	Case 2:20-cv-00700-JLR-MLP Docur	nent 176 Filed 12/11/20 Page 1 of 4					
1 2		District Judge James L. Robart Magistrate Judge Michelle L. Peterson					
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8	UNITED STATES DISTRICT COURT WESTERN DISTRICT OF WASHINGTON						
9	WILFREDO FAVELA AVENDANO;						
0	J.A.M.; NAEEM KHAN; on behalf of themselves and all others similarly situated,	Case No. 2:20-cv-700-JLR-MLP					
		MALTESE DECLARATION IN					
1	Petitioners-Plaintiffs,	SUPPORT OF PETITIONERS'- PLAINTIFFS' MOTION FOR					
2	v.	TEMPORARY RESTRAINING ORDER					
3	NATHALIE ASHER, Director of the Seattle Field Office of U.S. Immigration and Customs Enforcement, et. Al.,						
5	Respondents-Defendants.						
	Respondents-Defendants.						
.6	I, Sydney Maltese, declare as follows:						
7	1. I submit this declaration in support	rt of Petitioners-Plaintiffs' motion for temporary					
8	restraining order.						
.9		onal knowledge of the facts set forth herein					
20							
21	and, if called as a witness, I could and would testify competently as set forth below.						
22	3. I am a paralegal with the Northwe	est Immigrant Rights Project, counsel of record					
23	for Petitioners-Plaintiffs.						
24	4. I certify that the attached exhibits	are true and correct copies of the following:					
	MALTESE DECLARATION - 1 Case No. 2:20-cv-700	NORTHWEST IMMIGRANT RIGHTS PROJECT 615 2nd Ave Ste. 400 Seattle, WA 98144 Tel: 206-957-8611					

	Case 2:20-cv-00700-JLR-MLP Document 176 Filed 12/11/20 Page 2 of 4								
1	Exhibit	Document							
2	A Executive Office of Immigration Review, <i>EOIR Stakeholder Update – Dec. 10</i> , 2020, recording EOIR Operational Status Update, (Dec. 10, 2020, 3:24PM)								
3	2020, regarding EOIR Operational Status Update, (Dec. 10, 2020, 3:24PM).BParsa Erfani, Nishant Uppal, Caroline Lee, COVID-19 Testing and Cases in Immigration Detention Centers, April-August 2020, JAMA (Oct. 29, 2020), https://jamanetwork.com/journals/jama/fullarticle/2772627 (last accessed Dec. 1 2020).								
4									
5									
6	С	Johns Hopkins University & Medicine, COVID-19 Dashboard by the Centerfor Systems Science and Engineering (CSSE) at Johns Hopkins, (updated Dec. 11,							
7 8		2020, 2:28PM), https://coronavirus.jhu.edu/map.html (last accessed Dec. 12, 2020).							
	D The New York Times, A New Grim Record for the U.S. As Daily Deaths from								
9 10	<i>Virus Top 3,000</i> , (updated Dec. 12, 2020), https://www.nytimes.com/live/2020/12/09/world/covid-19-coronavirus (last accessed Dec. 12, 2020).								
	F								
11 12	E	Washington State Department of Health, <i>COVID-19 Data Dashboard</i> , (updated Dec. 10, 2020), https://www.doh.wa.gov/Emergencies/COVID19/DataDashboard (last accessed Dec. 12, 2020).							
13	F Katie Thomas, <i>FDA Advisory Panel Gives Green Light to Pfizer Vaccine</i> , New York Times, (Dec. 10, 2020), https://www.nytimes.com/2020/12/10/health/covivaccine-pfizer-fda.html?action=click&module=Top%20Stories&pgtype=Homepage; (last accessed Dec. 12, 2020).								
14 15									
16	G Centers for Disease Control and Prevention, <i>Frequently Asked Questions Abou</i>								
17		<i>COVID-19 Vaccination</i> , (Dec. 3, 2020), https://www.cdc.gov/coronavirus/2019-ncov/vaccines/faq.html (last accessed Dec. 12, 2020).							
18	Н	Immigration and Customs Enforcement, ICE Guidance on COVID-19: ICE Detainee Statistics (updated Dec. 9, 2020), www.ice.gov/coronavirus (last							
19		accessed Dec. 12, 2020).							
20	I Department of Homeland Security Notice of Custody Determination pursuant to review conducted to comply with requirements in <i>Fraihat v. ICE</i> ; 445 F. Supp. 3								
21		709 (C.D. Cal. 2020) for Naeem Sohail Khan, (Dec. 1, 2020).							
22	I declare under penalty of perjury under the laws of the state of Washington and the laws								
23 24	of the United States that the foregoing is true and correct.								
	MALTESE DECLARATION - 2 Case No. 2:20-cv-700 NORTHWEST IMMIGRANT RIGHTS PROJECT 615 2nd Ave Ste. 400 Seattle, WA 98144								

Seattle, WA 98144 Tel: 206-957-8611

Executed this 11th day of December, 2020, in Seattle, Washington.

Tel: 206-957-8611

Sydney Maltese NORTHWEST IMMIGRANT RIGHTS PROJECT MALTESE DECLARATION - 3 Case No. 2:20-cv-700 615 2nd Ave Ste. 400 Seattle, WA 98144

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CERTIFICATE OF SERVICE

I hereby certify that on December 11, 2020, I electronically filed the foregoing and ttached declaration with the Clerk of the Court using the CM/ECF system, which will send otification of such filing to those attorneys of record registered on the CM/ECF system. DATED this 11th day of December, 2020. s/ Aaron Korthuis Aaron Korthuis Northwest Immigrant Rights Project 615 Second Avenue, Suite 400 Seattle, WA 98104 (206) 816-3872 (206) 587-4025 (fax) MALTESE DECLARATION - 4 NORTHWEST IMMIGRANT RIGHTS PROJECT Case No. 2:20-cv-700 615 2nd Ave Ste. 400 Seattle, WA 98144

Tel: 206-957-8611

EXHIBIT A



Aaron Korthuis <aaron@nwirp.org>

EOIR Stakeholder Update - Dec. 10, 2020

U.S. Department of Justice <usdoj@public.govdelivery.com> Reply-To: usdoj@public.govdelivery.com To: aaron@nwirp.org Thu, Dec 10, 2020 at 3:24 PM



EOIR Operational Status Update

Due to a possible COVID-19 exposure, the Tacoma Immigration Court closed at 2 p.m. today, Dec. 10, for cleaning, consistent with CDC guidelines. Any known close contacts have been notified. Please monitor EOIR's website for information about the agency's operations nationwide.

Executive Office for Immigration Review Office of Policy Communications and Legislative Affairs Division PAO.EOIR@usdoj.gov 703-305-0289



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EXHIBIT B

Letters

RESEARCH LETTER

COVID-19 Testing and Cases in Immigration Detention Centers, April-August 2020

Individuals detained by US Immigration and Customs Enforcement (ICE) live in congregate settings, and thus have a disproportionately high risk of contracting coronavirus disease 2019 (COVID-19). To reduce spread of COVID-19,

+ Related article

ICE published its Pandemic Response Requirements in April 2020. These require-

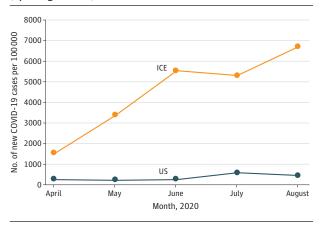
ments established social distancing and disinfection protocols, testing guidelines, and expedited detainee release. This analysis examined COVID-19 testing and cases per month among ICE detainees.

Methods | Cumulative numbers of COVID-19 reverse transcriptase-polymerase chain reaction tests, confirmed cases, and COVID-19-related deaths among all ICE detainees from April 1 to August 31, 2020, were extracted from ICE's website. These data come from a continually updated database of all facilities housing detainees, including county jails.¹ New COVID-19 tests and cases per month were calculated from April to August 2020 by subtracting cumulative counts at each month end. Corresponding data for the US population were obtained from the US Census Bureau.^{2,3} Mean daily ICE populations per month, retrieved from the ICE Statistics Fiscal-Year 2020 data set, were compared with the prepandemic population in February.⁴ This cohort study used public, deidentified data and was determined not to constitute human participants research by the Harvard Medical School institutional review board.

Monthly test and case rates per 100 000 persons were calculated for detainees using the mean daily ICE population per month. Corresponding monthly rates were calculated for the US population on the final day of each month.³ Test positivity rates, defined as reported cases divided by reported tests, were calculated. Rate ratios are reported for ICE detainees vs the US population. Data were analyzed using Microsoft Excel version 16.40.

Results | By August 2020, ICE's mean daily detained population decreased 45% to 21 591 from the prepandemic February population of 39 319. On August 31, ICE reported 5379 cumulative COVID-19 cases and 6 related deaths among its detainees. Cases were reported in 92 of 135 facilities, with 20 facilities accounting for 71% of cases.

The monthly case rate per 100 000 detainees increased from 1527 in April to 6683 in August (**Figure**). The monthly test rate per 100 000 detainees increased from 3224 in April to 46 874 in July, but decreased to 36 140 in August (**Table**). The test positivity rate among detainees decreased from 47% in April to 11% in July but increased to 18% in August. Figure. Monthly Coronavirus Disease 2019 (COVID-19) Case Rate per 100 000 Persons for Immigration Detention and US Populations (April-August 2020)





Detainee testing rates in July increased 1354% from April, while case rates increased 247%. In August, the testing rate decreased 23% from July, while the case rate and test positivity rate increased by 26% and 64%, respectively.

From April to August 2020, the mean monthly case rate ratio for detainees, compared with the US population, was 13.4 (95% CI, 8.0-18.9), ranging from 5.7 to 21.8 per month. The mean monthly test rate ratio for detainees, compared with the US population, was 4.6 (95% CI, 2.5-6.7), ranging from 2.0 to 6.9 per month.

Discussion Despite ICE's mitigation efforts, COVID-19 case rates among detainees increased every month from April to August. An increase in testing appears to only partially explain the increasing monthly case rates. COVID-19 testing expanded more rapidly among detainees than the US population. However, a consistently higher monthly case rate and test positivity rate among detainees suggest that COVID-19 is escalating more rapidly inside detention centers compared with the US population.

COVID-19 spread within facilities may be partially due to challenges faced implementing the Pandemic Response Requirements.⁵ An independent assessment of facilities' mitigation strategies is necessary to identify and address existing gaps in these efforts. Strategies that have proven effective in other congregate facilities, such as mass asymptomatic testing and changes in dormitory-style housing, should be considered.⁶

Limitations of the study include relying on ICE's publicly available data, which may be subject to reporting delays and missing components. Given limited asymptomatic detainee testing, monthly case rates may be underestimates.⁶ Comparison of rates between detainees and the US population is

jama.com

Letters

	April	May	June	July	August	Monthly mean (95% CI)
ICE detention						
Population ^a	31 828	27 193	24 208	22 554	21 591	
Reported No. of COVID-19 cases ^b	486	916	1336	1194	1443	
Reported No. of individuals tested for COVID-19	1026	1751	7732	10 572	7803	
Monthly case rate per 100 000 persons	1527	3369	5519	5294	6683	4478 (2695-6261)
Monthly test rate per 100 000 persons	3224	6439	31940	46 874	36 140	24923 (8123-41723)
Test positivity rate, %	47	52	17	11	18	
US general population ^a						
Monthly case rate per 100 000 persons	266	218	254	578	442	352 (217-486)
Monthly test rate per 100 000 persons	1587	3266	4651	6985	6739	4646 (2632-6659)
Test positivity rate, %	17	7	5	8	7	
ICE vs US						
Rate ratio						
Monthly case rate	5.7	15.4	21.8	9.2	15.1	13.4 (8.0-18.9)
Monthly test rate	2.0	2.0	6.9	6.7	5.4	4.6 (2.5-6.7)

Abbreviations: COVID-19, coronavirus disease 2019; ICE, US Immigration and Customs Enforcement.

^a Monthly population data were used to calculate month rates. ICE monthly population is the mean daily population per month. US monthly population is the general population on the last day of each month.

limited by differences in testing and reporting methods. ICE also provides limited data for facility staff; thus, this analysis represents an incomplete picture of COVID-19 epidemiology inside facilities.

Parsa Erfani, BA Nishant Uppal, BS Caroline H. Lee, BA Ranit Mishori, MD, MHS Katherine R. Peeler, MD

Author Affiliations: Harvard Medical School, Boston, Massachusetts (Erfani, Uppal, Lee); Department of Family Medicine, Georgetown University School of Medicine, Washington, DC (Mishori); Division of Medical Critical Care, Boston Children's Hospital, Boston, Massachusetts (Peeler).

Corresponding Author: Katherine R. Peeler, MD, Boston Children's Hospital, 300 Longwood Ave, Boston, MA 02115 (katherine.peeler@childrens.harvard.edu).

Accepted for Publication: October 13, 2020.

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Author Contributions: Mr Erfani and Dr Peeler had full access to all of the data in the study and take responsibility for the integrity of the data and the accuracy of the data analysis.

Concept and design: Erfani, Uppal, Lee, Peeler.

March 2020 was 5379 (the first 4 cases were reported in March 2020).

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Erfani, Uppal, Lee, Peeler.

Critical revision of the manuscript for important intellectual content: All authors. *Statistical analysis:* Erfani, Uppal.

Administrative, technical, or material support: Erfani, Uppal, Lee, Mishori. Supervision: Peeler.

Conflict of Interest Disclosures: Dr Mishori reported being a senior medical advisor to Physicians for Human Rights. Dr Peeler reported being an unpaid medical expert for Physicians for Human Rights. No other disclosures were reported.

