Below is an article on the latest regarding the $815M in federal funding for various COVID testing supplies. We realize it may raise more questions than answers. After this was announced over a month ago by Carole Johnson, Testing Coordinator of the White House COVID-19 Response Team, there has been no further information or details. Rest assured we are working on getting answers and will update LPA members as soon as pertinent details become available. Thank you.

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Pipette Tip Supply Gaps Snarl Cash Infusion for Covid-19 Testing

- Billions in relief law for schools' point-of-care tests
- Shortages of testing equipment will continue

By Shira Stein and Jacquie Lee | March 16, 2021 5:39AM ET

Covid-19 test backlogs stemming from lab supply manufacturing snags are expected to continue despite the billions of dollars Congress is pumping into testing programs.

Part of the $48.7 billion that Congress set aside for testing and contact tracing under the latest Covid-19 relief law will likely go toward domestic production of pipette tips and other supplies that have been difficult to get during the pandemic. But even with the extra funds, there's still a limited number of companies with the expertise and capacity to make those products, lab officials and supply chain consultants say.

"Money can't buy more of stuff that's not there," said Peter Kyriacopoulos, chief policy officer for the Association of Public Health Laboratories. "Money can help, but it is a dynamic situation and I'm not sure whether the fact is hugely the money or whether the effect is due to the demand as the situation changes."

Covid-19 testing demand has slowed recently. But lab officials worry it will spike if hot spots emerge this summer as states reopen faster than the Centers for Disease Control and Prevention recommends.

And demand is high for pipette tips and plastic wells, which hold liquids and are needed for almost every type of lab work—including testing for sexually transmitted disease or screening newborns for illnesses. Pipette tips and micro pipettes are on the Food and Drug Administration's device shortage list.

White House officials are aware of the U.S.'s over-reliance on global plastic production. The money is intended to address that problem, but whether the onshoring process will be fast enough to meet testing needs is unclear.

Pipette Tip Problem

The cash for testing and contract tracing will boost earlier investments, Biden administration officials said. They announced plans Feb. 17 to put $650 million toward testing in schools and congregate settings and $815 million toward domestic manufacturing of testing supplies.

The earlier investments are expected to solve some problems relatively quickly. Schools will get needed funds to buy point-of-care tests. Data sharing programs will get a financial boost, as will the administrative work necessary to run new testing sites.

But capacity is still a problem. Without more supplies, labs could continue to struggle.

"We need to build the capacity to produce these materials or we'll continue to face shortages that will sidetrack our work in expanding access to testing," White House Testing Coordinator Carole Johnson told reporters Feb. 17. She noted that specialized paper used in antigen test are among the supplies in need.

But many pipette tip designs are proprietary and only made by a handful of companies— including Hamilton Medical and Tecan Group Ltd.—which only exacerbates the shortage, said Andy Brailo, chief customer officer for hospital supply-purchasing group Premier Inc.

High regulatory expectations also make medical supply production difficult, Eric Blank, chief program officer for the Association of Public Health Laboratories, said. "These are things that have to meet very high specifications."

The dire need for pipette tips even has the FDA stepping out of its usual oversight role.

"It's very serious," FDA Acting Commissioner Janet Woodcock said at a recent Milken Institute event. The "FDA has gotten much more involved in the downstream details of the supply chain for different products than it has been in the past," she said.

'Cautiously Optimistic'

The earlier funds were intended as a “bridge” until the relief bill passed into law so the administration can “fully expand testing and ensure that any American can get a test when they need one,” Johnson told reporters.

But it’s not clear when the money will ease production issues. Kyriacopoulos hopes to see some improvements by the middle of the year thanks to the influx of federal funding.

“What we heard about six months ago is it would be nine months for some production facilities to be making materials,” he said. But he isn’t sure if that was just hypothetical or when the clock on that nine-month timeline started ticking.

Diagnostic makers seem more optimistic about labs’ capacity.

“We’re cautiously optimistic that the labs on both sides of that equation have the ability to ramp up,” said Susan Van Meter, executive director of AdvaMedDx, a division for medical diagnostics makers within AdvaMed. “I don’t think we’ve hit our peak yet of what would be the maximum capacity of testing across the country.”

About 95% of testing kits come with most, if not all, of the supplies needed to run the test, Van Meter said. Some testing companies also include consumable products like pipette tips and well trays, and some of those companies have invested in companies that make these products, she added.

Roche, for example, has invested $300 million in the past year to increase manufacturing of instruments, tests, and consumables like pipette tips.

The extra funding for domestic supply production “could help strengthen the nation’s response to the current COVID-19 health crisis and also better prepare us for future pandemics,” said Roche spokesperson Patrick Barth.

But Soumi Saha, vice president of advocacy for Premier Inc., said she’s looking for the administration to provide more information on the production of these testing supplies—how much will be made, when they’ll be available, and how they’ll be distributed—so labs know what to expect.

“It seems that the supplies necessary to perform the testing has always been the rate limiting step,” Saha said.

—With assistance from Jeannie Baumann

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