD, NC).

5/22/2021	478	323	-9.5%
5/23/2021	460	154	-12.8%
5/24/2021	450	347	-14.9%
5/25/2021	436	545	-17.7%

§The 7-day average values are updated as of May 25, 2021, and may differ from values presented on previous director's bullets due to ongoing incorporation of jurisdictions' historical data.

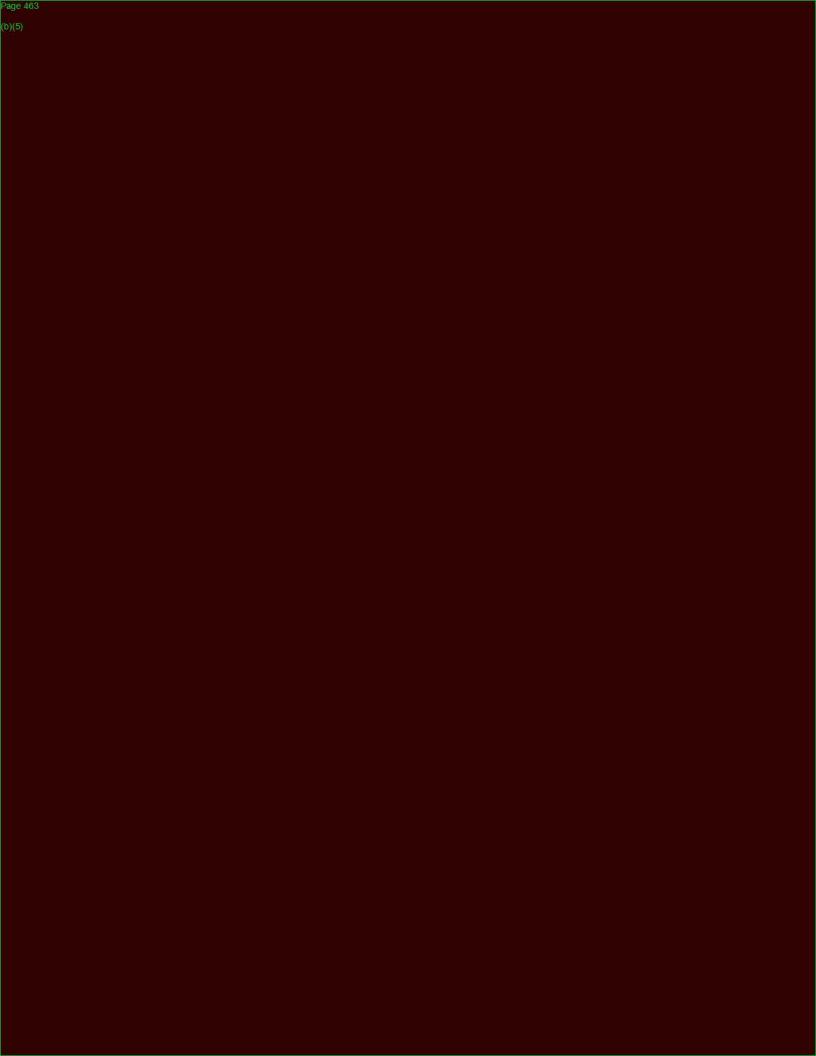
SARS-CoV-2 National and Regional Variant Proportions: The data below show weighted
estimates for specimens collected through May 8, 2021 and NOWCAST\*\* predictions for
specimens collected during the two-week period ending May 22, 2021. The proportions
corresponding to the bar on the far right and are enumerated in the table. Below is a
summary of the predictions.

