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Democracy Dies in Darkness

Trump's Operation Warp Speed promised a flood of covid vaccines. Instead, states are expecting a trickle.

The administration pledged several hundred million doses in 2020. Companies will actually ship about 10 percent of that.

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Federal officials have slashed the amount of coronavirus vaccine they plan to ship to states in December because of constraints on supply, sending local officials into a scramble to adjust vaccination plans and highlighting how early promises of a vast stockpile before the end of 2020 have fallen short.

Instead of the delivery of 300 million or so doses of vaccine immediately after emergency-use approval and before the end of 2020 as the Trump administration had originally promised, current plans call for availability of around a tenth of that, or 35 to 40 million doses.

Two vaccines, from manufacturers Pfizer and Moderna, which both use a novel form of mRNA to help trigger immune response, are on the verge of winning Food and Drug Administration clearance this month. Approval would cap an unprecedented sprint by government and drug companies to develop, test and manufacture a defense against the worst pandemic in a century — part of the Operation Warp Speed initiative that promised six companies advance purchase orders totaling $9.3 billion.

As planning accelerated for distributing supplies, the government began to further lower expectations. To make sure supplies don't run out and leave some people only partially immunized, the government said it would stagger deliveries to ensure that states have enough supply for the second shot, required 21 days later for the Pfizer vaccine, which is expected to be first to gain approval.

Lower-than-anticipated allocations have caused widespread confusion and concern in states, which are beginning to grasp the level of vaccine scarcity they will confront in the early going of the massive vaccination campaign.

"I come from a family of seven siblings, and best practice was always to have seven of everything being given out," said Joe Sullivan, a senior health adviser in Oregon, which is expecting about 35,000 doses in the initial wave from Pfizer. "But we know that's not possible in this case."

Maine, meanwhile, saw its allotment fall from a previous estimate of 36,000 to just 12,675 doses, officials in the state said. "This is far less than what is needed for Maine and proportionally for other states as well," Gov. Janet Mills (D)

The drop-off is a product of manufacturing problems, bottlenecks in the supply of raw materials and other hurdles in ramping up clinical-trial production of 5 liters of protein-based vaccine at a time to commercial-scale fermentation of 2,000-liter batches, the companies and the Trump administration said.

“There were a couple of our vaccine candidates that took significantly longer, in terms of failed batches, in terms of not having the purity we sought,” Paul Mango, deputy chief of staff for policy at the Department of Health and Human Services, said in an interview. He declined to say which company experienced batch failures.

“We have cracked the code on these things but we’re two months behind on some of them,” Mango said. Several states said they were expecting an allocation from Moderna about twice the size of the initial wave from Pfizer, roughly a week later.

The flow is expected to accelerate in January and February but still will not meet the bold predictions of Trump and the leader of Operation Warp Speed, pharmaceutical executive Moncef Slaoui, who said in the White House Rose Garden in May that he was confident “several hundred million” doses of vaccine would be ready by the end of December.

Instead, Slaoui said this past week that officials are now planning to ship 35 to 40 million doses by the end of the year, enough for up to 20 million people under a two-shot regimen.

Pfizer is expected to win emergency authorization for its vaccine soon after an FDA advisory committee meets on Dec. 10. In November, the company cut its manufacturing projection for 2020 from 100 million doses to 50 million doses. It said it remains on track to produce 1.3 billion doses in 2021.

The company’s lower estimate got little notice at the time, tucked at the bottom of a Nov. 9 news release announcing the stunning news that its vaccine was more than 90 percent effective. The news buoyed stock markets and triggered optimism that a solution to the pandemic was in sight.

As Pfizer began large-scale production, the company said, it encountered difficulties procuring sufficient amounts of raw ingredients. A number of specialized materials are required to create the vaccine, including nucleotides, the building block of the mRNA.

“Bringing it all together in a first-time, very large-scale operation, is no simple feat,” said company spokeswoman Amy Rose. “It’s as complicated as the research-and-development piece.”

Moderna, a Massachusetts biotech company that has never before had a product on the market, did not make early public predictions of how much of its mRNA vaccine it would produce by the end of 2020. The company said it is now on track to have 20 million doses available in December and between 500 million to 1 billion available by the end of 2021. As with Pfizer, Moderna’s vaccine is a two-shot regimen.

“The swing factor between 500 million and 1 billion [doses] is raw materials,” Moderna chief executive Stephane Bancel said in an interview, adding that as the company massively ramped up its production by a factor of 1,000 this year, the demand strained its supply chain. “Some of our suppliers were not ready for that, of course,” Bancel said.

components of mRNA itself and enzymes.

“If one ingredient is missing we have to wait,” Bancel said.

AstraZeneca said earlier in the year it would begin delivering the first of 300 million doses of viral-vector vaccine to the United States in September, an ambitious prediction that passed unfulfilled. AstraZeneca declined to comment. Other companies have either declined to say how much vaccine they expect to have available or won’t report phase 3 clinical data until later in 2021.