1. US Immigration and Customs Enforcement. ICE guidance on COVID-19. Accessed August 31, 2020. https://www.ice.gov/coronavirus

2. The COVID Tracking Project. US historical data. Accessed August 31, 2020. https://covidtracking.com/data/national

3. US Census Bureau. US and world population clock. Accessed August 31, 2020. https://www.census.gov/popclock/

4. US Immigration and Customs Enforcement. Detention management. Accessed August 31, 2020. https://www.ice.gov/detention-management

5. Office of Inspector General. Early experiences with COVID-19 at ICE detention facilities. Published June 18, 2020. Accessed August 31, 2020. https://www.oig. dhs.gov/sites/default/files/assets/2020-06/OIG-20-42-Jun20.pdf

6. Hagan LM, Williams SP, Spaulding AC, et al. Mass testing for SARS-CoV-2 in 16 prisons and jails—six jurisdictions, United States, April-May 2020. *Morbidity and Mortality Weekly Report*. Published August 21, 2020. Accessed August 31, 2020. https://www.cdc.gov/mmwr/volumes/69/wr/mm6933a3.htm

EXHIBIT C

Case 2:20-cv-00700-JLR-MLP Document 176-3 Filed 12/11/20 Page 2 of 2

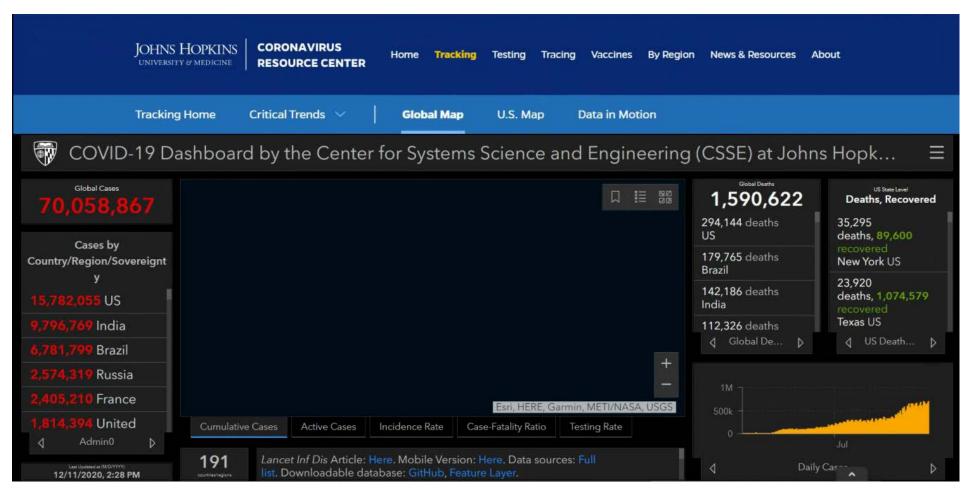


EXHIBIT D

U.S., Breaking a Record, Tops the 3,000 Daily Death Mark

10 nytimes.com/live/2020/12/09/world/covid-19-coronavirus

December 9, 2020

Last Updated Dec. 11, 2020, 12:55 p.m. ET3 hours ago

3 hours ago

Canada has approved a vaccine, and may vaccinate its citizens before the U.S. does. As intensive care units exceed capacity, Plan B's are in short supply for hospitals.

This briefing has ended. Follow our live coverage of the coronavirus pandemic here.

A grim new record for the U.S. as daily deaths from the virus top 3,000.





A coronavirus test site in San Francisco on WednesdayCredit...Jim Wilson/The New York Times

Just one week after the United States broke a daily record for coronavirus deaths, it did so again on Wednesday, when officials across the country reported at least 3,011 new fatalities.

Last week's record -2,885 deaths reported in a single day - was a milestone because not since the pandemic's first peak, in spring, had so many deaths been reported. The high point then was 2,752 deaths, on April 15.

As a brutal surge gathers speed across the country, the country went on last week to record its most coronavirus-related deaths over a seven-day period.

With a seven-day average of 2,249 deaths, the U.S. broke the previous mark of 2,232, set on April 17. Seven-day averages can provide a more accurate picture of the virus's progression than daily death counts, which can fluctuate.

And all the while, the United States is speeding toward another stunning total: 300,000 total deaths since the coronavirus slipped into the country at the beginning of the year and began laying siege. At least 288,000 deaths have been recorded, according to a <u>New York Times database</u>.

The milestones are being toppled as U.S. officials race to approve and distribute a Covid-19 vaccine for Americans. Britain began vaccinating its own citizens this week, and Canada appears near to doing the same.

But things have moved more slowly in a country still mired over a presidential election that took place more than a month ago, with many Republicans refusing to acknowledge the results and some working actively to undo them.

Regardless of the outcome, on Wednesday, a glance at any coronavirus map of the country made one thing clear: With very few exceptions, every state is a red state now.

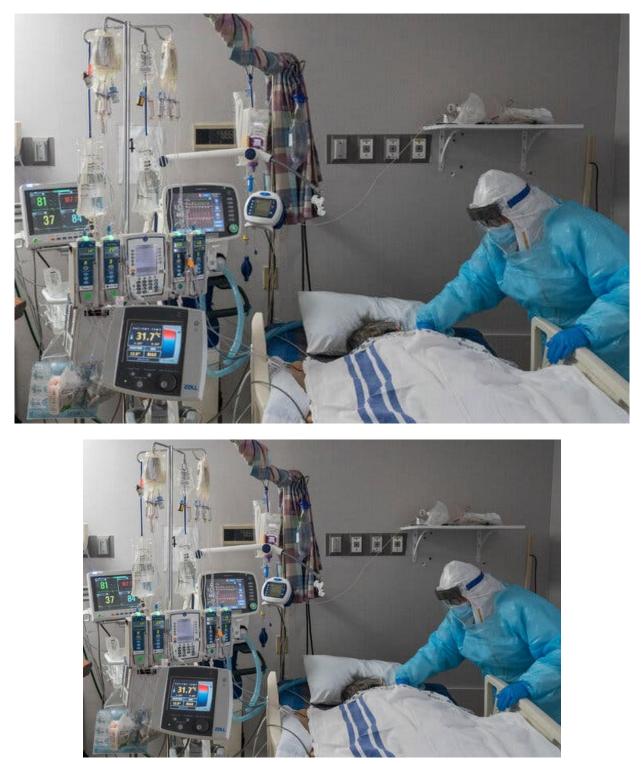
- Eric Nagourney

Tracking the Coronavirus >

Where cases per capita are highest			
~			
<u>R.I.</u>			
Ind.			
Alaska			
Idaho			
Kan.			
Nev.			
Utah			
<u>S.D.</u>			
Minn.			
Ohio			
Ariz.			
Ariz. N.D.			
Tenn.			
Neb.			
<u>Del.</u>			

Just how full are U.S. intensive care units? New data paints an alarming picture.

Case 2:20-cv-00700-JLR-MLP Document 176-4 Filed 12/11/20 Page 5 of 44



An intensive care unit in Houston on Monday. More than a third of Americans live in areas where hospitals are running critically short of ICU beds.Credit...Go Nakamura/Getty Images

At the five-hospital Tanner Health System west of Atlanta, the first emails about capacity land in the inboxes of Dr. Benjamin Camp, the chief medical officer, and Deborah Matthews, the chief nursing officer, at about 6:30 a.m. each day. Then the juggling starts.

Early in the Covid-19 pandemic, they expanded the number of critical care beds at the largest of the Tanner hospitals in Carrollton to 20 beds from 12, and in nearby Villa Rica to 10 beds from six.

But even that is not enough now: All 30 beds are full most days, leaving Dr. Camp and Ms. Matthews to scramble from before dawn to the end of the day.

"The worry is," Ms. Matthews said, "what are you going to do with the 31st I. C.U. patient? What are you going to do with the next patient who needs to be on a ventilator? You have contingency plans for all of that, but you are just constantly thinking about those things."

Hospitals across the country are operating near or above capacity as they cope with a growing flood of Covid-19 cases. New data released this week by the federal Department of Health and Human Services gives a detailed geographic picture of the crisis.

The onslaught has been relentless.

Overall, Tanner's hospitals are now treating about 82 Covid-19 patients, four times as many as they had in late summer. The federal data shows that both the Carrollton and Villa Rica hospitals have been operating at well over 100 percent of their usual capacity. The Carrollton hospital normally has 148 beds, but it has been running 180, Dr. Camp said.

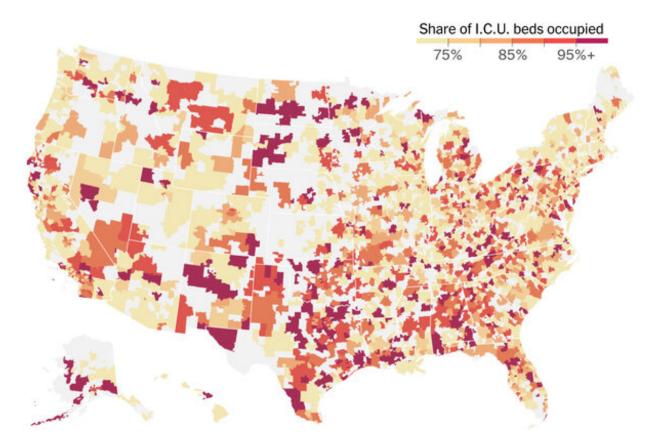
With so many hospitals facing the same problems, the elasticity in the health care system is gone. Hospitals that fill up cannot count on being able to transfer patients elsewhere, and medical workers are being run ragged.

"There is not a lot of wiggle room," said Loy Howard, president of the Tanner Health System. "I have been doing this for 35 years, and I have not seen this kind of wear and tear on the staff."

Hospitals in cities large and small are running short of intensive care beds. In El Paso, just 13 of the 400 intensive care beds were unoccupied last week. In Fargo, N.D., there were just three. In Albuquerque, there were zero.

In all, more than one-third of Americans live in areas where hospitals are running critically short of intensive care beds. Hospitals serving more than 100 million Americans reported having fewer than 15 percent of intensive care beds still available as of last week, according to a New York Times analysis of the federal <u>data</u> released on Monday.

It is the first time federal government has published detailed geographic information on Covid-19 patients in hospitals, something public health officials have long said <u>would be crucial</u> to responding to the epidemic and understanding its impact.



<u>'There's No Place for Them to Go': I.C.U. Beds Near Capacity</u> Across U.S.

More than a third of Americans live in areas where hospitals are running critically short of intensive care beds.

— <u>Neil MacFarquhar</u>, <u>Lauren Leatherby</u>, <u>John Keefe</u>, <u>Lucy Tompkins</u>, <u>Charlie Smart</u> and Matthew Conlen

Advertisement

Continue reading the main story

Canada approves the vaccine made by Pfizer and BioNTech, and shots may begin next week.



Canada Approves Pfizer-BioNTech Coronavirus Vaccine

After completing an independent review, Health Canada, the country's drug regulator, announced on Wednesday that it had approved the coronavirus vaccine made by Pfizer and BioNTech and that shots could start being given as early as next week.

This is a momentous occasion. I mean, the geek in me is amazed that we — no one would have thought. I think, you know, even when we looked back at the first discovery of the virus, that less than a year later we'd be authorizing and then distributing a vaccine. So I think it's just a testament to the decades of science and technology and research that's gone into the development of that vaccine. I think it's a testament to the work of regulators internationally working together. It's a testament to our team that's really dedicated an incredible amount of time and energy and resources to do that. And I think, you know, it's an exceptional day for Canada. When we do an authorization, it means that we've looked at it and the benefits outweigh the potential risks. But it is still a drug. It's still a vaccine, and there are potential risks, even if they're rare. So that's why it's important that we continue to monitor it. So I would say to Canadians, you know, we've authorized it. If it is their turn to get the vaccine, they absolutely should feel comfortable getting that. But we still do need to continue to monitor it as we would any product, because, obviously, when we do the research, the research are done in clinical trials. They're done in smaller groups of people under ideal conditions. And we need to get information from the vaccine as it goes out and starts to get used in higher numbers of people, not only in Canada, but around the world.

00:00

1:22

1:22Canada Approves Pfizer-BioNTech Coronavirus Vaccine After completing an independent review, Health Canada, the country's drug regulator, announced on Wednesday that it had approved the coronavirus vaccine made by Pfizer and BioNTech and that shots could start being given as early as next week.CreditCredit...Pool photo by Frank Augstein

Canada <u>has approved the coronavirus vaccine</u> made by Pfizer and BioNTech, its drug regulator said on Wednesday, opening the possibility that Canadians will start receiving it next week.

The regulator, Health Canada, said it had completed a full, independent review of the data on the vaccine's safety and effectiveness. While Britain approved the vaccine earlier, it did so on an emergency basis, was limited to a single production run and largely relied on Pfizer's analysis. Bahrain has also issued an emergency approval.

"It's a testament to the work of regulators internationally," said Dr. Supriya Sharma, the chief medical adviser at Health Canada. "It's an exceptional day for Canada."

Canada has ordered a total of 76 million doses from Pfizer. (An earlier version of this article incorrectly reported that the order had been for six million doses.) Maj. Gen. Dany Fortin, the Canadian military officer overseeing distribution of the vaccine to provincial health care systems, said Pfizer would start shipping the vaccine from a plant in Belgium on Friday.

That could make it possible, he said, for Canadians to begin receiving shots as early as next Wednesday.

If that timeline holds up, Canadians may receive injections of the vaccine from the U.S.based company before Americans do. Canada expects to receive an initial batch of 249,000 doses. Each person will require two doses.

Dr. Sharma said that the vaccine was subject to the same degree of review as any previous drug or vaccine. But to accelerate that process, Health Canada began reviewing data from clinical trials and manufacturing tests as it was being generated, allowing for a "rolling review."

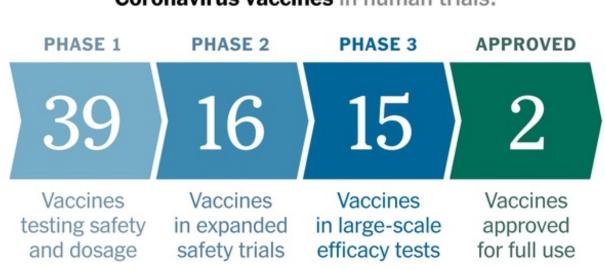
When asked why her group was able to approve the vaccine ahead of the Food and Drug Administration in the United States, Dr. Sharma said, apparently jokingly, "we're just better."

She added: "We're not in a race with any other regulator. We're trying to beat the virus."

It will be up to Canada's provincial governments to decide who will first be vaccinated. Dr. Howard Njoo, the country's deputy chief public health officer, said a federal panel has recommended that the first injections be given to people over the age of 80, residents and workers of long-term care homes, health care workers and Indigenous communities.

François Legault, the premier of Quebec, said his province will first target long-term care homes, which have been the main source of Covid-related deaths in the province.

The vaccine will be distributed to provinces based on their populations. But because the Pfizer-BioNTech vaccine must be shipped and stored at extremely low temperatures until shortly before use, General Fortin said, it will not be sent to Canada's remote and sparsely populated northern territories.



Coronavirus Vaccine Tracker

A look at all the vaccines that have reached trials in humans.

– <u>Ian Austen</u>

Pennsylvania's governor, Tom Wolf, says he has tested positive for the coronavirus.

