House Committee on Energy and Commerce
Subcommittee on Oversight and Investigations
Pathway to a Vaccine: Efforts to Develop a Safe, Effective and Accessible COVID-19 Vaccine
July 21, 2020
10:00 AM, Virtual Hearing via Cisco Webex

Purpose
The purpose of this hearing is to examine the current state of COVID-19 vaccine development

Members Present
Chairman DeGette, Ranking member Guthrie, Representatives Pallone, Griffith, Schakowsky, McKinley, Kennedy, Mullin, Ruiz, Walden, Kuster, Burgess, Castor, Duncan, Sarbanes, Brooks, Peters, Upton, Eshoo, Tonko, Carter, O'Halleran

Witnesses
Dr. Mene Pangalos., Executive Vice President, BioPharmaceuticals R&D, AstraZeneca
Dr. Macaya Douoguih., Head of Clinical Development and Medical Affairs, Janssen Vaccines, Johnson & Johnson
Dr. Julie Gerberding., Executive Vice President and Chief Patient Officer, Merck
Dr. Stephen Hoge., President, Moderna
Mr. John Young., Chief Business Officer, Pfizer

Opening Statements
(8:24) Rep. Pallone said that the extent of the COVID-19 crisis cannot be overstated. Sadly, this crisis will only continue unless significant action is taken. The research teams that are working around the clock to develop a COVID-19 vaccine are true American heroes. In addition, the American public deserves to know that a vaccine that hits the market has gone through the appropriate safety channels and tests. The House passed HEROS Act would require the administration to develop a national vaccine distribution plan. This is an essential step in protecting the public's health. Unfortunately, the administration has no plan to do this. This is not new, the administration has failed at every step in responding to this pandemic.

(12:20) Rep. Eshoo said that a potential vaccine offers great hope to Americans. All eyes are on pharmaceutical manufacturers to develop a safe, affordable and accessible vaccine for all Americans.

(14:00) Ranking member Guthrie said that the COVID-19 pandemic has been a tough challenge for the country. However, the progress made on the vaccine front provides hope. Companies are using their own funds at their own risk to develop a COVID-19 vaccine. In addition, the federal government is supporting several initiatives to assist with the development of a vaccine. The testimonies today

will be of vital interest to the American people. In addition, the Trump Administration has made significant progress in assuring that any vaccine developed will go through the appropriate safety protocol. The leading vaccine candidates are required to enroll 30,000 participants in Phase III trials. There will be no shortcuts on speed and efficacy standards. Many manufacturers have already committed to offering affordable doses of any vaccine to at risk populations.

(19:05) Chairman DeGette said that this committee has a long history of supporting the development of vaccines. This committee has a duty to conduct oversight of manufacturers charged with developing critical vaccines. We are 6 months into the public health crisis and infections continue to increase all across the country. It has become clear that the US will not contain this virus unless there is a robust national plan charged by leading public health officials. All across the country, people are having to make difficult decisions based on health and economic concerns. Luckily, it is possible that a COVID-19 vaccine could be available by the end of the year. However, we must remember that much can still go wrong. No timeline is guaranteed. The nation must be prepared not only to develop a vaccine but to deliver a vaccine.

(24:50) Rep. Walden said that the witnesses before the committee today are literally working to save the world. This month, committee Republicans released a report with recommendations on how the nation should prepare to develop and distribute a vaccine to the public. Operation Warp Speed is progressing at an unprecedented pace. This would not have been possible without the investments made by the private sector. Operation Warp Speed is taking financial risks, but not safety risks. It is also critically important for the manufacturers to work to increase vaccine confidence across the nation. This will be increasingly important as influenza season collides with COVID-19.