Americans and state officials are already having to adjust their expectations to a slower rollout of vaccines.

Operation Warp Speed officials said that, within 24 hours of the Pfizer vaccine winning clearance, the government would begin releasing 6.4 million doses, in two stages: enough for the first shot, followed three weeks later by enough for the second shot. Once the Moderna vaccine is authorized, perhaps a week after Pfizer’s, 12.5 million doses would begin to be released, under a similar schedule.

Army Gen. Gustave Perna, the logistical chief of Operation Warp Speed, has said those initial bursts of vaccine would be followed by a weekly “cadence” of shipments.

Health officials in numerous states said they expected to vaccinate fewer people than they had originally anticipated with the first wave of the Pfizer vaccine. The sharp decrease in expected doses reoriented their planning in the final stages of preparation for a logistical ordeal as complex as a military campaign.

Some of the calculations were technical — whether to send the shots to an even narrower set of hospitals or to include the same number of facilities but restrict immunization to the most at-risk health care workers. Other decisions involved more fundamental questions of access and how to balance public awareness with limited supply.

In Maine, the current proposed allotment “would barely enable us to vaccinate emergency department and ICU front line staff,” said Nirav Shah, director of Maine’s Center for Disease Control and Prevention and president-elect of the Association of State and Territorial Health Officials.

Maine has about 6,000 emergency department and intensive-care front line staff who would meet the criteria to be vaccinated in the initial round, state officials said.

State and local officials said they always expected vaccine supply would be limited in the early weeks after authorization. But the increased constraints are compounding the allocation and implementation challenges of getting doses to people in the first priority groups, said Jeff Duchin, a top official at the Seattle and King County Health department.

“We will need to make decisions on where to send a very limited supply initially that will leave many unsatisfied until the supply improves to meet demand. For example, is it preferable to give more sites a smaller number of doses, or a few sites more doses, when all serve people in the first tier to be offered vaccine?” Duchin said.

A CDC advisory committee recommended this past week that health-care personnel and residents of long-term care facilities be the first to get the limited doses once a vaccine is authorized. Because of the limited supply, the advisory committee’s work group suggested a standardized approach for health-care systems to prioritize their personnel even

Few officials seemed to know exactly why they are receiving fewer doses.

“There has been some lack of clarity in terms of what states are going to get,” said Rachel Levine, Pennsylvania’s health secretary and president of the state health official association. “We’re not crystal clear.”

The initial supply “will not even touch all of our hospitals,” said Mandy Cohen, secretary of the North Carolina Department of Health and Human Services. “We knew this was going to be a process, and we’ve tried to set expectations on the front end.”

The government’s decision to hold back the booster shot, Cohen said, adds a new layer of complexity.

“I think one of the hardest pieces of this is the matching of that first dose to the second dose and getting that timing exactly right,” she said. “In the trial setting, when Pfizer and Moderna did that, it’s a very controlled setting. We don’t have data to say what happens if you come in on day 22. We’ll be working very hard to follow the protocols.”

Randall Williams, Missouri’s health director, said he’s confident the state will be able to complete the initial phase of immunization by early in the new year. A sharp drop-off in the initial allocation from Pfizer — from 180,000 to 51,000 in Missouri’s case — just means the doses will be more spaced out through the first month, rather than arriving immediately after the FDA grants approval, Williams said.

The shots will even be sufficient to cover residents of long-term care facilities, whom he had not originally factored into planning for the first priority group. “In some ways, this puts us ahead of where we thought we were going to be,” Williams said.

Federal officials, acclaiming the expected arrival of vaccines, are also begging people to be patient. “We will have more and more people getting vaccinated,” said Adm. Brett Giroir, the assistant secretary of health and human services during a visit Wednesday to Louisiana, saying “most Americans” might have to wait until May or June.

Experts agreed the administration’s plan to pay companies billions of dollars in advance to spur manufacturing in parallel to the initiation of clinical trials — a strategy never attempted on such a massive scale — must still be considered a success. The advance payments eliminated or reduced financial risk for the companies, which have raced to ramp up production of doses that are still in the pipeline, if coming slower than originally pledged.

“They have done better than I could have imagined they could have done,” said Barry Bloom, a professor and expert in immunology and infectious diseases at the Harvard T.H. Chan School of Public Health.

Each of the coronavirus vaccine manufacturers contracted by the government, with the exception of Pfizer, will get paid for delivery stockpiles of vaccine even if they fail to win emergency authorization, according to Operation Warp Speed. Together, the six received advance purchase orders of $9.3 billion, according to a tally by analysts at the Wall Street firm Bernstein. Some received additional subsidies of hundred of millions of dollars for research and development.

“This money certainly has been important in helping these companies build out their manufacturing capacity ahead of time. It’s just that it’s really hard to do so,” said Rachel Sachs, a law professor and specialist in pharmaceutical pricing at Washington University in St. Louis.