Coronavirus vaccines in human trials:

Case 2:20-cv-00700-JLR-MLP Document 176-4 Filed 12/11/20 Page 11 of 44



Gov. Tom Wolf of Pennsylvania is isolating at home after announcing he had tested positive for the coronavirus.Credit...Julio Cortez/Associated Press

Gov. Tom Wolf of Pennsylvania <u>announced on Twitter</u> on Wednesday that he had tested positive for the coronavirus.

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"I have no symptoms and am feeling well and I am in isolation at home," he wrote. "I am following CDC and Department of Health guidelines." Referring to his wife, he wrote, "Frances has been tested and, as we await the result, is quarantining at home with me."

The governor added that he was performing his duties remotely, "as many are doing during the pandemic."

"As this virus rages, my positive test is a reminder that no one is immune from COVID," Mr. Wolf said. "Following all precautions as I have done is not a guarantee, but it is what we know to be vital to stopping the spread of the disease."

Mr. Wolf, a Democrat, is at least the ninth U.S. governor to report receiving a positive test result, though in the case of Mike DeWine of Ohio, the result was <u>almost immediately</u> <u>contradicted</u> by another test and is thought to have been a false positive. Several other governors have quarantined when a family member, staff member or close associate tested positive.

So far, none of the governors have reported experiencing severe illness. The first governor known to have tested positive was Gov. <u>Kevin Stitt of Oklahoma</u>, a Republican, in mid-July.

- Patrick J. Lyons

The U.K. says people with severe allergies should not take the Pfizer-BioNTech vaccine while two reactions are under investigation.

Case 2:20-cv-00700-JLR-MLP Document 176-4 Filed 12/11/20 Page 13 of 44



Thousands of Britons received the first clinically authorized, fully tested coronavirus vaccine on Tuesday, with many people reporting few side effects.Credit...Andrew Testa for The New York Times

Thousands of Britons <u>received the first clinically authorized</u>, <u>fully tested coronavirus</u> <u>vaccine</u> on Tuesday, with <u>people reporting minimal side effects</u>.

But two health workers with a history of serious allergies had reactions after being given the vaccine, British drug regulators said on Wednesday. As they investigate what precisely

caused the reactions, the regulators warned that people prone to severe allergic reactions should not receive the Pfizer-BioNTech vaccine for the time being.

Scientists said that for the vast majority of people, the new advice should not cause any concerns about receiving the coronavirus vaccine, and that it was difficult to protect against certain rare reactions with any new vaccine.

Dr. Anthony S. Fauci, the nation's leading expert on infectious diseases, said on Wednesday that the allergic reactions were concerning but most likely rare, the kind of effects that show up when a vaccine moves out of testing and into broader distribution.

"If I were a person that had an underlying allergic tendency, I might want to be prepared that I might get a reaction and therefore be ready to treat it," Dr. Fauci said, in a webcast moderated by Sanjay Gupta of CNN, sponsored by Harvard and The New England Journal of Medicine.

Dr. Fauci acknowledged that the problem could turn out to affect a lot of people.

"That's one of the reasons why it's important to cover the waterfront with different vaccine platforms," he said, adding, "If in fact we do find out that there is a consistent issue of a certain subset of people like those with allergic reactions, you'll always have other vaccine platforms that you can use and hopefully you will not see that with those other platforms."

Because of their severe allergies, the two health workers carried adrenaline pens, the generic term for an EpiPen. The National Health Service said that both workers were recovering well after being treated for symptoms of anaphylactoid reactions that they developed shortly after their shots.

Regulators said the reactions were "associated with administration" of the vaccine, but did not describe the health workers' symptoms or what kind of treatment they received.

"We know from the very extensive clinical trials that this wasn't a feature," Dr. June Raine, the chief executive of Britain's Medicines and Healthcare products Regulatory Agency, said on Wednesday.

As a precaution, British regulators said, "any person with a history of a significant <u>allergic</u> <u>reaction to a vaccine</u>, medicine or food," like people who have anaphylactoid reactions or carry an EpiPen, should not receive the Pfizer-BioNTech vaccine. They said that the vaccines should be delivered only at sites with access to resuscitation measures.

Dr. Moncef Slaoui, the head of the Trump administration's Operation Warp Speed, said that a panel of experts meeting in the United States on Thursday to consider Pfizer's application for emergency authorization would likely discuss the allergic reactions. He said he thought that the United States would also advise people with a history of severe allergic reactions not to get the vaccine "until we understand exactly what happened" in the British cases.

After authorizing the Pfizer-BioNTech vaccine for emergency use last week, <u>British</u> <u>regulators</u> said that people with a hypersensitivity to ingredients in the vaccine should not be given the shot. But the regulators' updated advice on Wednesday expanded that warning to cover anyone with a history of significant allergic reactions.

The regulators are now investigating the two cases from Tuesday, a process that experts said would involve looking at whether the reactions stemmed from the vaccine itself or were incidental. The regulators said they would release updated advice once they do.

Allergic reactions are a very rare response to some vaccines. Anaphylactic reactions, the most serious of those responses, are estimated to occur around once every 100,000 to 1,000,000 doses of the most commonly given vaccines, according to the <u>Institute for</u> <u>Vaccine Safety at the Johns Hopkins Bloomberg School of Public Health</u>.

A 2015 study supported by the Centers for Disease Control and Prevention in the United States turned up 33 confirmed cases of vaccine-triggered anaphylaxis among more than 25 million vaccine doses, translating to a rate of 1.3 cases of such reactions in every million doses of vaccine.

<u>Pfizer's vaccine trials</u>, which included tens of thousands of participants, excluded people with a history of reacting badly to vaccines, or having severe allergic reactions to any ingredients in the coronavirus vaccine.

Among those who participated in the trials, a very small number of people had allergic reactions. A <u>document published by the Food and Drug Administration</u> in the United States on Tuesday said that 0.63 percent of participants who received the vaccine reported potential allergic reactions, compared to 0.51 percent of people who received a placebo.

In Pfizer's late-stage clinical trial, one of the 18,801 participants who received the vaccine had an anaphylactic reaction, according to <u>safety data published by the F.D.A. on Tuesday</u>. None in the placebo group did.

Scientists said that there is a very small risk of allergic reactions to any vaccine, just as there is to food and medicines. And anaphylactic reactions to any new vaccine or medicine are particularly difficult to prevent ahead of time.

"Anaphylaxis is almost always very specific, with some known overlaps between exposures, but just because I'm allergic to peanuts doesn't mean I'm allergic to bee stings," said Dr. Naor Bar-Zeev, a pediatric infectious diseases specialist and epidemiologist at Johns Hopkins Bloomberg School of Public Health. He added, "Rare events — and anaphylaxis is among the rarest of all — can never be known from Phase 3 trials or before licensure."

Dr. Bar-Zeev said the risk of rare side effects from vaccines, especially amid a pandemic, had to be balanced against the risk of contracting the disease itself. But he said that even in the best of circumstances, very rare side effects are only discovered well after clinical trials are conducted and new drugs and vaccines are licensed.

In wealthier countries, he added, regulators have well-established systems for identifying rare side effects, and those events will become evident more quickly in the midst of mass vaccinations.

With any new medicine or vaccine, he said, "Anaphylaxis will occur, will be treatable, and if treated, will be unlikely to cause death. The risk is very, very small indeed."

Dr. Jesse Goodman, a professor of medicine and infectious diseases at Georgetown University and the former F.D.A. chief scientist, said that it was difficult to fully evaluate the British cases without more details.

But he said that clinical trials typically enroll healthier people than the general population, and that safety issues can come up as the vaccines are administered to the general public.

"The people in clinical trials are different, generally healthier, so as vaccines are used outside of trials things will occur that may or may not be due to the vaccine," he said. "So to ensure safety and maintain confidence, it becomes really important to sort out quickly whether or not they are related."

Unlike most new vaccines, which are gradually rolled out over years as people slowly visit their doctors and get new shots, the new coronavirus vaccines will quickly be given to many more people than received it in clinical trials.

"They're large, well-performed studies, but they're still of tens of thousands of people," he said of the clinical trials. "It does mean we need those strong safety monitoring systems."

People with latex allergies can also, on rare occasions, have severe allergic reactions to vaccines held in vials or syringes with latex.

The changing guidance from British regulators testified to the careful monitoring of vaccines that follows an emergency authorization, like the one issued in Britain last week for the Pfizer-BioNTech vaccine. The speed with which regulators warned people on Wednesday was a sign that the monitoring system was effective, scientists said, and reassurance that people did not need to hesitate to get a coronavirus vaccine.

"For the general population, this does not mean that they would need to be anxious about receiving the vaccination," said Stephen Evans, a professor of pharmacoepidemiology at the London School of Hygiene and Tropical Medicine.

He added, referring to a famous British love-it-or-hate-it yeast paste: "One has to remember that even things like Marmite can cause unexpected severe allergic reactions."

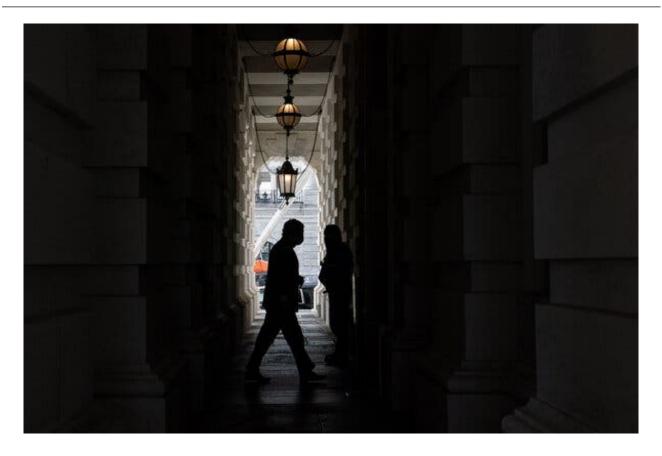
Denise Grady, Katie Thomas and Carl Zimmer contributed reporting.

– <u>Benjamin Mueller</u>

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Moderate lawmakers struggle to finalize a bipartisan stimulus deal as leaders remain at odds.





Senator Mitch McConnell, the majority leader, arriving at the Capitol on Wednesday.Credit...Anna Moneymaker for The New York Times

A bipartisan group of moderate lawmakers circulated details about their \$908 billion stimulus compromise but was still struggling to reach agreement on crucial details, as congressional leaders remained at odds on an economic relief plan to address the pandemic.

The moderates' six-page framework, which was obtained by The New York Times, said the group had an "agreement in principle" for providing \$160 billion to state and local governments and offering liability protections to businesses "as the basis for good faith negotiations," but it omitted any substantive details about how to address the thorniest impediments to their agreement.

The lack of specifics underscored the remaining hurdles for the group — led by Senators Susan Collins, Republican of Maine, Joe Manchin III, Democrat of West Virginia — as it works to strike a deal in the coming days. Yet there is no guarantee that their plan will advance. Democratic leaders have called it a starting point for negotiations, but Senator Mitch McConnell, Republican of Kentucky and the majority leader, has not endorsed it. And the Trump administration presented its own \$916 billion proposal on Tuesday with notable differences.

Mr. McConnell had suggested earlier Tuesday that Democrats drop their demand for funding for state and local governments in exchange for Republicans dropping their insistence on including a liability shield for businesses, but his idea was immediately rejected by Democrats. And the administration proposal offered by Steven Mnuchin, the Treasury secretary, contained both.

The moderates' framework would revive a lapsed weekly federal unemployment benefit at

\$300 a week for 16 weeks, from the end of December to April, and extend a series of unemployment programs set to expire at the end of the month.

It notably does not include another round of stimulus checks, which some lawmakers including Senators Bernie Sanders, the Vermont independent, and Josh Hawley, Republican of Missouri — have lobbied for in recent days. Mr. Mnuchin's proposal would include a \$600 stimulus check for each American, but would not revive the supplemental unemployment benefit.

The original \$2.2 trillion stimulus law enacted in March distributed \$1,200 stimulus checks and established the enhanced unemployment benefits at \$600 a week through July, which President Trump later <u>extended unilaterally at \$300 a week for most workers</u>.

Speaker Nancy Pelosi and Senator Chuck Schumer of New York, the minority leader, urged Republicans to allow bipartisan talks to move forward, calling them the best opportunity for compromise.

In response, Mr. McConnell slammed the two Democrats for rejecting both the White House offer and his overture on Tuesday, his first major concession since efforts to reach agreement on another coronavirus relief deal began.

"At every turn, they have delayed, deflected, moved the goal posts, and made the huge number of places where Congress agrees into a hostage of the few places we do not," Mr. McConnell said.

The moderates' plan would repurpose money Mr. Mnuchin clawed back from the Federal Reserve and leftover funds in the expired Paycheck Protection Program and allow small businesses to receive another loan from the popular small-business program. It would provide \$10 billion to child care providers, \$25 billion in rental assistance, \$82 billion for education providers, \$6 billion for vaccine development and distribution and \$7 billion for state, local and tribal governments to conduct testing and tracing.

To give negotiators additional time to reach an agreement both on a stimulus deal and the dozen annual spending bills, lawmakers in the House overwhelmingly passed a stopgap measure extending the government funding deadline to Dec. 18 from Friday.

- Emily Cochrane

A Chinese vaccine wins its first approval in the U.A.E., which says it is 86 percent effective.

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A Sinopharm vaccine production plant in Beijing. The Chinese vaccine maker has been running trials in 10 countries.Credit...Zhang Yuwei/Xinhua, via Associated Press

The United Arab Emirates approved a Chinese coronavirus vaccine on Wednesday, citing preliminary data showing that it was 86 percent effective. The move, the first full approval of a Chinese vaccine by any nation including China, could bring the vaccine a step closer to widespread use around the world.

The announcement by the Emirates' Ministry of Health and Prevention was the first official indicator of a Chinese vaccine's potential to help stop the pandemic. If trials elsewhere produce similar findings, the Chinese vaccines <u>could offer a lifeline to developing countries</u> that cannot afford vaccines developed in Western nations that are likely to be more expensive and more difficult to store and distribute.

Chinese government officials and Sinopharm, the state-owned maker of the vaccine, were silent on Wednesday about the Emirati announcement. Scientists noted that the announcement was lacking in data and other critical details.

Sinopharm would not confirm or comment on the news, even hours after it was reported. A spokeswoman for the company hung up the phone when reached and did not respond to messages and calls afterward.

The news release from the Emirati government did not give important specifics, like the number of Covid-19 cases that were analyzed or the ages of volunteers, leaving it unclear to scientists how Sinopharm came to its conclusions about the vaccine's effectiveness.

"The devil is in the details," said Beate Kampmann, director of the Vaccine Center at the London School of Hygiene and Tropical Medicine. "It's very difficult to judge this without seeing the number of cases. The main thing is, the trial results need to be made public."