<u>Testimony</u>

(31:42) Dr. Pangalos said AstraZeneca is seeking to develop a novel vaccine for the prevention of COVID19. AstraZeneca has entered into an exclusive licensing arrangement with the University of Oxford for the global development, production, and supply of the University's potential COVID-19 vaccine candidate, AZD1222. AstraZeneca is proud to confirm that the novel vaccine candidate has begun late-stage clinical trials based on data from pre-clinical studies and Phase I/II clinical trials in over 1,000 healthy volunteers. Second, through scientific expertise in infectious disease and proprietary antibody discovery technology, AstraZeneca has rapidly mobilized research efforts toward discovering novel coronavirus-neutralizing antibodies as a prophylactic and possible treatment approach against COVID-19 disease. The team is currently designing an accelerated development program, working with scientists, governments, multilateral organizations, and manufacturers around the world, with the aim of reaching clinical trials within a matter of weeks. Third, AstraZeneca has initiated new clinical trials to investigate new and existing medicines to see how they could protect organs from damage or suppress the body's overactive immune response in severely ill patients. As the SARS-CoV-2 virus is new, the scientific community is constantly learning about the virus and advancing our understanding on how best to tackle and treat this disease. To support the goal of providing broad and equitable access as quickly as possible, AstraZeneca has entered into agreements with the U.S., and certain other governments and organizations, for supply of hundreds of millions of doses of our vaccine. The cost of the doses of the vaccine under those agreements will provide no profit for AstraZeneca.

(37:00) Dr. Douoguih said working closely with health authorities, Johnson & Johnson (J&J) is pursuing an accelerated approach that allows us to progress our program significantly faster than normal development timelines, which typically takes between five and seven years. J&J has formed an important partnership to assist in R&D funding with the Biomedical Advanced Research and Development Authority (BARDA), part of the U.S. Department of Health and Human Services. Under the current contract with BARDA, Johnson & Johnson will receive approximately $500 million for vaccine research and development. The agreement with BARDA supports the co-funding of vaccine research and development efforts, including preclinical, clinical development, and the production of clinical trial material. As progress is made, J&J will continue to work with the FDA, NIAID, BARDA, DoD and other global authorities to prepare for the Phase 3 trial. The goal is to complete the Phase 3 trial and have results in-hand in early 2021. Based upon the safety, efficacy, and immunogenicity data from 5 this trial and the cumulative data generated from our other trials, J&J would then enter into discussions with the FDA and other health authorities regarding regulatory authorizations for emergency use and licensure. J&J is committed to bringing an affordable COVID-19 vaccine to the public on a not-for-profit basis for emergency pandemic use. Our not-for-profit framework is consistent with established vaccine costing methodologies. The price will be determined based on one cost structure, with all appropriate costs included. J&J is pursuing external validation of its not-for-profit calculation approach and external audit / certification of not-for-profit price. As a result of manufacturing capacity and through new U.S. vaccine manufacturing partnerships, J&J will have the capability to produce over 1 billion vaccine doses in 2021. At least four hundred million of these doses will be manufactured in the United States.

(41:20) Dr. Gerberding said that a long history of developing vital medicines and vaccines has shown Merck that durable scientific solutions take time, expertise, and experience to discover and deliver to the people and communities who so desperately need them. Merck has been leveraging existing partnerships and building new ones within industry and across sectors toward a common goal: ending this pandemic. Today, Merck is advancing three programs – two vaccines and one antiviral medicine – with a strong sense of urgency and the necessary investment of effort and resources. Once a vaccine is developed and approved for use, it will need to be produced at a scale never seen before. Under normal circumstances, manufacturing and distributing a vaccine is exceedingly complex, requiring hundreds of steps and thousands of complex tests, all validated to ensure that every single vial has the identical high quality and safety. When we think about what will be needed to address this pandemic, we are talking about orders of magnitude beyond what the industry is currently doing. Currently, the global vaccine industry is already operating close to full capacity – not only is there not a lot of excess capacity available, but it is not always easily transferable from making one vaccine to another. In order to meet anticipated global demand for SARS-CoV-2 vaccines, the industry will need to approximately double its current manufacturing capacity. At the end of the day, whatever vaccines are finally approved will not be helpful unless people can access them – and are willing to do so. Merck has a long track record of making vaccines and medicines accessible and affordable globally, and Merck will do that for any eventual SARS-CoV-2 vaccines and medicines as well. Merck urges strengthening of the systems that support routine immunization systems and preparing now to adapt them to mobilize for mass vaccination programs once pandemic vaccines are available. Merck stands ready to assist governments, organizations, and companies as we work together to solve this public health crisis.

