Biotechnology Innovation Organization

Pennsylvania House Health Committee
Treatment Options in Pennsylvania for COVID-19 – Part II
Tuesday, October 20, 2020

Testimony by Amy Walker, Biotechnology Innovation Organization (BIO)

Chairwoman Rapp, Democratic Chair Frankel, and members of the House Health Committee, thank you for the invitation to speak with you today regarding the status of research and development of COVID-19 vaccines, therapeutics, and diagnostics. My name is Amy Walker and I am the Director for Infectious Diseases Policy at the Biotechnology Innovation Organization, or BIO.

BIO is the world's largest trade organization representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 countries. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotechnology products. BIO's membership includes developers and manufacturers of vaccines, therapeutics, diagnostics, and medical countermeasures against emerging infectious diseases, pandemic pathogens, and other health security threats. As the leading biotech trade association, BIO is working to help accelerate R&D of biotech solutions to the current pandemic; help patients weather the storm of the pandemic, and enhance US preparedness for future public health emergencies.

As you know, when a novel coronavirus emerged in China late last year, no products existed to treat or prevent this disease. While we are developing products that are proven to be effective and safe, I am pleased to say that the biopharmaceutical industry has made quick progress in accelerating research in this area.

The public-private partnership between the biotech industry and the U.S. government is leading the global race to develop vaccines and cures to protect individuals from the novel coronavirus. Specifically, our industry is devoting our expertise, resources, and capabilities to identify science-based solutions and medical treatments to combat this threat. These efforts have encompassed unparalleled collaboration and cooperation between industry, academia, non-governmental organizations, and governments around the world.

Pennsylvania is playing a vital role in the research, testing, and manufacturing of these products. A number of the biotechnology companies answering the call on COVID-19 have research and manufacturing facilities in the state. Pennsylvania's academic institutions have laid the foundation for later stage work in partnership with biotechnology companies.

BIO has developed a suite of tools to help connect stakeholders and provide information. One such tool is a vaccines and therapeutics pipeline tracker, which cross-

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references information from industry databases and company public announcements. This information is available publicly for free at bio.org/covidpipelinetracker. The tracker aims to provide timely information and therefore is updated every week.

As of Monday, October 14th, there were public announcements of more than 750 programs for COVID-19 vaccines and therapeutics that have been launched over the past 9 months. More than 90% of products are being developed by biotechnology companies. More than 70% of products in the pipeline have been discovered by small companies, and more than 50% have been discovered by companies based in the US.

With regard to products for COVID-19, we're really talking about three different pipelines. Of the more than 750 products in the pipeline,

- 25% are vaccines to prevent infection;
- 27% are antivirals or antibodies targeting the SARS-COV-2 virus itself; and
- 48% are treatments for secondary effects of infection.

Approximately 40% of all products are at clinical-stage development and they're being tested in actual people. The majority – or 70% of the clinical stage pipeline are treatments for COVID-19 related illness.

Many more novel technologies are being deployed and tested. More than 60% of the pipeline are biologics and vaccines, while around a third of products are traditional small molecule. The products in clinical stage show a variety of modalities and technologies – ensuring that we have many shots on goal for success.

Many of the clinical-stage drugs have been repurposed, having been approved or being developed for other diseases, which gave them a head start in initiating trials quickly, while the majority of vaccines are new for COVID-19, and are therefore moving to Phase 3 took longer.

The majority of the antivirals in clinical testing are antibody treatments. Of the antibodies in development, most are currently in Phase 1, though a few products have advanced as far as Phase 3. Additionally, the treatment pipeline reflects many of the systemic impacts that we've seen with COVID-19 illness. COVID-19 disease has also been linked to secondary effects such as acute respiratory distress syndrome and cardiovascular issues, and so more than 25% of the pipeline seeks to mitigate these impacts.

In the vaccines space, work that had been done to address the previous outbreaks of SARS and MERS are being tested against COVID-19. The use of tested platform technologies has accelerated the pace of research. For the 2003 SARS epidemic, it took 20 months from publication of the genetic sequence of the virus genome to development of a vaccine candidate. For SARS-CoV2 the first Phase I vaccine clinical trial began a mere three months after the genetic sequence of the virus was available.

Companies are compressing timelines through parallel rather than sequential R&D and manufacturing work. In addition, Operation Warp Speed was started in May with the goal of having a fully tested vaccine by January 2021 and accelerating therapeutics development. Operation Warp Speed has partnered with eight companies to de-risk the R&D process by providing funding for development, manufacturing, and procurement of vaccines and therapeutics. These awards are large scale: most partnerships are upwards of $1 billion.