Still, the news that a Chinese vaccine was found to be 86 percent effective comes as a boost to China's biomedical ambitions, even though that figure falls short of the performance reported for vaccines developed by <u>Pfizer</u> and <u>Moderna</u>, which have said that their vaccines are more than 90 percent effective.

The vaccine could also help bring China closer to fulfilling a pledge by China's top leader, Xi Jinping, to make a vaccine a "global public good."

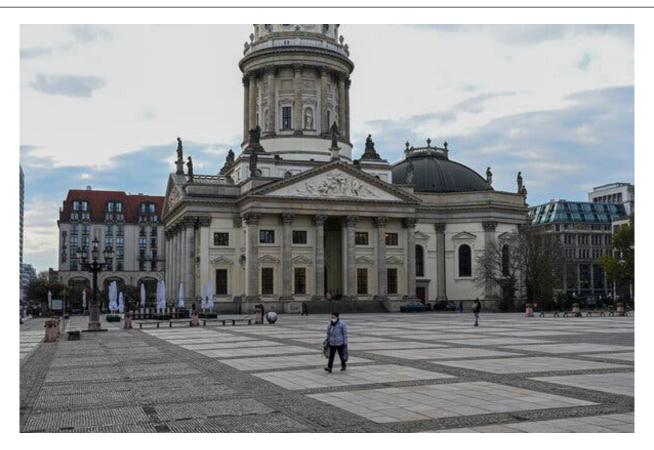
The Emirates is one of 10 countries where Sinopharm is testing two coronavirus vaccine candidates. The health ministry <u>said</u> it had reviewed an interim analysis of data from late-stage clinical trials that also showed the vaccine was 100 percenteffective in preventing moderate and severe cases of the disease. It did not say whether it had conducted an independent analysis of the raw data. The ministry said there were no serious safety concerns.

The results announced by the Emirates bode well for Sinopharm's vaccines to obtain full regulatory approval in China, which <u>Sinopharm sought</u> before final trials were complete. The company is also conducting trials in Bahrain, Jordan, Peru, Argentina and elsewhere.

"I think it could hit the market in China very soon, and there will be news within the next one to two weeks," said Tao Lina, a vaccine expert in China and a former immunologist at the Shanghai Center for Disease Control and Prevention. - <u>Sui-Lee Wee</u>

GLOBAL ROUNDUP

Angela Merkel calls for stricter lockdown measures, and other news around the world.



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Berlin's Gendarmenmarkt square would usually be hosting a bustling Christmas market.Credit...Lena Mucha for The New York Times

Chancellor Angela Merkel pleaded with Germans to meet fewer people and stay at home over the holidays in an impassioned speech to lawmakers on Wednesday, as her country saw <u>a record number of deaths</u> from the coronavirus.

"I'm sorry, from the bottom of my heart, I am really sorry," the visibly emotional chancellor said during a budget debate in Parliament. "But if the price we pay is 590 deaths a day then I have to say this is not acceptable."

Ms. Merkel, a physicist who <u>won praise in the spring</u> for her detailed explanations of the science behind why Germans needed to stay at home, was frustrated five weeks ago when the governors of the country's 16 states agreed only to partial restrictions that left most stores and schools open.

The result has been stubbornly high numbers of new infections and record numbers of people dying from the virus — as many in the first seven days of December as died in traffic accidents across the country in all of 2019, according to a report by Germany's National Academy of Sciences that urged a strict lockdown over Christmas and New Year.

Through early testing, contact tracing and a coordinated effort from all levels of government, Germany emerged from the first wave of the virus with <u>relatively few fatalities</u> and enough intensive care beds to take on patients from neighboring countries.

But even as other European countries, including Belgium, France and Ireland, returned to severe restrictions on movement in October, Germany's governors continued to squabble over how best to handle the virus, citing the different experiences in their regions.

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State authorities are responsible for health policy in Germany and, without their cooperation, the chancellor has been helpless to enforce stricter measures. While some of the states with the highest infection numbers and most crowded hospitals have already tightened restrictions, ordering schools closed and imposing curfews, others have stressed the importance for people of gathering for Christmas.

How difficult the situation has been for the chancellor, as a scientist, was apparent, as she pounded her fist in anger and pressed her palms together in supplication, urging people to begin scaling down their activities in the coming 14 days and calling for schools to break early for Christmas and shun outdoor stands selling seasonal treats such as mulled wine or fresh waffles.

"If we have too many contacts before Christmas and then later this becomes the last Christmas we celebrate with our grandparents, then we missed something," Ms. Merkel said. "We would do well to really take seriously what scientists tell us."

In other developments across the world:

- In **Japan**, Prime Minister Yoshihide Suga's cabinet has extended funding until June for a program that subsidizes domestic tourism, a Transport Ministry official said on Wednesday. The government has already scaled back the nearly \$13 billion "Go to Travel" program in places where infection rates are high, and the Tokyo metropolitan government has asked the elderly and people with underlying illnesses not to participate. Preliminary figures <u>suggest</u> that those who participate experience a higher incidence of symptoms associated with Covid-19.
- The period of self-isolation and quarantine will be reduced to 10 days from 14 days in **Wales** beginning Dec. 10, officials said Wednesday. "We know that self-isolating is hard for people and we believe families, communities and business will welcome the announcement today to safely reduce the days in which people have to isolate," said Vaughan Gething, the minister for health and social services.

– <u>Melissa Eddy</u>, <u>Christopher F. Schuetze</u>, Hisako Ueno, <u>Mike Ives</u> and <u>Derrick Bryson</u> <u>Taylor</u>

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Cuomo relents on in-person news briefings in New York, and switches to Zoom.





Gov. Andrew M. Cuomo of New York, pictured in November, has regularly held in-person briefings since the peak of the New York outbreak in the spring.Credit...Darren Mcgee/Office of Governor Andrew M. Cuomo, via Associated Press

With the coronavirus re-emerging in New York, Gov. Andrew M. Cuomo began holding his popular news briefings virtually on Wednesday, rather than in person with reporters in the same room.

The shift, months after the virus first devastated the state, will put Mr. Cuomo in sync with other leaders who transitioned away from in-person briefings long ago, including Mayor

Bill de Blasio and Gov. Gavin Newsom of California.

Richard Azzopardi, a senior adviser to Mr. Cuomo, said that "given the new stricter C.D.C. guidelines released Friday and the reality of rising cases in New York, going remote is now the most prudent action."

While <u>none of the directives</u> released by the Centers for Disease Control and Prevention last week were new, the stark warnings in the guidance reflected deepening concern at the agency that the pandemic is spiraling out of control. The agency urged Americans to wear masks indoors and avoid indoor spaces outside the home, labeling indoor dining as a "high-risk" scenario.

Despite months of mounting evidence of <u>the virus's airborne transmission indoors and the</u> <u>effectiveness of proper face coverings</u>, Mr. Cuomo did not wear a mask when he addressed reporters from behind a dais, flanked by aides who tended to remove their masks after entering the room.

"We have sat in these seats six feet apart, socially distanced, without masks, since Covid started," Mr. Cuomo said in October <u>when confronted by a reporter</u> about his decision to not wear a mask. "The rule is six feet apart. And that's what we do."

Gov. Philip D. Murphy of New Jersey continues to hold in-person briefings regularly in Trenton, wearing a mask before standing up from the dais but taking it off when answering questions from reporters, who are masked and socially distanced.

At the peak of the New York outbreak in the spring, Mr. Cuomo's daily briefings were televised nationally, elevating the governor's profile and offering viewers a rare window into his relationship with the press as he fended off question after question from local reporters. The briefings were typically held in the State Capitol in Albany or in a cramped room in his Manhattan office, with capacity capped and chairs for reporters spaced to ensure social distance.

As the virus waned in New York, however, Mr. Cuomo has held in-person briefings less frequently, opting instead for conference calls with reporters.

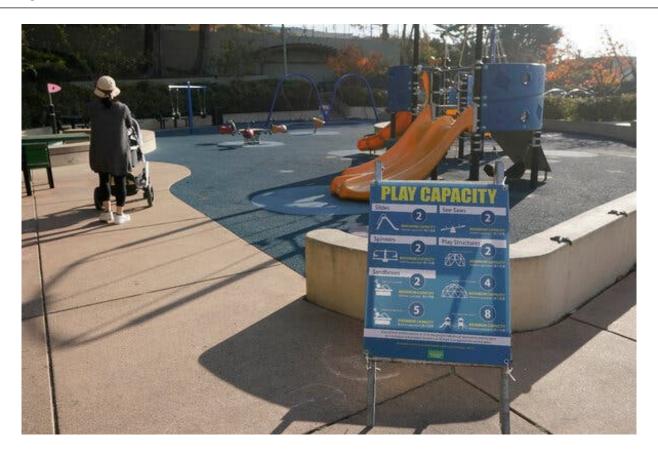
During an in-person briefing in his Midtown office on Monday, plexiglass partitions were placed between the governor and his aides for the first time, a last-ditch attempt at creating a safe environment. His staff wore masks during the presentation, but Mr. Cuomo did not.

The next day, Mr. Cuomo's office said his briefings would be held through Zoom "until further notice."

"We are making every effort to protect public health and balance it with the need for reporters across the state to continue to have access, so they can continue to do their jobs," Mr. Azzopardi said in a statement.

<u>Luis Ferré-Sadurní</u>

In a reversal, California says playgrounds can remain open despite stay-at-home orders.





Guidelines for capacity limits on play structures on a playground in San Francisco on Wednesday.Credit...Jeff Chiu/Associated Press

After getting blowback from parents and local officials, California has reversed course, and will now allow public playgrounds to remain open under the state's stay-at-home orders.

In an update on Wednesday, <u>the California Department of Public Health said that</u> "playgrounds may remain open to facilitate physically distanced personal health and wellness through outdoor exercise."

The <u>stringent regional stay-at-home orders</u> that took effect in much of the state on Sunday night initially called for public playgrounds to be closed. But parents, local officials and public health experts <u>pushed back fiercely</u>, arguing that playgrounds are a safe and essential way for families to get fresh air and exercise with very low risk of contracting the virus.

"We have learned a lot about how to mitigate spread, including masks, distancing, ventilation and hand hygiene," Monica Gandhi, an infectious disease doctor and professor of Medicine at the University of California, San Francisco, wrote in an email. "Therefore, to institute the same measures as in March, including shutting down of playgrounds, outdoor dining (where there has been no data to show that this is unsafe), and prohibiting members of different households to gather outside, is draconian and not data-driven."

Many Californians expressed relief at the move and <u>thanked the state for adjusting its</u> <u>guidance</u>. "Families spoke out, we introduced a resolution, they will now allow playgrounds to open. The right decision," <u>Matt Haney</u>, a member of the San Francisco board of supervisors, wrote on Twitter.

A dozen state legislators wrote a letter to Gov. Gavin Newsom on Friday arguing that

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closing playgrounds would be especially hard on low-income families who "may have little to no outdoor space of their own available." On Wednesday, those legislators <u>expressed</u> <u>gratitude</u> that the governor listened.

"Every parent knows how important playgrounds are for our youngest Californians," <u>wrote</u> <u>Assemblywoman Lorena Gonzalez</u> on Twitter.

Los Angeles County followed the state's lead on Wednesday and changed its pandemic restrictions to allow playgrounds to reopen, "so that all children can have safe access to the outdoors," the county supervisor, Hilda Solis, <u>said in a statement</u> posted on Twitter.

"Play is crucial for childhood development," Ms. Solis said. "But low-income communities of color living in dense housing often do not have access to a yard."

The county had closed its playgrounds before the governor announced the state restrictions. Public health officials have said that it was difficult to enforce compliance with social distancing at those sites.

Some older Californians were less fortunate on Monday.

The United States Forest Service announced it would <u>close the campgrounds</u> at eight national forests in California to help stem the spread of the virus. The announcement comes as most of California has entered a <u>new round of lockdowns</u>. The eight national forests with closed campgrounds are: Angeles, Cleveland, Inyo, Los Padres, San Bernardino, Sequoia, Sierra and Stanislaus.

Residents will still be permitted to visit the parks during the day, but may not use overnight accommodations. The order will remain in effect until Jan. 6.

– <u>Giulia McDonnell Nieto del Rio</u> and <u>Allyson Waller</u>

Here's how pandemic aid attracted hordes of gleeful and gutsy scammers.





Chris Hurn, chief executive of Fountainhead Commercial Capital, said fraud associated with the Paycheck Protection Program had tested his faith in humanity.Credit...Todd Anderson for The New York Times

Chris Hurn wasn't surprised scammers were trying to get government money. An enormous relief effort like the \$523 billion Paycheck Protection Program is bound to attract grifters.

As thousands of applications for government-backed loans flooded into his firm, Fountainhead Commercial Capital, it reported at least 500 suspicious cases to federal officials, Mr. Hurn said. But what shocked him was the brazen glee of the scammers who got money anyway.

At least a dozen times, "someone tried to defraud us, got turned down and then followed up to taunt us that they got their loan," said Mr. Hurn, Fountainhead's chief executive.

Four months after the federal government's signature coronavirus relief program for small businesses expired, investigators and lawmakers have only scratched the surface of schemes that illicitly tapped its forgivable loans. The program's hastily drafted and frequently revised rules, its removal of normal lending guardrails and governmental pressure to swiftly approve applications created the ideal conditions for thievery to thrive.

"We couldn't believe how many people were trying to take advantage and game the system," said Mr. Hurn, whose firm made more than 8,000 loans. "A lot of my employees, including me, were a little frustrated with humanity."

So far, the Justice Department has brought criminal charges against more than 80 people accused of stealing at least \$127 million from the relief program, but there's far more to uncover. The House Select Subcommittee on the Coronavirus Crisis said it had <u>identified</u> <u>more than \$4 billion</u> in potentially improper loans, and some bankers believe the total will be much higher.

- <u>Stacy Cowley</u>

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Cuomo offers more specifics on the state's vaccine and hospitalization plans.



Cuomo Outlines Coronavirus Vaccine Distribution Plan

Gov. Andrew M. Cuomo said New York's first allocation of the Pfizer-BioNtech vaccine could arrive as soon as this weekend if it's approved. Nursing home residents and staff members would be the first to get doses, followed by high-risk medical workers.