(47:30) Dr. Hoge said that over the past few months, Moderna has been pleased to collaborate with the U.S. government during the development of our vaccine candidate. This collaboration includes not only working together to test a possible COVID-19 vaccine, but also to build the manufacturing and distribution capacity needed to deliver a safe and effective vaccine to the American people. Moderna is a young, innovative biotechnology company that seeks to improve patients' lives by creating a new generation of transformative medicines based on messenger RNA. Creating a new generation of medicines is a challenging endeavor. Over the past ten years, Moderna raised over $5 billion in funding from their strategic collaborators and investors who recognize the potential of the unique mRNA approach. The story of mRNA-1273 really begins before any of us had ever heard of COVID-19. Since 2015, Moderna has worked to develop mRNA vaccines for coronaviruses, such as the SARS and MERS viruses. That experience, and Moderna's own proprietary technologies developed through years of research, put Moderna in a unique position to respond to the current pandemic. Merck is set to begin a Phase 3 trial this month. 30,000 participants are expected to enroll in a randomized and placebo-controlled study, conducted in collaboration with NIAID. Like the earlier Phase 1 and Phase 2 trials, the Phase 3 is a two-vaccine regimen with the doses delivered 28 days apart. The primary focus of our Phase 3 trial is determining whether mRNA1273 can prevent symptomatic COVID-19 diseases, along with other secondary considerations, such as whether the vaccine can prevent severe COVID-19 disease. Recognizing the need to have a robust manufacturing capability that can be executed at scale quickly, Merck announced a long term agreement with Lonza Ltd., a Swiss-based company with manufacturing sites in the U.S. and elsewhere, which should allow Merck to reach an annual manufacturing capacity of more than 500 million doses for worldwide usage.

(52:10) Mr. Young said Pfizer has made decisions during this pandemic based on three clear priorities. First, ensuring the safety and well-being of colleagues. Second, ensuring the continued supply of medicines and vaccines to patients around the world. Finally, continuing the commitment to collaborate and play a role in discovering breakthrough therapies and vaccines to fight this crisis. On March 13, 2020, Pfizer's Chairman and CEO Albert Bourla announced Pfizer's five-point plan to help scientists and companies across the biotechnology ecosystem bring forward potential therapies and vaccines for COVID-19 and prepare the industry to respond more effectively to future health crises. To date, Pfizer has not accepted any federal government funding for a vaccine development program as it is recognized that Pfizer is uniquely positioned with the scientific expertise and experience, manufacturing scale and financial resources to have the potential to deliver a potential vaccine without funding from the federal government. If clinical trials progress well, and Pfizer receives regulatory approval, Pfizer hopes to be able to manufacture up to 100 million doses by the end of 2020 and potentially more than 1.3 billion doses in 2021 globally, subject to final dose selection from our clinical trial. Pfizer and BioNTech are currently running two trials in parallel with Pfizer leading the U.S. trials and BioNTech leading the EU trials. The clinical trials in the U.S. and EU have been designed to test the same candidates. Pfizer is working closely with regulatory authorities, including the FDA, to accelerate the program while ensuring that safety is the top priority. Pfizer is maintaining the highest standards in the development process. However, in order to reduce the normal time taken for such a development program, Pfizer is doing steps in parallel rather than sequentially, which requires more financial capital to be deployed at risk but is the only way to cut significant time from the development program while maintaining safety as the key priority. In the event that the clinical development program is successful, Pfizer has already begun the work to scale up production for global supply.

Questions and Answers

(57:20) Chairman DeGette asked what the probability is that a vaccine will be developed by the end of the year. **Dr. Pangalos** said that is a difficult question to answer. He is encouraged by the progress that is made. If there is efficacy data, it could be available by the end of the year. **Dr. Hoge** said that he is cautiously optimistic. The data that has been published provides encouragement. More information will be known in the fall. **Mr. Young** said that he is very encouraged by early data coming out of trials. He hopes that phase III trials will begin soon. **Dr. Douoguih** said that she hopes to have doses ready by March 2021. **Dr. Gerberding** said that Merck expects to be in clinical trials very shortly.

(1:03:00) Ranking member Guthrie asked if the unprecedented speed in vaccine development is sacrificing safety and efficacy. **Dr. Pangalos** said safety and efficacy are not being compromised. Regulatory bodies are not lowering their standards for oversight and approval. **Dr. Douoguih** said that safety and efficacy are at the heart of vaccine development. **Dr. Gerberding** said that there is a lot that is unknown about the virus. Thus there are special safety concerns to look out for. Merck will not accelerate their safety and efficacy development standards. **Dr. Hoge** said it is possible to bring forward an effective vaccine in a safe way. **Mr. Young** said that Pfizer believes the vaccine will be safe and effective.

