

Companies scramble to expand coronavirus vaccine supply

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56

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[coronavirus vaccines](#) authorized in the United States is accelerating, even as companies with experimental vaccines nearing the end of trials struggle to meet ambitious manufacturing targets.

That means the United States should have 200 million doses each from the companies with authorized shots, Pfizer-BioNTech and Moderna — enough to guarantee that more than 70 percent of adults will be able to get the two-shot vaccination by the end of July. That is comparable to the share of adults [some polls suggest](#) will be willing to roll up their sleeves.

“I think the U.S. will most probably be one of the first countries of size to get its population protected,” Stéphane Bancel, chief executive of Moderna, said this week at a keynote panel for the JP Morgan Healthcare Conference, an annual biopharmaceutical investor conference.

But doses on paper are different from [vials in the freezer](#) — or [vaccinations in people’s arms](#), as the past months have demonstrated. [Distribution challenges](#) have received most of the attention, as unused doses stack up. But the risk of raw ingredient shortages, manufacturing delays and other unforeseen production issues loom as the next potential bottleneck as companies work to reach a massive scale of manufacturing.

Pfizer-BioNTech and Moderna increased their forecast for global production during the past two weeks, citing growing experience and efficiency of manufacturing. But companies with vaccine candidates still in clinical studies have reported manufacturing challenges, echoing [Pfizer’s slipped timeline last fall](#), when the company slashed its production forecast from 100 million doses by the end of 2020 to 50 million.

Johnson & Johnson, which has a [one-dose vaccine](#) in the final phase of testing, agreed to a contract with the U.S. government to provide 12 million doses by the end of February. But

this week, Moncef Slaoui, scientific adviser for Operation Warp Speed, the Trump administration's initiative to speed development of vaccines, said the company was on track to have a "single-digit million number of doses available in the second half of February." The start of a clinical trial for a vaccine candidate from the company Novavax was delayed by months, partly because of manufacturing delays.

Johnson & Johnson spokesman Jake Sargent said production of the company's vaccine candidate has begun and the drugmaker was confident it could deliver the amount of vaccine it promised for 2021, but did not specify when doses would be delivered.

"We remain in active discussions with regulators, including on the approval and validation of our manufacturing processes," Sargent said.

Novavax's trial, initially set to begin in October, started in late December. Chief executive Stanley C. Erck said at JP Morgan that the company has now established a "robust" manufacturing process.

"It's the challenge of going from small scale to large scale, and you learn things along the way," Erck said.

Beyond the 400 million doses from Moderna and Pfizer-BioNTech, the United States has agreed to purchase 600 million doses of vaccine candidates in development — which, if they are shown to be effective and companies can meet manufacturing targets, will expedite the vaccination campaign. Having multiple vaccines that are developed using different technologies would insulate against supply-chain shortages or delays stemming from the vagaries of creating complex biologic products.

Norman W. Baylor, president of Biologics Consulting and a former vaccine regulatory expert at the Food and Drug Administration, stressed that manufacturing a vaccine at industrial scale is not easy. Even as companies say they are gaining confidence they will be able to surpass already ambitious targets, Baylor called for greater transparency about how many doses are being produced and released each week.

"All of a sudden, you get this phone call saying, 'Norman, we're having problems, and we're not going to be able to release vaccine for a month,' " Baylor said, recalling past vaccine shortages.

Baylor said vaccine companies are stretching to meet unprecedented demand, often with new technologies that haven't been used at massive scale, complicating planning. Contrast that with pediatric vaccines, a familiar product for drugmakers. In the United States, about 4 million doses of various pediatric vaccines are administered annually. Now, pharmaceutical companies are racing to make billions of doses of the coronavirus vaccine and get them out the door

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“You might run into something, especially with a biologic system, where it’s not behaving like it should,” Baylor said. “It’s not like making aspirin.”

Pfizer-BioNTech executives announced recently that they would produce 2 billion doses globally this year — a 50 percent increase over previous estimates. Pfizer realized after it began delivering vaccine that its five-dose vials contain a sixth dose that regulators said can be used. The rest of the increase reflects more efficient manufacturing and ramp-up of raw ingredients, Pfizer chief executive Albert Bourla said at JP Morgan.

“We say what we mean, and we mean what we say. So, when we say something, we feel confident that we will be able to do that,” Bourla said. “We do things very differently and out of the box in the way that we treat partners in raw materials, so that we can have manufacturing from specialized raw materials at the scale that is needed.”

Some vaccination sites, including those represented by Premier, a health-care company that represents an alliance of more than 4,100 health systems, have expressed concerns they do not have enough syringes and needles to administer the sixth dose in the Pfizer vials.

The Department of Health and Human Services said it is working with Pfizer and a distributor to increase syringe and needle supplies.

Pfizer spokeswoman Amy Rose acknowledged it is not certain the company can deliver 2 billion doses but that the company is increasingly confident it can reach that goal.

“We have confidence that we can achieve this aspiration based on our extensive vaccine expertise and manufacturing network; and we maintain the same confidence that we will mitigate inherent risks as we bring on additional raw material suppliers, add redundancies in our capabilities and add capacity with contract manufacturers,” Rose said in an email.

Moderna last week revised its forecast for how many doses it can produce globally this year, from 500 million to 600 million. Moderna initially set a wide target for production this year, suggesting the company would strive to make 1 billion doses, but would commit to produce half the amount — a range that shows how many uncertainties exist.

At a JP Morgan presentation, Bancel, the Moderna CEO, unpacked two factors affecting the projection. The first is the manufacturing yield — the number of doses the company gets from each batch — which sometimes will be higher than expected and other times lower. The other factor is availability of raw materials. Although the company has been working to secure and diversify its suppliers, Bancel said he could not know for certain that on a given calendar date the necessary raw materials would be on hand, even as the company has been

calendar date the necessary raw materials would be on hand, even as the company has been working to build up back up supply.

“We’re running 24/7. So, if for one shift ... if that day, there’s one raw material missing, we cannot start making products and that capacity will be lost forever because we cannot make it up,” Bancel said.

A tug-of-war between distribution and supply may emerge in coming months, but in the United States, leaders of Operation Warp Speed are already anticipating the possibility of a surplus of vaccine. And the challenges in implementing doses could become trickier as more people are vaccinated.

Scott Gottlieb, a former FDA commissioner in the Trump administration, told CNBC’s “[Squawk Box](#)” that he expects demand to plateau.

“We’re living in this sort of belief that the demand here is endless, and it’s not,” Gottlieb said. “I think by the end of February, we’re going to find that we have to open up eligibility pretty wide to get people to come in to get inoculated. We’re not going to be in this rationing situation.”

Updated August 19, 2021

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