The state has set up 90 regional distribution centers that are capable of cold storage. This is a different definition of cold storage. This is like really, really cold storage. Not every facility can do it. Not every hospital can do it. But we've identified 90 regional centers that can keep the vaccine at the required temperature, and they'll act as distribution centers for that region. It could arrive as soon as this weekend. That assumes the F.D.A. does act right away. The F.D.A. does approve it. And the military turns around and ships it immediately. But it could actually be coming this weekend. Further allocations will be in the following weeks. Our state priority: Nursing home residents, first, nursing home staff — there was a discussion about do you do the residents or did or do you do the staff? New York, we decided to do both the residents and the nursing home staff. Then you go to high-risk hospital workers. The allocation by region, again, this is based on number of nursing home residents, number of nursing home staff and number of high-risk health care workers. After we take care of all the high-risk, health care workers, we'll then move to all long-term and congregate care staff and residents, then E.M.S. and other health care workers. And then essential workers, general population, starting with those who have the highest risk.

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1:48Cuomo Outlines Coronavirus Vaccine Distribution Plan Gov. Andrew M. Cuomo said New York's first allocation of the Pfizer-BioNtech vaccine could arrive as soon as this weekend if it's approved. Nursing home residents and staff members would be the first to get doses, followed by high-risk medical workers.CreditCredit...Justin Lane/EPA, via Shutterstock

Gov. Andrew M. Cuomo of New York offered more specifics on Wednesday for how a coronavirus vaccine, once authorized by federal regulators, <u>would be distributed across the state</u>, and laid out plans for how hospitals should deal with the surging number of cases.

Mr. Cuomo said New York City would get 72,000 of the initial doses of the Pfizer-BioNTech vaccine once the state receives them, which he said may be as soon as this weekend. Long Island will get 26,500 of the initial doses, he said, and the Mid-Hudson region 19,200.

The governor said the allocations were based on the number of nursing home residents and workers in each region, as well as the number of high-risk medical workers; those groups are the first priorities for vaccination.

The next people in line are residents and employees of long-term and congregate care facilities; then emergency medical service and other health care workers; then other kinds of essential workers; and finally, the rest of the population.

Mr. Cuomo also discussed the state's "surge and flex" program, which is intended <u>to keep</u> <u>hospitals from becoming overwhelmed</u> by transferring patients when necessary.

He said Dr. Howard Zucker, the state health commissioner, had written a letter to hospital and nursing home administrators outlining how to prevent overcrowded conditions, which proved disastrous in the spring.

"This is a hospital capacity crisis," Mr. Cuomo said, warning that "they're going to have to be extraordinarily flexible and nimble to handle the additional caseload that is coming up."

In his letter, Dr. Zucker called on individual hospitals and systems to alert the state before they reach 80 percent of capacity, and even earlier during a surge.

He also asked hospitals to report staffing or personal protective equipment shortages as well as bed occupancy. Nursing homes are required to have a 60-day stockpile of personal protective equipment, and hospitals must have 90 days' worth.

"As we learned in the spring, keeping a watchful eye on capacity ensures that there is support in place and/or alternative plans to prevent any facility from being overwhelmed," Dr. Zucker wrote.

Mr. Cuomo also said the Centers for Disease Control and Prevention had agreed to allow undocumented immigrants to receive vaccinations without having to provide identifying information, setting aside a <u>Trump administration requirement</u> that has caused consternation in some states

Administration officials have said collecting names, addresses, birth dates, ethnicities and other information was "critically necessary" to ensure that people receive follow-up doses and to assess the vaccine's effectiveness and safety.

Mr. Cuomo, however, said that it would seem as if "you were trying to use the vaccination to identify undocumented people," and that it could undercut the vaccination drive.

"If undocumented people don't get vaccinated," he said, "it compromises their health, and it compromises the whole program."

The governor also said the state had joined a program that would allow pharmacy employees to vaccinate employees and residents at nursing homes.

In Mr. Cuomo's <u>first virtual briefing</u> - a precaution taken because of the rising number of cases in the state and country - the governor said 4,993 people were hospitalized.

Mayor Bill de Blasio of New York City made a rare appearance at the briefing to join Mr. Cuomo in calling for Congress to provide more federal relief money to help the state recover economically from the pandemic. <u>Daniel E. Slotnik</u>

The U.S. will initially hold back half the first vaccine supply.





Gen. Gustave F. Perna, chief operating officer of Operation Warp Speed, at a news briefing in November.Credit...Stefani Reynolds for The New York Times

A top federal vaccine official said Wednesday that 2.9 million doses of Pfizer's Covid-19

vaccine will be shipped around the country in the first week after it is authorized by the Food and Drug Administration — half of the initial shipment from Pfizer.

On a call with reporters, <u>Gen. Gustave F. Perna</u>, the chief operating officer for Operation Warp Speed, the federal effort to speed a vaccine to market, said that 2.9 million doses would be sent out once the vaccine is authorized, and 2.9 million saved for booster shots, which are given three weeks later. The remaining 500,000 of an available 6.4 million doses are to be held in reserve, in case they are unexpectedly needed.

Health care workers and nursing home residents will be the first groups to receive the vaccine.

General Perna said he had decided to set aside the doses earmarked for the second shot out of caution.

"Eventually, we will become much more confident in our manufacturing, our distribution process, state handling, et cetera," he said. "And then the requirement for reserve won't be necessary."

An outside panel of experts is scheduled to meet on Thursday to consider whether the Pfizer vaccine, which was developed with a German company, BioNTech, should be authorized for limited use. The vaccine was found to be 95 percent effective in a clinical trial. The Food and Drug Administration is expected to make its decision within days.

But supply will initially be limited.

Pfizer, <u>which had to scale back its initial estimates</u> because of manufacturing struggles, has said it can provide about 25 million doses to the United States before the end of the year, and has a contract to provide 100 million doses in total by March. The company is <u>in</u> <u>negotiations with the federal government</u> over supplying additional doses next year, but has said it may not be able to do so until June. The vaccine has already been authorized in the United Kingdom, Bahrain and Canada.

A similar vaccine, developed by Moderna, could also be authorized within weeks, and government officials have said they hope to have given 20 million people their first dose of that vaccine before the end of the year.

— <u>Katie Thomas</u>

In wary communities, children are left without playmates and parents are concerned.

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Suzanne and Ilya Gendelman and their daughter, Mila, at a playground in San Francisco.Credit...Cayce Clifford for The New York Times

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Alice McGraw, 2 years old, was walking with her parents in Lake Tahoe this summer when another family appeared, heading in their direction. The little girl stopped.

"Uh-oh," she said and pointed: "People."

She has learned, her mother said, to keep the proper social distance to avoid risk of infection from the coronavirus. In this and other ways, she's part of a generation living in a particular new type of bubble — one without other children. They are the toddlers of Covid-19.

Gone for her and many peers are the play dates, music classes, birthday parties, the serendipity of the sandbox or the side-by-side flyby on adjacent swings. Many families skipped day care enrollment in the fall, and others have withdrawn their children amid the new surge in coronavirus cases.

With months of winter isolation looming, parents are growing increasingly worried about the developmental effects the ongoing social deprivation are having on their very young children.

"People are trying to weigh pros and cons of what's worse: putting your child at risk for Covid or at risk for severe social hindrance," said Suzanne Gendelman, whose daughter, Mila, 14 months old, regularly spent rug time with Alice McGraw before the pandemic.

"My daughter has seen more giraffes at the zoo than she's seen other kids," Ms. Gendelman said.

It is too early for published research about the effects of the pandemic lockdowns on very young children, but childhood development specialists say that most children are likely to be OK because their most important relationships at this age are with parents.

Still, a growing number of studies highlight the value of social interaction to brain development. Research shows that neural networks influencing language development and broader cognitive ability get built through verbal and physical give-and-take — from the sharing of a ball to exchanges of sounds and simple phrases.

These interactions build "structure and connectivity in the brain," said Kathryn Hirsh-Pasek, director of the Infant Language Laboratory at Temple University and a senior fellow at the Brookings Institution. "They seem to be brain feed."

Dr. Hirsh-Pasek characterized the current environment as a kind of "social hurricane" with two major risks: Infants and toddlers don't get to interact with one another and, at the same time, they pick up signals from their parents that other people might be a danger. "We're not meant to be stopped from seeing the other kids who are walking down the street," she said.

<u>Matt Richtel</u>

Advertisement

Continue reading the main story

Men with the virus are hospitalized and die at higher rates than women.





Trina Owens, a registered nurse, tending to Andre Johnson, a Covid-19 patient, at Roseland Community Hospital in Chicago on Tuesday.Credit...Shannon Stapleton/Reuters

Doctors noticed a sex disparity early in the pandemic: Men infected with the coronavirus were hospitalized at much higher rates than women, and men died at higher rates.

The gap was first observed in China, then seen in Italy and in New York City. Now a large global study has confirmed that men with Covid-19 are at higher risk than women for both severe disease and death.

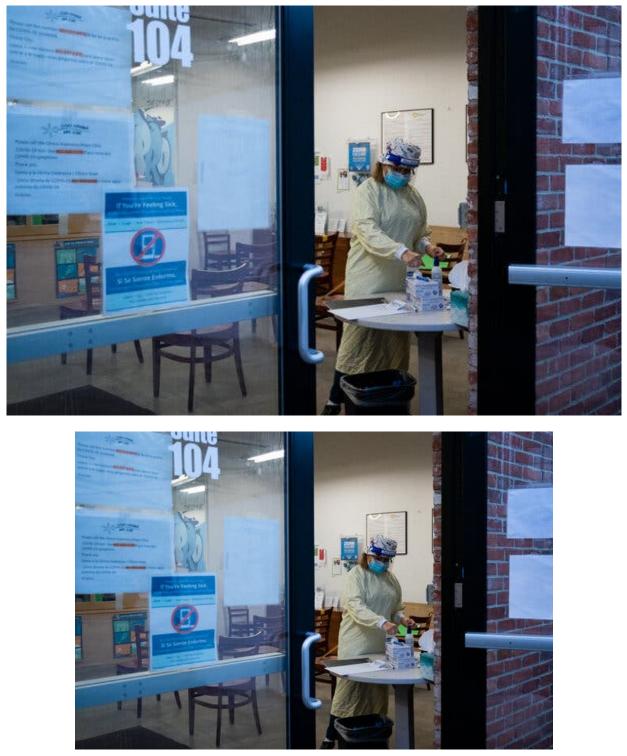
The analysis, published in <u>Nature Communications</u> on Wednesday, examined more than 3 million Covid-19 cases in dozens of countries and most American states. While the researchers found no differences in the proportion of male and female patients infected with the virus, men were nearly three times as likely to be admitted to intensive care than women, and 40 percent more likely to die.

The sex bias is a "worldwide phenomenon," with only a "few exceptions," the authors wrote, and the disparity has implications both for medical care as well as for mitigation strategies — and specifically, vaccination.

— <u>Roni Caryn Rabin</u>

The virus spreads at wildfire speed in tiny Rhode Island, surpassing rates of new cases elsewhere.

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A medical assistant cleaning her hands at Hope Clinic in Providence, Rhode Island in November.Credit...Elizabeth Frantz for The New York Times

Rhode Island, the smallest U.S. state in area, now has the fastest spread of coronavirus, with more new cases per capita being reported than any other state, <u>according to a New</u> <u>York Times database</u>.

While rates of new cases have climbed throughout the Northeast in recent weeks, Rhode Island has gotten much worse much faster than its neighbors. Over the past week, it has averaged more than 1,300 new cases a day, or 123.5 cases for every 100,000 people.

By contrast, Connecticut is averaging 78.2 cases for every 100,000, and Massachusetts 71. Midwestern states like South Dakota and Minnesota that had the worst spread in the nation a few weeks ago have fallen down into the 90s by this measure.

The state moved aggressively in the spring to try to keep the virus out, establishing quarantine rules and setting up checkpoints on major highways to stem the flow of people from hard-hit New York. Its case counts stayed relatively low for most of the summer. But after Labor Day and the start of the school year, case numbers began climbing steadily, and have not slowed since.

Gov. Gina Raimondo has imposed a two-week "pause" on the economy, and with health care workers in short supply, the state Department of Health has begun issuing temporary licenses to doctors, nurses and others who have retired, are visiting the state or have recently completing training programs.

"We need you," the governor implored on Twitter.

Experts attribute some of Rhode Island's relative vulnerability to its compact size and the concentration of its population in Providence, the capital. In contrast, next-door Massachusetts has large rural areas where case rates are low, but in Rhode Island an outbreak is likely to spread quickly through densely packed urban households. Studies indicate that <u>as many as half</u> of Covid-19 cases arise through transmission from <u>one member of a household to another</u>.

"One of the things Rhode Island suffers from in the context of Covid is that it's not a very big state in terms of its footprint," said Samuel Scarpino, an assistant professor at the Network Science Institute at Northeastern University. "It's as though Massachusetts was getting reported on in terms of only what's happening in Boston."

On surveys that measure social distancing and masking, Rhode Island is about even with Massachusetts and other states in the Northeast, Dr. Scarpino said. But the nationwide mobility data that his laboratory tracks shows that people in Rhode Island, like those elsewhere, have been leaving home to go to work this month and last at a rate of about 60 percent of what was once normal, compared to only 40 percent in early September. Rhode Island also ranked above the U.S. average in mobility over the Thanksgiving holiday.

"All of those things contribute to more cases getting into households," Dr. Scarpino said.

Other factors that might be contributing to the heavy Rhode Island caseload, Megan L. Ranney, an emergency room physician and associate professor at Brown University

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<u>suggested on Twitter</u>, include a large population of college students whose return in the fall seeded some transmission chains and — in a pandemic that has disproportionately affected low-income workers who cannot afford to stay home — the state's high poverty rate compared with others in the region. Like some other states, Rhode Island only imposed new restrictions on restaurants, bars and gyms after case counts had begun to surge.

"At the end of the day, regardless of the reason," Dr. Ranney tweeted, "our hospitals are overwhelmed & everyone knows someone who's sick."

- <u>Amy Harmon</u>

Protesters disrupt a health board meeting in Idaho, massing outside members' homes.





Demonstrators converged on Central District Health offices in Boise, Idaho, to disrupt a meeting called to discuss more mandates to combat the spread of COVID-19.Credit...Darin Oswald/Idaho Statesman, via Associated Press

The Central District Health board in Boise, Idaho, <u>tried to meet Tuesday evening</u> to consider imposing a mask mandate and other measures. But the meeting was beset from the very beginning.

Before the board had even completed roll call, one commissioner, Diana Lachiondo, interrupted to say she was stepping out to phone the police, because protesters had gathered outside her home. Four minutes later, she tearfully interrupted again, saying she had to leave the meeting because the protesters had begun banging on the door, where her 12-year-old son was home alone.

The board tried to carry on with business, hearing from a doctor about how the pandemic has overwhelmed his staff. But then the meeting was hastily adjourned at the request of the city's mayor and chief of police, who told the board it was unsafe to continue.