(1:08:20) Rep. Pallone asked what can be done if the FDA approves something that does not have appropriate safety and efficacy standards. **Dr. Pangalos** said that no regulators have indicated that they will lower their standards. All data from clinical trials will be made publically available. The FDA will not be the only regulatory body overseeing the vaccines. **Dr. Douoguih** said that J&J has minimum safety and efficacy standards which would prevent them from bringing a bad drug to market. **Rep. Pallone** asked how adverse events are handled. **Dr. Hoge** said that all of these adverse events are published.

(1:13:40) Rep. Griffith asked if the FDA guidelines are appropriate for developing a safe and effective vaccine. **Mr. Young** said yes. **Rep. Griffith** asked what the FDA is requiring from companies to verify that corners are not being cut. **Dr. Gerberding** said that the FDA is not loosening any standards, so it is essentially business as usual. All data has to pass rigorous standards. **Dr. Pangalos** said that the FDA is working under their normal standards. **Dr. Douoguih** said that the FDA has very stringent approval channels. **Dr. Hoge** said that the FDA is the gold standard for oversight. **Rep. Griffith** asked if the companies have learned any lessons to assist with future vaccine development. **Mr. Young** said that they have learned to leverage older research. Significant progress has also been made surrounding mRNA.

(1:19:25) Rep. Schakowsky asked if a vaccine will be sold at cost and if contract transparency will be provided to verify this. **Dr. Hoge** said they will not sell it at cost. **Dr. Pangalos** said that under their agreement with BARDA they will sell doses to the government at no profit. **Dr. Gerberding** said yes to transparency but no to selling at cost. **Dr. Douoguih** said that it will be sold at cost during the public health emergency. **Rep. Schakowsky** asked if the companies that have received taxpayer dollars have entered into an agreement to assure affordability in pricing of vaccines or treatments. **Dr. Hoge** said they do not have a supply agreement with the US government. **Dr. Pangalos** said that the agreement with BARDA has an agreement to provide 300

million doses at no cost. **Dr. Gerberding** said that Merck has no agreement with BARDA. **Dr. Douoguih** said no. **Rep. Schakowsky** asked if Pfizer will commit to developing an affordable vaccine. **Mr. Young** said that during the time of the pandemic, Pfizer will price the vaccine at an affordable level.

(1:25:35) Rep. McKinley asked if children should go back to school. **Dr. Pangalos** said he will send his children back to school if they open up. **Dr. Hoge** said that he has not made a decision on this topic. **Dr. Gerberding** said there is a great deal of local variability. More science is needed on pediatric transmission. **Rep. McKinley** asked if any of the ingredients in a vaccine formula will come from China. **Mr. Young** said no. **Dr. Pangalos** said for the US supply, all of the development will be done in the US. **Rep. McKinley** asked if companies are insulted by the insinuation that a drug that is not safe may be brought to market. **Dr. Pangalos** said no, it is a reasonable concern.

(1:31:10) Rep. Kennedy asked if there has been any engagement in developing a plan to distribute a vaccine to at risk communities. **Dr. Pangalos** said AstraZeneca has an agreement to provide the US with 300 million doses. These doses should go to at risk communities first. The administration will determine this distribution. **Dr. Douoguih** said that distribution is up to the administration. However, J&J will release distribution recommendations. **Dr. Gerberding** said that currently there is no plan because Merck does not have a product. **Dr. Hoge** said that the administration is in charge of this.

(1:37:05) Rep. Mullin asked if manufacturing capacity will need to be ramped up to meet the vaccine demand. **Mr. Young** said that Pfizer has a dedicated supply chain in the United States. Pfizer believes they will be able to leverage their supply chain to meet the demand. **Dr. Pangalos** said that AstraZeneca has made progress in ramping up the supply chain capacity. **Dr. Hoge** said that Moderna has been working on scaling up their manufacturing capabilities. **Dr. Gerberding** said that Merck is securing the ancillary supplies to produce the necessary doses. **Dr. Douoguih** said J&J is currently increasing the scale of the supply chain. **Rep. Mullin** asked if this manufacturing is happening in China. **All witnesses** said no. **Rep. Mullin** asked if manufactures have plans to expand their manufacturing in the United State. **All witnesses** said yes.

(1:42:15) Rep. Ruiz asked what Merck is doing to ensure that the distributions of vaccines are going to at risk communities. **Dr. Gerberding** said that it is the CDCs responsibility to make decisions about allocation. The National Academy of Medicine should release a plan. **Rep. Ruiz** asked what Pfizer is doing to ensure the distribution of vaccines are going to at risk communities. **Mr. Young** said that he agrees with Dr. Gerberding. The federal government is in charge of this task.