Efforts are being made to ensure that the acceleration does not come at the expense of safety and efficacy data. The clinical trials for the vaccines are enrolling a high number of patients to help ensure the data on safety and efficacy are robust. These Phase 3 studies are being conducted using clinical trials designs that represent the gold standard in vaccines R&D – randomized, placebo-controlled, event-based trials. FDA has announced that they are using rolling submissions to review data on products as it is submitted rather than en masse at the end and recently provided guidance on the use of Emergency Use Authorizations (EUAs) that show high scientific standards are being upheld. In September, industry leaders issued a pledge that affirmed that companies would "follow the science" and not seek FDA review until robust data has been collected through clinical trials.

While progress is promising, there are a few macrolevel challenges to getting these products to the American public.

The pandemic has highlighted existing disparities in health care, infection risk, and confidence in our medical system. Companies have been proactive in seeking diverse populations from communities especially hard-hit by COVID-19 to ensure that the products are safe and effective for the people who need them most. Even so, recruitment of communities of color lags behind where we would like to be.

We are facing a record scale-up to manufacture vaccines and therapeutics to meet the needs in America and globally. In addition to scaling up production for the products themselves, scale up is needed for ancillary products like needles, syringes, and adjuvants to ensure that there are not bottlenecks with fill-finish capacity. This all must be done to increase capacity and not pull manufacturing capacity or supplies from existing routine of vaccinations or therapeutics. We don't want shortages of drugs or outbreaks of other diseases on top of COVID-19.

Now that trials and manufacturing of vaccines are underway, attention is turning to how we will get the vaccines to people once authorized or approved by the FDA. Manufacturing is scaling up but supply of vaccines will be constrained initially – we won't have 300M doses, much less 600M doses available the day after FDA's decision.

The CDC's Advisory Committee on Immunization Practices (ACIP), which makes recommendations for all vaccines used in the US, convened a COVID-19 Work Group in April. This group has been meeting nearly weekly since then and ACIP has held monthly public meetings since June to discuss COVID-19 vaccine development and prioritization transparently. As inputs into their process, ACIP is using other frameworks developed by

respected groups such as the National Academies of Science, Engineering, and Medicine; Johns Hopkins University; and the World Health Organization. The current focus is on a risk-based approach – getting vaccine first to those most at risk of exposure to COVID-19, with health care workers, older adults and adults with numerous chronic conditions, and essential workers being outlined as preliminary groups. Final decisions on prioritization will be made once we know what vaccines are ultimately authorized or approved and that data for those vaccines among different population groups.

Operation Warp Speed issued their distribution plan and guidance to states on September 16th. States' initial distribution plans were due to CDC on Friday, October 16th and refinement and adjustments to the plans will continue throughout a vaccination campaign. Vaccines will largely be distributed using existing infrastructure, with some improvements as needed. Additionally, we will likely have multiple COVID-19 vaccines authorized, which will not be interchangeable and each with different dosing schedules. This makes ensuring that individuals receive follow-up doses of the correct vaccine more complex. While we do not know when a vaccine will be authorized and what special considerations like cold chain requirements will be for those vaccines, we are pleased to see that planning for these complexities is happening in advance. We hope that Pennsylvania will be a leader in ensuring the State's immunization infrastructure is prepared for a vaccination campaign on a scale not previously seen.

Finally, public confidence in the safety and efficacy of any potential COVID-19 vaccines and treatments are also a concern. Polling numbers related to the number of people who are willing to get a COVID-19 vaccine are lower than expected, with many people citing concerns around the acceleration of testing. The promise of COVID-19 vaccines can only be fully realized when people are willing to get the vaccine and we must work together to communicate the importance of this vaccine, provide fact-based information about the development process and what accelerated actually means, and the rigorous and continuous testing that these products will undergo.

With COVID-19, we must learn from the mistakes of previous outbreaks and bring products across the finish line – if not for this outbreak, then for the next. If resources had been available to advance research on SARS and MERS products over the past decade, we might have been even further along on COVID-19 products today.

The biotechnology industry is committed to bringing safe and effective vaccines, therapeutics, and diagnostics across the finish line for people in Pennsylvania, the United States, and around the world. As this important work continues, remember to wash your hands frequently, wear a mask and social distance, cover your coughs and sneezes, and get your flu shot.

Thank you again for the opportunity to speak to the Committee today. I look forward to your questions.