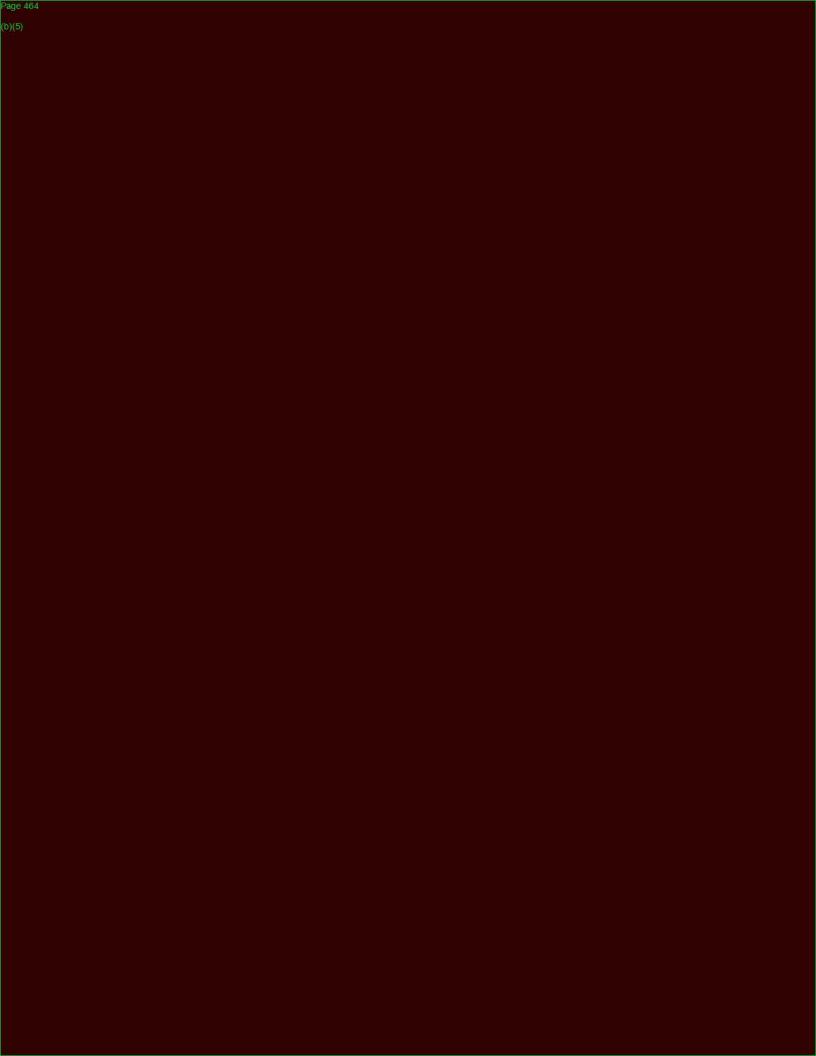


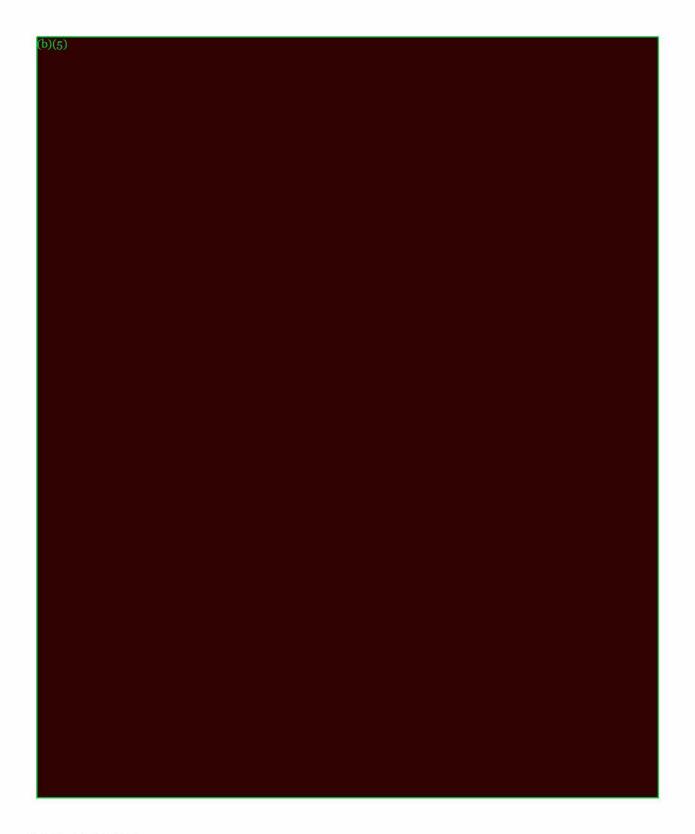


\*\* The Nowcast estimates use a multinomial regression model of weighted sequencing data to estimate variant proportions and prediction intervals. The nowcast provides timely estimates while accounting for limited sequence data availability, as samples from that interval are still being processed. Nowcast estimates are projections and may differ from weighted estimates generated at later dates.