Protesters had gathered outside the Central District Health building in Boise, as well as the homes of Ms. Lachiondo and at least two other board members, to protest the mitigation measures the board was considering for four of Idaho's most populous counties. The police set up barricades at the building to keep protesters from entering.

The proposed measures included a mask mandate for public and private places where people of different households could not remain at least six feet apart. The board received more than 3,000 written public comments about the proposal over four days.

Another board member, Dr. Ted Epperly, later told <u>The Idaho Statesman</u> that about 15 protesters gathered outside his house during the meeting, "beating garbage cans and flashing strobe lights through my windows," and that two people had knocked on his door.

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The Boise Police Department said one person was arrested on charges of misdemeanor trespassing inside the Central District Health building. Investigators were also securing warrants to arrest others involved for disturbing the peace, the police said in a statement.

Mayor Lauren McLean of Boise wrote on Twitter that the protesters had come from "outside our community," and that their purpose was to "disrupt local government in action, to intimidate their families."

"This is not OK," she wrote. "Let me be clear: we will hold offenders accountable."

- Lucy Tompkins

Correction: Dec. 9, 2020

An earlier version of a home page summary misstated when Britain approved Pfizer's coronavirus vaccine. It was last week, not Tuesday.

EXHIBIT E

Wisshington State Department of Health

For more information about the 2019 Novel Coronavirus situation, please visit our COVID-19 page.

Emergencies > COVID-19 > Data Dashboard

COVID-19 Data Dashboard

Dashboard | Data Tables | Data Downloads | Reports | Technical Notes | View other WA State COVID-19 dashboards 3

The Department of Health and Microsoft's AI for Health team have partnered to create the interactive data dashboard below.

Website Last Updated 4:30 PM 12/10/2020

Data shown as of previous day at 11:59 pm PT.

December 10, 2020 data note: Today's total case counts may include up to 300 duplicates. Negative test results data from November 21, 2020 through today are incomplete, as are positive test results from November 30 - December 6, 2020, thus testing numbers should be interpreted with caution. The COVID-19 Disease Activity tab is the most accurate representation of COVID activity and is updated daily as new cases are identified and duplicates are resolved.

Summary Data Tables

County	Confirmed Cases	Hospitalizations	Death
Adams 🕫	1,458	80	1:
<u>Asotin</u> ⊿	791	36	1
Benton 🕫	9,423	541	14
<u>Chelan</u> 🗷	2,578	112	2
<u>Clallam</u> 2*	573	24	
<u>Clark</u> ♂	10,525	576	12
<u>Columbia</u> Z	58	9	
<u>Cowlitz</u> ⊯	1,744	87	1
<u>Douglas</u> ⊠	1,412	67	1
<u>Ferry</u> ⊠	132	5	
Franklin 2*	7,399	411	7
<u>Garfield</u> ♂	60	2	
<u>Grant</u> ♂	4,529	223	3
<u>Grays Harbor</u>	1,331	78	1
Island C	759	55	1
<u>Jefferson</u> ♂	188	17	
King 🗗	51,596	3,546	89
Kitsap C*	2,988	172	3
Kittitas 🖙	1,307	35	2

https://www.doh.wa.gov/Emergencies/COVID19/DataDashboard

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County	Confirmed Cases	Hospitalizations	Deaths
Klickitat 2	315	16	3
Lewis 🕫	1,562	107	17
Lincoln C	200	14	4
Mason 🕫	1,120	46	12
<u>Okanogan</u> ♂	1,302	75	14
<u>Pacific</u> ⊿	284	10	3
Pend Oreille	305	17	3
<u>Pierce</u> ℤ	19,925	1,539	283
<u>San Juan</u> ♂	67	3	0
<u>Skagit</u> ♂	2,399	161	30
<u>Skamania</u> 7	139	6	1
Snohomish 7	17,210	1,300	302
<u>Spokane</u> <i>⊡</i>	20,194	1,125	270
Stevens 7	853	51	10
<u>Thurston</u> ⊿	3,519	245	46
<u>Wahkiakum</u> 🕫	41	0	0
<u>Walla Walla</u>	2,569	145	27
<u>Whatcom</u> ♂	2,802	161	51
Whitman 7	2,510	48	25
<u>Yakima</u> ⊠	15,055	928	296
Unassigned	1,191	11	4
Total	192,413	12,084	2,850

Cumulative Confirmed Cases, Hospitalizations and Deaths by County

Confirmed Cases, Hospitalizations and Deaths by Age

Age Group	Percent of Cases	Percent of Hospitalizations	Percent of Deaths
0-19	15%	2%	0%
20-39	40%	14%	1%
40-59	28%	27%	9%
60-79	13%	39%	39%
80+	3%	18%	50%
Unknown	0%	0%	0%

Cumulative Confirmed Cases, Hospitalizations and Deaths by Age

Confirmed Cases, Hospitalizations and Deaths by Sex

Confirmed Cases by Race/Ethnicity

> >

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Hospitalizations by Race/Ethnicity	>
Deaths by Race/Ethnicity	>
Hospitalizations and Ventilations	>

Data Downloads

• Cases and Deaths by Week of Illness Onset, County, and Age (XLS) - Updated weekly on Sundays.

Reports

Modeling Situation Reports

- Multisystem Inflammatory Syndrome in Children Associated with COVID-19 in Washington State (PDF) 11/7/20, updated monthly
- <u>Statewide COVID-19 Outbreak Report (PDF)</u> 12/10/2020 updated weekly
- · Antigen-positive COVID-19 Cases (PDF) 12/09/2020 updated weekly
- <u>Case Investigation and Contact Tracing Metrics for DOH Centralized Investigations (PDF)</u> 12/09/2020 updated weekly
- <u>COVID-19 Morbidity and Mortality by Race, Ethnicity and Language in Washington State (PDF)</u> 12/09/2020 updated weekly
- Confirmed Cases by Industry Sector (PDF) 11/10/2020
- Death Category Report (PDF) 7/14/2020
- · Long-term Care Report (PDF) 12/8/2020 updated weekly

Technical Notes

Time delays and lags

Minor time delays in the collection of laboratory testing data, confirming cases, hospitalizations, and deaths occur regularly due to processing and reporting variation between data sources. This variation is due to differences in individual actions, laboratory capacities, and case confirmation and reporting processes.

After analyzing time lags between steps, the Washington State Department of Health (DOH) increased the period of incomplete reporting for most metrics to 10 days to ensure that 90% of data are accounted for in our posted numbers. For each metric shown on a time trend, the incomplete data period is shown in light gray. We provide a Learn More link with more detail on the period of incomplete data.

Number of infections

Public health experts agree that the true number of people who have been infected with COVID-19 in Washington greatly exceeds those that have been laboratory-confirmed. It is very difficult to know exactly how many people in Washington have been infected to date, since most people with COVID-19 experience mild illness and testing is still not widely available.

Cases

Effective June 16, 2020, cases are added to the DOH dashboard according to the date a person's first positive COVID-19 laboratory test result was entered into the Washington Disease Reporting System. Previously, the date a case was reported to DOH was used as the case date. Our current approach provides a more accurate designation of case confirmation dates while shifting less than 10% of case counts by date, most noticeably for cumulative case counts and graphics.

Testing

Two important data issues continue to affect results presented on the testing tab: 1) the delayed entry of negative lab results into our data system; and 2) the lack of an assigned county for about 21% of negative test results. These issues impact some counties disproportionately. Washington State Department of Health (DOH) continues to work on a sustainable solution.

Effective August 25, 2020, DOH changed the methodology for reporting test results. The total *number of tests* are now reported instead of the total number of *individuals tested*. New positive and negative test counts include all molecular tests (by specimen collection date) of individuals who have not previously tested positive. Multiple test results from the same day are counted only once and we exclude repeat tests on an individual after the first positive result. This methodology has been applied to the entire dashboard timeframe. The changes in our testing methodology did not affect dashboard testing trends.

Deaths

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Deaths are reported to the state by health care providers, medical examiners/coroners, local health departments, and others. For this reason, the statewide count of deaths often lags behind the counts of local health departments.

As of December 10, 2020, death counts on our dashboard reflect those in our official vital records database (the Washington Health and Life Events System) where the cause of death was confirmed or suspected to have been COVID-19. If COVID-19 is later ruled out as the official cause of death, we will remove these deaths from our dashboard. We no longer report preliminary death information recorded in other systems.

DOH updates COVID-19 death data on normal working days, Monday-Friday and adds the counts collected on weekends to the following Monday and Tuesday reports.

EXHIBIT F

12/11/2020

The New Hork Times | https://nyti.ms/2JR1kpO

F.D.A. Advisory Panel Gives Green Light to Pfizer Vaccine

The blessing of these experts means that the agency will likely OK the vaccine's use, paving the way for health care workers to begin getting shots next week.

By Katie Thomas, Noah Weiland and Sharon LaFraniere

Dec. 10, 2020

Pfizer's Covid-19 vaccine passed a critical milestone on Thursday when a panel of experts formally recommended that the Food and Drug Administration authorize the vaccine. The agency is likely to do so within days, giving health care workers and nursing home residents first priority to begin receiving the first shots early next week.

The F.D.A.'s vaccine advisory panel, composed of independent scientific experts, infectious disease doctors and statisticians, voted 17 to 4, with one member abstaining, in favor of emergency authorization for people 16 and older. With rare exceptions, the F.D.A. follows the advice of its advisory panels.

With this formal blessing, the nation may finally begin to slow the spread of the virus just as infections and deaths surge, reaching a record of more than 3,000 daily deaths on Wednesday. The F.D.A. is expected to grant an emergency use authorization on Saturday, according to people familiar with the agency's planning, though they cautioned that last-minute legal or bureaucratic requirements could push the announcement to Sunday or later.

The initial shipment of 6.4 million doses will leave warehouses within 24 hours of being cleared by the F.D.A., according to federal officials. About half of those doses will be sent across the country, and the other half will be reserved for the initial recipients to receive their second dose about three weeks later.

The arrival of the first vaccines is the beginning of a complex, monthslong distribution plan coordinated by federal and local health authorities, as well as large hospitals and pharmacy chains, that if successful, will help return a grieving and economically depressed country back to some semblance of normal, maybe by summer.

"With the high efficacy and good safety profile shown for our vaccine, and the pandemic essentially out of control, vaccine introduction is an urgent need," Kathrin Jansen, a senior vice president and the head of vaccine research and development at Pfizer, said at the meeting.

The vote caps a whirlwind year for Pfizer and its German partner BioNTech, which began working on the vaccine 11 months ago, shattering all speed records for vaccine development, which typically takes years. It is also a triumph for the F.D.A., which has upheld its reputation as the world's gold standard for drug reviews despite months of political pressure from President Trump, who has sought to tie his political fortunes to the success of a vaccine. The Pfizer vaccine has already been given to people in Bahrain and Britain, where it was authorized on Dec. 2. Canada approved it on Wednesday.

The U.S. authorization of Pfizer's vaccine is expected to be followed soon by one for Moderna's version, which uses similar technology and has also shown promising results in clinical trials. Operation Warp Speed, the Trump administration's multibillion-dollar program to fast-track vaccine development, pre-ordered 100 million doses of Pfizer's vaccine in July and heavily backed the development and manufacturing of Moderna's vaccine.

More than 100 F.D.A. employees have worked nearly round the clock to review the application Pfizer submitted on Nov. 20, compressing months of analysis into weeks as they pored over thousands of pages of clinical trial and manufacturing data.

Earlier this week, career scientists at the F.D.A. published an analysis showing the vaccine worked across a variety of demographic groups and that it was somewhat effective even after the first of two doses.

During the daylong meeting on Thursday, panel members peppered company and agency experts with detailed questions about the safety and efficacy of the vaccine, which was found to be 95 percent effective in a late-stage clinical trial. Some members expressed concern that there was not enough data from 16- and 17-year-olds to know whether the vaccine would help them, but the committee decided the benefits for that group outweighed the risks.



Outside Pfizer's headquarters in Manhattan. Carlo Allegri/Reuters

Some members asked about the likelihood for serious allergic reactions, given the news that regulators in Britain recommended this week that people with a history of anaphylactic allergic reactions to medicines and foods not get the vaccine while they investigate two cases of allergic reactions among health care workers. Pfizer officials said there were no cases of serious allergic reactions in the trial of 44,000 participants. People with a history of allergic reactions to vaccines were excluded from the study.

One of the panel members, Dr. Paul Offit of the Children's Hospital of Philadelphia, said he feared that statements by British regulators as well as remarks by Moncef Slaoui, a top U.S. vaccine official, could lead "tens of millions" of people with severe allergies to reject the vaccine even though evidence of a link to the shots was unclear. He asked Pfizer to conduct a separate study of people with a history of severe allergies, because "this issue is not going to die until we have better data."

CORONAVIRUS BRIEFING: An informed guide to the global outbreak, with the latest developments and expert advice.

Sign Up

The F.D.A. said that it had asked Pfizer to include allergic reactions in its safety tracking plan and would include a warning in its instructions on the use of the vaccine.

One of the most hotly contested issues was how the broad authorization of the vaccine might affect the continuing clinical trial. Some experts have argued that, ethically, trial volunteers who received a placebo should be offered the vaccine once it is authorized, but others worried that move could tarnish the long-term results of the trial.

During the public portion of the meeting, consumer and public health advocates largely pushed the agency to authorize the vaccine, noting the urgency of the pandemic. One speaker, who identified himself as Kermit Kubitz, noted that he had no conflicts of interest to declare except for "a lot of elderly relatives."

"They need this vaccine yesterday," he said.

But advocates also asked regulators to be transparent about potential safety issues and to closely track the vaccine once it becomes available. Several said such measures were necessary to reassure a public that is hesitant to take a new vaccine, particularly Black and Native American people who have historically been mistreated by the medical community. "Before authorization is granted, affected communities need to have confidence that the vaccine is safe and effective," said Sarah Christopherson of the National Women's Health Center.

By insisting that the advisory committee vote on any vaccine, regulators created a shield against White House pressure to approve a product before the presidential election. When the panelists met in October to discuss the F.D.A.'s guidelines for approving Covid-19 vaccines, they urged the agency to take its time and cautioned that rushing the process could risk missing

12/11/2020

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vital safety data and further erode public trust.

The scene that played out on Thursday — in which outside experts spent hours engaging government officials in an intense but often highly technical discussion about vaccine science — did not always make for exciting viewing. But the circumstances were certainly dramatic, as the experts were being asked to carefully weigh the risks and benefits of the vaccine, even as the United States reached the grim milestone of recording more than 3,000 Covid deaths on Wednesday and as thousands of people in Britain had already received it.

