How Industry Collaboration and Partnerships are Supporting COVID-19 Vaccine Manufacturing

Across the industry, biopharmaceutical companies are working around the clock to meet the demands of COVID-19 manufacturing. Companies are working to source needed raw materials and other supplies and increasing manufacturing capacity to get COVID-19 vaccine shots in as many arms as possible. Even prior to knowing the efficacy of particular vaccine candidates, companies have proactively been seeking to increase their own manufacturing capabilities as well as collaborate with other manufacturers who shared available capacity to support efforts to increase production. These partnerships have been key, so that as safety and effectiveness data were compiled and vaccines were authorized by regulatory agencies, manufacturing could ramp up quickly.

Yet even after laying significant groundwork, global vaccination efforts face challenges stemming from the innate and unavoidable complexities within the manufacturing scale up processes for vaccines. To overcome these hurdles, biopharmaceutical companies have established partnerships to help support increased manufacturing output and speed up the ability to fight COVID-19 as distribution capacity is expanded around the globe.

Here are four questions that provide greater context to these efforts:

How complex is COVID-19 vaccine manufacturing?

Manufacturing vaccines on a global scale is a highly complex, specialized and intensive bio-process given that COVID-19 vaccines are complex biologic products. The two vaccines which first received emergency use authorizations (EUAs) from the U.S. Food and Drug Administration (FDA) rely on a completely new approach to creating vaccines: mRNA technology. mRNA technology has been decades in the making with new technological platforms for manufacturing playing a pivotal role in enabling the rapid development of COVID-19 vaccines.

As additional vaccines are authorized such as the vaccine granted an EUA on February 27, there will be different manufacturing approaches for different vaccines, with each required to comply with strict FDA-mandated requirements. Expectations for reviewing any manufacturing changes will also be established by the U.S. Food and Drug Administration and followed by manufacturers.

The process of manufacturing COVID-19 vaccines safely, effectively and consistently on a global scale is incredibly challenging. Due to the complex vaccine manufacturing process, it is misguided to assume that vaccine manufacturing production can be turned on at a moment's notice. This has been reinforced by noted biopharmaceutical researcher, Derrick Lowe.

PolitiFact has also described the misleading claim as "mostly false" because it "oversimplifies the vaccine manufacturing process" and "ignores critical facts."

How are companies and other stakeholders working collaboratively to increase manufacturing?

Even before the FDA authorized a COVID-19 vaccine, biopharmaceutical companies were scaling up manufacturing capacity. Companies have been identifying other manufacturers with the appropriate expertise, technical capabilities and facilities, and they have entered into partnerships and agreements to further speed up the production of vaccines.

These partnerships are being undertaken by companies together with knowledge of which facilities and their staff can help produce vaccine candidates. These collaborations are done with specific considerations in mind and are highly technical in nature, often focused on a single step or stage of the overall manufacturing process.

Why is it important for individual biopharmaceutical companies to identify their own potential manufacturing partners?

The biopharmaceutical industry has the unique expertise, technological capacity and supply chains to be able to develop, manufacture and distribute safe and effective vaccines. There are existing relationships and opportunities for manufacturing companies to appropriately communicate with each other, explore partnerships and share knowledge of approximate capabilities and capacities. As such, it is important to allow vaccine manufacturers to continue to identify the right partners based on their specific needs to help boost manufacturing capacity and distribution.

Forcing or mandating relationships between ill-fit partners or trying to introduce new partners from outside the ecosystem is destined to lead to suboptimal outcomes. Ensuring the safety, efficacy and quality of vaccines is a top priority for everyone involved in vaccine production and distribution.

Are intellectual property protections a barrier to producing and manufacturing COVID-19 vaccines?

No, and in fact, intellectual property (IP) protections enabled the industry to lay the foundation with decades of investment to respond to the COVID-19 pandemic. As the industry continues to expand vaccine production and deliver medicines to patients in need, reliable IP protections have been critical in supporting research, development and manufacturing partnerships on COVID-19 vaccines and therapeutics. Companies are licensing technologies and sharing know how with other manufacturers and partners to increase global capacity and get vaccines to citizens around the world. Moreover, innovators need strong and reliable IP protections to research, develop and manufacture new therapeutics and vaccines and new manufacturing and technology platforms to improve patients' lives during the current pandemic and beyond.

The biopharmaceutical industry has embraced its leadership role in responding to COVID-19 and continues to establish effective partnerships to boost manufacturing capacity to help keep pace with global demand, so that vaccines make it to those in need as quickly as possible.

America's biopharmaceutical companies remain committed to ensuring that treatments and vaccines developed for COVID-19 are available to all who need them. For more information on COVID-19 vaccines currently in clinical development, visit: phrma.org/Coronavirus/Activity-Tracker