## • STLT Support TF

o STLT's Health Department and Deployment Sections are working quickly to mobilize support for Washington State's Department of Health (WA DOH) and the 27 cases of

- Myocarditis/Pericarditis identified as potentially associated with COVID-19 mRNA vaccination. STLT responded to WA's request for assistance and held two calls this week, including with Vaccine TF, to plan an epidemiologic investigation of these cases. WA plans to start collecting medical records in a standardized format as early as 5/28 and will have a CDC epidemiologist deployed to WA to assist.
- The STLT School Field Work Section is providing technical assistance to the Lake County Health Department (Illinois) in evaluating the impact of modified quarantine on secondary transmission of SARS-CoV-2 in 33 K-12 schools. Individuals within 3-6 ft. of a COVID-19 case can be exempted from quarantine and continue in-person learning if mitigation strategies were in place at time of exposure. Exempted contacts get tested 5-7 days following exposure. Data from these schools will be compared with data on cases and contacts from 15 K-12 schools who will not implement modified quarantine.

#### MMWR Releases

One MMWR report related to the COVID-19 Response is scheduled as part of the <u>regular</u> <u>issue</u> of the Weekly, with the embargo lifting Thursday, May 27<sup>th</sup> at 1:00 PM. Please note that the title, content, and timing might change.

# Notes from the Field: Impact of the COVID-19 Response on Scale-up of HIV Viral Load Testing — PEPFAR-Supported Countries, January—June 2020

- BLUF: Routinely reported data from all PEPFAR-supported countries was reviewed for viral load testing coverage of ART patients and rates of viral load suppression since the COVID-19 pandemic began. Viral load testing coverage decreased during January–March 2020. After routine services were reinstated (April–June 2020), viral load testing coverage increased, and viral suppression remained stable.
- o Key Points:
  - Viral load coverage for all PEPFAR-supported countries was stable at 78% during September—December 2019.
  - Viral load testing coverage decreased to 71% during January—March 2020, likely the result of limited access to clinical and laboratory services during the pandemic.
  - After routine services were reinstated (April–June 2020), viral load testing coverage increased to 75%.
  - Among ART patients who received viral load testing, the percentage who were virally suppressed remained stable at 91% during October 2019–March 2020, and increased to 92% during April–June 2020
- Summary/abstract: CDC and the U.S. President's Emergency Plan for AIDS Relief (PEPFAR) are committed to maintaining an international response to the HIV epidemic, even as countries face the challenge of controlling the COVID-19 pandemic. The Joint United Nations Programme on HIV/AIDS has set the following 95-95-95 targets for HIV infection control by 2030: 1) ensure that 95% of HIV-positive persons are aware of their HIV status, 2) ensure that 95% of these persons receive antiretroviral treatment (ART)

and 3) facilitate viral load testing and suppression (viral load ≤1,000 HIV RNA copies per mL of blood) among 95% of persons with HIV infection. Because the limited availability of skilled laboratorians and restricted ART access could decrease viral load testing, the effects of the COVID-19 pandemic on viral load testing were examined. The period reviewed was September 2019 through June 2020. Viral load testing coverage for all PEPFAR-supported countries was stable during September—December 2019. However, viral load testing coverage decreased during January—March 2020, likely the result of limited access to clinical and laboratory services during the pandemic. After routine services were reinstated (April—June 2020), viral load testing coverage increased. Despite the challenges of controlling the COVID-19 pandemic, PEPFAR-supported countries should continue advancing toward the 95-95-95 by 2030 goals with expansion of viral load testing for all persons with HIV infection who are receiving ART.

# CDC COVID-19 Response Update Report DIRECTOR'S BRIEF

## **Thursday, May 27, 2021**



US Department of Health and Human Services Centers for Disease Control and Prevention

#### Preliminary COVID-19 COVID Case and Death Data<sup>1</sup>

Data Through	Total Cases	New Cases	Total Deaths	New Deaths
May 26, 2021	33,018,797	24,428	589,389	968

Source: State-level Aggregated Case and Death Counts (ACDC)

#### **COVID-19 Summary**

	<b>Cumulative Total</b>	Daily	7-Day Daily	<b>Change from Prior</b>
			Average	7-Day Period
Cases <sup>2</sup>	32,994,369	20,956	22,139	-23.0%
Hospital Admissions <sup>3</sup>	2,221,407	2,688	3,146	-11.4%
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Test Positivity <sup>4</sup>	8.0%	N/A	2.6%	-14.0%
Source: HHS Protect	-	10.		

### COVID-19 Vaccinations in the United States<sup>5</sup>

	Total Doses Allocated	Total Doses Delivered	Total Doses Administered	Number of People Receiving ≥1 Dose (% Population)	Number of People Fully Vaccinated (% Population)
Overall US	493,339,485	359,849,035	289,212,304	165,074,907 (49.7)	131,850,089 (39.7)
Population ≥18 Years of Age <sup>6</sup>	N/A	N/A	N/A	159,488,319 (61.8)	129,784,042 (50.3)
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