The F.D.A. has struggled, internally and externally, to move fast on its vaccine and treatment deliberations in order to curb the deadly virus's spread — but not so fast as to undermine public confidence. It was a thin line to walk, and not helped by the torrent of troubling accusations by Mr. Trump and his advisers that the agency was moving too slowly.

Just days before Pfizer submitted its application, the company sent an enormous tranche of manufacturing data to the F.D.A. — including materials on how it was scaling up production — leaving regulators scrambling to evaluate it in time for a possible authorization.

As part of its oversight, the F.D.A. also had teams review company production facilities and clinical trial sites, where they verified that records corresponded to the accounts Pfizer had submitted to federal regulators.

At the same time, regulators were evaluating an equally complex emergency authorization application submitted by Moderna, whose data will be examined publicly during another F.D.A. outside advisory meeting next week.

The Road to a Coronavirus Vaccine >
Answers to Your Vaccine Questions
As the coronavirus vaccine get closer to U.S. authorization, here are some questions you may be wondering about:
If I live in the U.S., when can I get the vaccine? While the exact order of vaccine recipients may vary by state, most will likely put medical workers and residents of long-term care facilities first. If you want to understand how this decision is getting made, this article will help.
When can I return to normal life after being vaccinated? Life will return to normal only when society as a whole gains enough protection against the coronavirus. Once countries authorize a vaccine, they'll only be able to vaccinate a few percent of their citizens at most in the first couple months. The unvaccinated majority will still remain vulnerable to getting infected. A growing number of coronavirus vaccines are showing robust protection against SEE MORE ∨

Regulators sometimes received documents from the companies as late as midnight and worked through the Thanksgiving holiday. Dr. Peter Marks, the top vaccine regulator at the F.D.A., joked last week at an event hosted by the American Medical Association that his team ate turkey sandwiches while examining documents.

"Among all global regulators, we are the ones that actually don't just look at the company's tables. We actually get down and dirty and we look at the actual adverse event reports, the bad spelling errors that are made by physicians sometimes, et cetera," he said at the event.

Dr. Stephen Hahn, the F.D.A. commissioner. Pool photo by Graeme Jennings

Dr. Stephen M. Hahn, the F.D.A. commissioner, kept a careful distance from the review, according to people familiar with it.

Dr. Hahn had caved to pressure earlier in the summer to authorize an old malaria drug, hydroxychloroquine, for use in Covid patients even though there was little evidence that it worked. That decision was reversed after the agency found the drug was unlikely to be effective in Covid patients and carried a risk of potentially dangerous side effects. And Dr. Hahn faced withering criticism from the scientific community after he exaggerated the benefits of another treatment, convalescent plasma, an error he later corrected.

Mr. Trump accused agency officials of being part of the "deep state" and hinted that a vaccine could come before "a very special day" — Election Day. The F.D.A.'s reputation appeared to be headed in the same direction as that of the Centers for Disease Control and Prevention, which was widely criticized for not standing up to the president.

But senior regulators — and eventually Dr. Hahn himself — pushed back. The agency's top career officials published an opinion piece in USA Today, acknowledging that the F.D.A.'s integrity had been called into question and insisting that they would "follow the science" during the pandemic. The agency prevailed in a battle with the White House over imposing more stringent guidelines for companies developing Covid vaccines.

"In this sort of environment, where there has been so much pressure and concern, the process does provide an important check and balance," said Dr. Jesse L. Goodman, who previously served as the F.D.A.'s chief scientist. Holding an open meeting also allows the public to "be sure that a broader scientific and clinical community is comfortable with the decision."

On Tuesday, the president held a summit intended to showcase the administration's role in developing a vaccine. "We are just days away from authorization from the F.D.A. and we're pushing them hard," Mr. Trump said at the event.

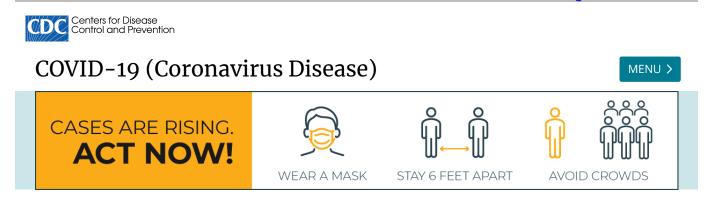
Many health care workers around the country are already raring to get the vaccine. Dr. Andrew Barros, a critical care physician in Charlottesville, Va., who is scheduled to get his Pfizer shot at 2:30 p.m. on Dec. 15, said he was "looking forward to having a sore arm and hopefully being one step closer to having Covid under control."

Pfizer's clinical trial will continue even after its vaccine is authorized by the F.D.A., and the company and F.D.A. will continue to watch for safety concerns.

Pfizer said on Thursday that it planned to apply for full approval in April 2021, after the company had collected six months of safety data. At that point, Pfizer would be allowed to sell its vaccine directly to hospitals and other health care providers.

Carl Zimmer and Katherine J. Wu contributed reporting.

EXHIBIT G



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Frequently Asked Questions about COVID-19 Vaccination

Updated Dec. 3, 2020 Print

In the United States, there is not yet an authorized or approved vaccine to prevent coronavirus disease 2019 (COVID-19). The federal government, through Operation Warp Speed 🖸, has been working since the pandemic started to make one or more COVID-19 vaccines available as soon as possible. Although CDC does not have a role in developing COVID-19 vaccines, CDC has been working closely with health departments and partners to develop vaccination plans for when a vaccine is available. CDC is working with partners at all levels, including healthcare associations, on flexible COVID-19 vaccination programs that can accommodate different vaccines and scenarios.

Below are answers to commonly asked questions. Regular updates will be made as needed.

Planning for a Vaccine

What is Operation Warp Speed's role with COVID-19 vaccines?

Operation Warp Speed is a partnership among components of the Department of Health and Human Services (HHS) and the Department of Defense to help develop, make, and distribute millions of vaccine doses for COVID-19 as quickly as possible while ensuring that the vaccines are safe and that they work. Learn more about Operation Warp Speed:

- HHS Fact Sheet: Explaining Operation Warp Speed ☑
- New England Journal of Medicine article: Developing Safe and Effective COVID Vaccines Operation Warp Speed's Strategy and Approach ☑

When will a COVID-19 vaccine be available in the United States?

The goal for Operation Warp Speed \checkmark is to deliver safe vaccines that work, with the first supply becoming available before the end of 2020. When a vaccine is authorized or approved in the United States, there may not be enough doses available for all adults. Supplies will increase over time, and all adults should be able to get vaccinated later in 2021. However, a COVID-19 vaccine may not be available for young children until more studies are completed.

What has been done to plan for the distribution of COVID-19 vaccines?

The federal government will oversee a centralized system to order, distribute, and track COVID-19 vaccines. All vaccines will be ordered through CDC. Vaccine providers will receive vaccines from CDC's centralized distributor or directly from a vaccine manufacturer.

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Many COVID-19 vaccine candidates are in development, and clinical trials are being conducted at the same time with large-scale manufacturing. With first doses expected before the end of 2020, planning and preparing for a COVID-19 vaccination program is very important.

Planning efforts have focused on every step and detail of the process, including:

- Establishing and testing logistics plans with manufacturers and commercial partners that are part of CDC's centralized COVID-19 vaccine delivery system
- · Coordinating the first distribution of vaccines and needed supplies from centralized locations
- Ordering processes for additional doses of the vaccine after the first supply has been shipped
- Receiving, storing, and handling vaccines properly at very specific temperatures
- Deciding who should receive a vaccine first, based on national recommendations, if there are not enough doses of the vaccine for everyone
- Giving the vaccines in a safe way during an ongoing pandemic
- Reporting on vaccine inventory, administration, and safety using a variety of new and enhanced data systems
- Expanding safety surveillance through new systems and additional information sources, as well as scaling up existing safety monitoring systems
- Developing plans to assess vaccine effectiveness, which means how well the vaccines protect against COVID-19 under real-life conditions
- Making sure timely, credible, and clear communication is provided to the public and stakeholders around all aspects of the vaccination program

This situation continues to change, and planning will progress as more information about any authorized or approved vaccines becomes available. A safe and effective COVID-19 vaccine is a critical component of the U.S. strategy to reduce COVID-19-related illnesses, hospitalizations, and deaths and to help society function as it did before COVID-19. The goal of the U.S. government is to have enough COVID-19 vaccine doses for all people in the United States who choose to be vaccinated.

Who has CDC worked with to plan for the distribution of COVID-19 vaccines?

State, tribal, territorial, and local jurisdictions: CDC is working with state, tribal, territorial, and local jurisdictions on the development of COVID-19 vaccination plans for their respective areas. CDC released a playbook on September 16, 2020, to provide specific information to consider during vaccination plan development. The playbook M was updated on October 30, 2020.

Private partners and federal agencies: CDC has also worked with private partners, such as chain and networks of independent pharmacies, and other federal agencies (e.g., the Indian Health Service) on plans to more widely distribute COVID-19 vaccines. For example, CDC is working with pharmacies to offer on-site COVID-19 vaccination services for residents in long-term care settings, including skilled nursing facilities, nursing homes, and assisted living facilities where most individuals are over 65 years of age.

Does CDC have a national campaign to address any concerns people may have about getting a COVID-19 vaccine?

No, CDC is not leading a national campaign on COVID-19 vaccination. CDC's vaccination activities fit within and are guided by a *Vaccinate with Confidence* strategic framework. This strategic framework focuses on strengthening vaccine confidence and preventing outbreaks of vaccine-preventable diseases in the United States. It builds on longstanding practices that CDC and partners have used to talk with the public and healthcare providers about the life-saving protection of vaccines.

The *Vaccinate with Confidence* strategic framework is being customized to address the unique information and health equity needs created by the COVID-19 pandemic. The new *Vaccinate with Confidence for COVID-19* strategic framework will strive to support public and healthcare personnel acceptance of future COVID-19 vaccines. CDC will provide

updates once the new strategic framework is completed.

How is CDC working to make sure people want to and can get vaccinated once a COVID-19 vaccine is available?

CDC is working with partners across the country to make sure people have the information they need to be confident in deciding to get vaccinated. Key priorities for CDC are:

- **Regularly sharing clear and accurate information** with people to make sure they understand the risks and benefits of getting vaccinated and can make informed decisions.
- Helping healthcare personnel feel confident in their decision to get a COVID-19 vaccine and helping healthcare providers answer their patients' questions about the vaccine.
- Engaging communities and individuals in an equitable and inclusive way to ensure that people have
 opportunities to ask questions and get clear, accurate information about the COVID-19 vaccine.

Easy access to COVID-19 vaccines is equally critical. CDC is working with public health, healthcare providers, and other partners to make sure people can easily get a COVID-19 vaccine and that cost is not a barrier.

Will there be enough vaccine for everyone?

When FDA first authorizes or approves the use of one or more COVID-19 vaccines in the United States, there may be a limited supply. This would mean that not everyone will be able to be vaccinated right away. It is understandable how concerning this would be for people, especially for those who are at increased risk for serious illness from this virus and for their loved ones.

That is why, early in the response, the federal government began investing in select vaccine manufacturers 🗹 to help them increase their ability to quickly make and distribute a large amount of COVID-19 vaccine. This will allow the United States to start with as much vaccine as possible and continually increase the supply in the weeks and months to follow. The goal is for everyone to be able to easily get a COVID-19 vaccine as soon as large quantities are available. Several thousand vaccination providers will be available, including doctors' offices, retail pharmacies, hospitals, and federally qualified health centers.

What can I do now to help protect myself from getting COVID-19 since a vaccine is not yet available?

You should cover your mouth and nose with a mask when around others, avoid close contact with people who are sick, stay 6 feet away from others, avoid crowds, and wash your hands often. Get more information about these and other steps you can take to protect yourself and others from COVID-19.

Vaccine Development

How many COVID-19 vaccines are under development?

Multiple COVID-19 vaccines are under development. As of November 24, 2020, large-scale (Phase 3) clinical trials are in progress or being planned for five COVID-19 vaccines in the United States.

Has there been a coronavirus vaccine developed before? What's known about it, and can it be helpful today in working toward a COVID-19 vaccine?

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Severe acute respiratory syndrome (SARS) and Middle East respiratory syndrome (MERS) are two diseases caused by coronaviruses that are closely related to the virus that causes COVID-19. Researchers began working on developing vaccines for these diseases after they were discovered in 2003 and 2012, respectively. None of the SARS vaccines ever made it past the first stages of development and testing, in large part due to lack of interest because the virus disappeared. One MERS vaccine (MVA-MERS-S) successfully completed a phase 1 clinical trial in 2019. Lessons learned from this earlier vaccine research have been used to inform strategies for developing a COVID-19 vaccine.

Why is it taking so long to develop a COVID-19 vaccine? It only took a few months for the H1N1 influenza (flu) vaccine to be developed.

When a new flu strain is identified, like H1N1 in 2009, vaccine manufacturers can use the same processes that are used to make the annual seasonal flu vaccine, saving valuable time. Unlike flu, coronaviruses do not yet have licensed vaccines or processes to build on. In addition, the coronavirus that causes COVID-19 is a new virus, so entirely new vaccines must be developed and tested to ensure they work and are safe. There are many steps in the vaccine testing and approval process. Multiple agencies and groups in the United States rightarrow correct and solution is available as quickly as possible.

Getting Vaccinated

How many shots of COVID-19 vaccine will be needed?

All but one of the COVID-19 vaccines currently in Phase 3 clinical trials in the United States need two shots to be effective. The other COVID-19 vaccine uses one shot.

Do I need to wear a mask when I receive a COVID-19 vaccine?

Yes. CDC recommends that during the pandemic people wear a mask that covers their nose and mouth when in contact with others outside your household, when in healthcare facilities, and when receiving any vaccine, including a COVID-19 vaccine. Anyone who has trouble breathing or is unable to remove a mask without assistance should not wear a mask. For more information, visit considerations for wearing masks.

Who is paying for COVID-19 vaccine?

Vaccine doses purchased with U.S. taxpayer dollars will be given to the American people at no cost. However, vaccination providers will be able to charge an administration fee for giving the shot to someone. Vaccine providers can get this fee reimbursed by the patient's public or private insurance company or, for uninsured patients, by the Health Resources and Services Administration's Provider Relief Fund.

Are there special considerations on who should get the COVID-19 vaccine first?

At first, there will be a limited supply of COVID-19 vaccine. Operation Warp Speed is working to get those first vaccine doses out once a vaccine is authorized or approved and recommended, rather than waiting until there is enough vaccine for everyone. However, it is important that the initial supplies of vaccine are given to people in a fair, ethical, and transparent way. Learn how CDC is making COVID-19 vaccine recommendations, including recommendations if there is a limited supply, based on input from the Advisory Committee on Immunization Practices (ACIP).

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If I have already had COVID-19 and recovered, do I still need to get vaccinated with a COVID-19 vaccine when it's available?

There is not enough information currently available to say if or for how long after infection someone is protected from getting COVID-19 again; this is called natural immunity. Early evidence suggests natural immunity from COVID-19 may not last very long, but more studies are needed to better understand this. Until we have a vaccine available and the Advisory Committee on Immunization Practices makes recommendations to CDC on how to best use COVID-19 vaccines, CDC cannot comment on whether people who had COVID-19 should get a COVID-19 vaccine.

Why would a vaccine be needed if we can do other things, like social distancing and wearing masks, \sim to prevent the virus that causes COVID-19 from spreading?

Stopping a pandemic requires using all the tools available. Vaccines work with your immune system so your body will be ready to fight the virus if you are exposed. Other steps, like covering your mouth and nose with a mask and staying at least 6 feet away from others, help reduce your chance of being exposed to the virus or spreading it to others. Together, COVID-19 vaccination and following CDC's recommendations to protect yourself and others will offer the best protection from COVID-19.

Do I need to wear a mask and avoid close contact with others if I have received 2 doses of the vaccine?

Yes. While experts learn more about the protection that COVID-19 vaccines provide under real-life conditions, it will be important for everyone to continue using **all the tools** available to us to help stop this pandemic, like covering your mouth and nose with a mask, washing hands often, and staying at least 6 feet away from others. Together, COVID-19 vaccination and following CDC's recommendations for how to protect yourself and others will offer the best protection from getting and spreading COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on steps everyone should take to slow the spread of the virus that causes COVID-19. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

When can I stop wearing a mask and avoiding close contact with others after I have been vaccinated?

There is not enough information currently available to say if or when CDC will stop recommending that people wear masks and avoid close contact with others to help prevent the spread of the virus that causes COVID-19. Experts need to understand more about the protection that COVID-19 vaccines provide before making that decision. Other factors, including how many people get vaccinated and how the virus is spreading in communities, will also affect this decision.

Are there other vaccines that can help prevent me from getting COVID-19?

There are currently no available vaccines that will prevent COVID-19. However, multiple agencies and groups in the United States 🖸 are working together to make sure that a safe and effective COVID-19 vaccine is available as quickly as possible.

A flu vaccine will not protect you from getting COVID-19, but it can prevent you from getting influenza (flu) at the same time as COVID-19. This can keep you from having a more severe illness. While it's not possible to say with certainty what will happen in the winter, CDC believes it's likely that flu viruses and the virus that causes COVID-19 will both be spreading during that time. That means that getting a flu vaccine is more important than ever.

Does immunity after getting COVID-19 last longer than protection from COVID-19 vaccines?

The protection someone gains from having an infection (called natural immunity) varies depending on the disease, and it varies from person to person. Since this virus is new, we don't know how long natural immunity might last. Some early evidence—based on some people— seems to suggest that natural immunity may not last very long.

Regarding vaccination, we won't know how long immunity lasts until we have a vaccine and more data on how well it works.

Both natural immunity and vaccine-induced immunity are important aspects of COVID-19 that experts are trying to learn more about, and CDC will keep the public informed as new evidence becomes available.

What percentage of the population needs to get vaccinated to have herd immunity to COVID-19? \sim

Experts do not know what percentage of people would need to get vaccinated to achieve herd immunity to COVID-19. Herd immunity is a term used to describe when enough people have protection—either from previous infection or vaccination—that it is unlikely a virus or bacteria can spread and cause disease. As a result, everyone within the community is protected even if some people don't have any protection themselves. The percentage of people who need to have protection in order to achieve herd immunity varies by disease.

Safety

How do I report it if I have a problem or bad reaction after getting a COVID-19 vaccine?

CDC and FDA encourage the public to report possible side effects (called adverse events) to the Vaccine Adverse Event Reporting System (VAERS) 🖸 . This national system collects these data to look for adverse events that are unexpected, appear to happen more often than expected, or have unusual patterns of occurrence. Learn about the difference between a vaccine side effect and an adverse event. Reports to VAERS help CDC monitor the safety of vaccines. Safety is a top priority.

Healthcare providers will be required to report certain adverse events following vaccination to VAERS. Healthcare providers also have to adhere to any revised safety reporting requirements according to FDA's conditions of authorized use throughout the duration of any Emergency Use Authorization; these requirements would be posted on FDA's website \square .

CDC is also implementing a new smartphone-based tool called **v-safe** to check-in on people's health after they receive a COVID-19 vaccine. When you receive your vaccine, you should also receive a **v-safe** information sheet telling you how to enroll in **v-safe**. If you enroll, you will receive regular text messages directing you to surveys where you can report any problems or adverse reactions you have after receiving a COVID-19 vaccine.

What does it mean if a clinical trial is temporarily paused?

Safety is a top priority during the vaccine approval process. It is not unusual for a clinical trial to be temporarily paused when a possible side effect (called an adverse event) is detected. Clinical trials are designed to pause when an unexpected health event (called a safety signal) is detected so scientists and physicians can investigate potential safety concerns. The approval process for COVID-19 vaccines is no different — safety is always the focus.

 \sim

EXHIBIT H

12/10/2020

Cfficial Website of the Department of Homeland Security



Report Crimes: Email or Call 1-866-DHS-2-ICE

NOTICE

Click here for the latest ICE guidance on COVID-19

ICE Guidance on COVID-19

Overview & FAQs

ICE Detainee Judicial Statistics Releases Previous Statements

Page information is recorded from a live database; data may change as the agency receives updated case information.

DETAINED POPULATION ¹	COVID-19 POSITIVE CASES CURRENTLY IN CUSTODY ²	DETAINEES TESTED
AS OF 12/04/2020	UNDER ISOLATION OR MONITORING AS OF	AS OF 12/04/2020
16,377	12/09/2020	70,085
,	496	

COVID-19 ICE Detainee Statistics by Facility

AS OF 12/09/2020

Custody/AOR/Facility	Confirmed cases currently under isolation or monitoring	Detainee deaths ³	
Atlanta Field Office			
Charleston County Detention Center	0	0	2
Columbia Regional Care Center	0	0	1
Folkston ICE Processing Center (D. Ray James)	11	0	83
Irwin County Detention Center	1	0	45
Robert A. Deyton Detention Center	1	0	4
Sheriff Al Cannon Detention Center	0	0	1
Stewart Detention Center	16	3	395
Baltimore Field Office			
Howard County Detention Center	1	0	1
Worcester County Jail	0	0	1
Boston Field Office			
Bristol County Detention Center	0	0	1
Cumberland County Jail	1	0	1
Franklin County House of Corrections	1	0	8
Strafford County Corrections	0	0	2
Wyatt Detention Center	1	0	4

Custody/AOR/Facility	Confirmed cases currently under isolation or monitoring	Detainee deaths ³	Total confirmed COVID-19 cases ⁴
Buffalo Field Office			
Buffalo (Batavia) Service Processing Center	0	0	50
Chicago Field Office			
Chase County Detention Facility	2	0	82
Clay County Justice Center	0	0	17
Dodge County Jail	2	0	2
Lincoln County Detention Center	0	0	1
McHenry County Adult Correctional Facility	0	0	5
Montgomery County Jail	0	0	1
Morgan County Detention Center	0	0	1
Pulaski County Detention Center	1	0	100
Dallas Field Office			
Bluebonnet Detention Facility	6	0	350
Eden Detention Center	0	0	62
Johnson County Law Enforcement Center	0	0	1
Kay County Detention Center	0	0	1
Moore Detention Center	0	0	34
Prairieland Detention Facility	2	0	120
Rolling Plains Detention Center	0	0	59
Denver Field Office			
Aurora Contract Detention Facility	15	0	133
Detroit Field Office			
Calhoun County Correctional Center	10	0	48
Geauga County Jail	0	0	1
Monroe County Jail	0	0	1
Morrow County Correctional Facility	0	0	51
Saint Clair County Jail	1	0	12
El Paso Field Office			
Cibola County Correctional Center	0	0	1
El Paso Service Processing Center	45	0	303
Otero County Processing Center	0	0	185
Torrance County Detention Center	0	0	55
Houston Field Office			
Coastal Bend Detention Center	0	0	12
Houston Contract Detention Facility	2	0	156
IAH Polk Adult Detention Facility	0	0	31
Joe Corley Detention Center	0	1	51

	Confirmed		
Custody/AOR/Facility	cases currently under isolation or monitoring	Detainee deaths ³	Total confirmed COVID-19 cases ⁴
Nontgomery Processing Center Houston)	2	0	222
Los Angeles Field Office			1
Adelanto ICE Processing Center	18	0	260
Miami Field Office			
Baker County Detention Center	5	0	10
Broward Transitional Center	1	0	160
Glades County Detention Center	1	1	179
Krome North Service Processing Center	1	0	210
Larkin Behavioral Health Center	0	0	2
San Juan Staging Facility	0	0	1
Wakulla County Jail	0	0	41
Newark Field Office		1	
Elizabeth Detention Center	17	0	37
Essex County Jail	0	0	8
New Orleans Field Office			
Adams County Correctional Center	4	0	105
Alexandria Staging Facility	16	0	199
Allen Parish Detention Center	0	0	12
Catahoula Correctional Center	0	0	119
Etowah County Jail	0	0	22
Hancock County Jail	0	0	1
Jackson Parish Correctional	2	0	111
LaSalle ICE Processing Center - Jena	3	0	82
LaSalle ICE Processing Center - Olla	0	0	25
Pine Prairie ICE Processing Center	0	0	65
Richwood Correctional Center	2	0	127
River Correctional Center	0	0	56
South Louisiana Correctional Center	17	0	24
Winn Correctional Center	5	1	248
New York City Field Office		1	
Bergen County Jail	0	0	6
Hudson County Jail	0	0	14
Philadelphia Field Office		1	
Cambria County Prison	0	0	11
Clinton County Correctional Facility	52	0	55
Pike County Correctional Facility	8	0	32
York County Prison	9	0	117
Phoenix Field Office			
CCA Florence Correctional Center	18	0	72

https://www.ice.gov/coronavirus

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Custody/AOR/Facility	Confirmed cases currently under isolation or monitoring	Detainee deaths ³	Total confirmed COVID-19 cases ⁴
Eloy Federal Contract Facility	6	0	266
Florence Detention Center	8	0	83
La Palma Correctional Facility	24	0	495
Salt Lake City Field Office			
Cache County Jail	0	0	15
Henderson Detention Center	2	0	24
Nevada Southern Detention Center	0	0	12
Nye County Jail	9	0	59
Washington County Jail	1	0	6
San Antonio Field Office			
El Valle Detention Facility	13	0	100
Karnes County Family Residential Center	1	0	90
Laredo Processing Center	0	0	7
LaSalle County Regional Detention Center	1	0	2
Limestone County Detention Center	29	0	88
Port Isabel Detention Center	10	0	199
Rio Grande Detention Center	4	0	165
South Texas Family Residential Center (Dilley)	13	0	19
South Texas ICE Processing Center (Pearsall)	38	0	269
T. Don Hutto Residental Center	1	0	1
Webb County Detention Center (CCA)	1	0	93
San Diego Field Office			
Imperial Regional Detention Facility	0	0	5
Otay Mesa Detention Center (San Diego CDF)	7	1	198
San Luis Regional Detention Center	0	0	20
San Francisco Field Office			
Golden State Annex Facility	0	0	3
Mesa Verde ICE Processing Center	0	0	59
Seattle Field Office			
Northwest ICE Processing Center (NWIPC)	0	0	21
St. Paul Field Office			
Douglas County Corrections	0	0	1
Freeborn County Adult Detention Center	0	0	5
Hardin County Jail	0	0	7
Kandiyoh County Jail	19	0	20

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Custody/AOR/Facility	Confirmed cases currently under isolation or monitoring	Detainee deaths ³	Total confirmed COVID-19 cases ⁴
Linn County Jail	0	0	2
Nobles County Jail	0	0	2
Phelps County Jail	0	0	2
Polk County Jail	0	0	15
Sherburne County Jail	0	0	2
Washington D.C. Field Office			
Caroline Detention Facility	8	0	49
Immigration Centers of America - Farmville	0	1	339
TOTAL	496	8	7,851

¹ ICE's FY 2019 Average Daily Population was 50,165.

² "Currently under isolation or monitoring" includes detainees who tested positive for COVID-19 and are currently in ICE custody under isolation or monitoring. This number excludes detainees who previously tested positive for COVID-19 and were either returned to the general population after a discontinuation of medical monitoring/isolation or are no longer in ICE custody.

³ "Detainee deaths" includes detainees who have died after testing positive for COVID-19 while in ICE custody; COVID-19 may not be the official cause of death.

⁴ "Total confirmed COVID-19 cases" is the cumulative total of detainees who have tested positive for COVID-19 while in ICE custody since testing began in February 2020. Some detainees may no longer be in ICE custody or may have since tested negative for the virus.

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Last Reviewed/Updated: 12/10/2020

EXHIBIT I

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DEPARTMENT OF HOMELAND SECURITY NOTICE OF CUSTODY DETERMINATION

01/2020 236 of title 8, Code of ase, you will be:
236 of title 8, Code of
:34 Determination o Office f #5 21
21
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language. uage) r (if applicable)
u

DHS Form I-286 (1/14)

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U.S. Department of Homeland Security	Continuation Page for	Form <u>I-286</u>
^{Alien's Name} KHAN, Naeem Sohail	File Number	Date 12/01/2020
	ODY DETERMINATION inuation)	
Pursuant to a review conducted to comply with requ WL 1932570 (C.D. Cal. Apr. 20, 2020), you have b Factors identified by the district court as placing yo upon contracting the COVID-19 virus."	een identified as having one or	more of the Risk
The Risk Factor(s) in your case are that you:	2	
Are age 55 or over		
Are Pregnant		
Have a Chronic Care Condition (As confirmed by a Condition: Diabetes	a medical professional)	
Upon review of the totality of the circumstances present in	your case, it has been determined the	nat you will:
Be released from custody, subject to conditions re	ferenced on Form I-286	
Remain detained, and the following facts form the	basis for your continued detention:	
Threat to Public Safety		1
Comments:		
-		
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1	· · ·	1
Signature Robert Mason	Title SDDO	
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