(1:48:05) Rep. Walden asked if all of the vaccine candidates require two doses to be effective. **Mr. Young** said yes. **Dr. Douoguih** said it is too early to tell. **Dr. Gerberding** said that there is hope that a single dose vaccine could be manufactured. **Rep. Walden** asked if the federal government is assisting manufacturers is acquiring ancillary supplies. **Dr. Pangalos** said the federal government has provided adequate assistance. **Dr. Gerberding** said Merck has acquired the necessary ancillary supplies. **Dr. Douoguih** said J&J would appreciate support if it is available. **Mr. Young** said Pfizer has all the necessary materials. **Dr. Hoge** said all of the necessary supplies

have either been secured or at least identified. **Rep. Walden** asked if manufacturers are comfortable with the FDA safety guidance. **Mr. Young** said yes.

(1:53:30) Rep. Kuster asked if it is true that financial risks are being taken as opposed to safety risks. **Dr. Pangalos** said yes. **Rep. Kuster** asked how much time is being saved. **Dr. Pangalos** said that is hard to answer, but a lot. **Rep. Kuster** asked if the 300 million doses promised to the US by AstraZeneca is a part of the 1 billion doses that AstraZeneca anticipates producing. **Dr. Pangalos** said no, those are separate.

(1:58:30) Rep. Burgess asked if there are additional steps the Administration should take to encourage people to get the vaccine once it is available. **Dr. Pangalos** said the FDA has already committed to being transparent with the approval process. The CDC should also develop materials to encourage the use of vaccines. **Dr. Douoguih** said that the outreach and distribution of educational materials needs to start now. **Dr. Gerberding** said that it is not enough to just use a government spokesperson. Medical leaders at the community level should lead this charge. **Rep. Burgess** asked if the federal government has been a helpful partner. **All Witnesses** said yes.

(2:04:20) Rep. Castor asked if the CDC has been critical in vaccine distribution efforts. **Dr. Gerberding** said that the CDC is essential in distributing the vaccine equitably. The CDC needs to be armed with the appropriate tools to deliver on this. **Rep. Castor** asked if operation warp speed leadership has engaged in distribution discussion. **Dr. Hoge** said yes.

(2:09:45) Rep. Duncan asked how a vaccine can be developed for the most vulnerable population, which is the 60+ population. **Dr. Gerberding** said that there needs to be more information on what happens when at risk populations take the vaccine. **Dr. Pangalos** said they are including this population in their trials. **Dr. Douoguih** said at these populations need to be included in the trials. **Dr. Hoge** said that individuals over the age of 65 have specifically been included in trials.

(2:16:00) Rep. Sarbanes asked how vaccines are able to be developed faster without sacrificing safety. **Dr. Gerberding** said that the biggest time saver is investing in manufacturing capacity. That usually does not happen until it is proven that the vaccine works. In addition, collaborative efforts with industry leaders made the process more efficient. **Rep. Sarbanes** asked if J&J and Astra Zeneca will commit to increasing manufacturing capacity regardless of whether their individual vaccine is effective. **Dr. Douoguih** said that is something to consider when they learn more about their vaccine. **Dr. Pangalos** said yes.

(2:21:45) Rep. Brooks asked what manufacturers are doing to educate the American people surrounding vaccine hesitancy. **Dr. Gerberding** said that it has to do with grass roots efforts. Merck is supporting local NGOs in bringing information to people. **Dr. Pangalos** said they are working to ensure that all data coming from trials will be made available to the public. **Dr. Douoguih** said investments in education need to start now. At risk communities will need prolonged engagement. **Dr. Hoge** said that data is being released publically. Transparency is key. **Mr. Young** said that clinical data is being transparently published.

(2:27:30) Rep. Peters asked if patients will be able to get a COVID-19 vaccine and flu vaccine at the same time. **Dr. Pangalos** said this will be looked at in future trials. It is unknown at this time. **Rep. Peters** asked if young children are included in a phase II trial. **Dr. Pangalos** said there is a pediatric trial planned. **Dr. Douoguih** said that J&J plans to conduct a pediatric trial. **Rep. Peters** asked how the US should strategize to ensure that other pharmaceuticals remain available in the US. **Mr. Young** said that a number of medicines have seen a surge in manufacturing in the US. It is critical to ensure the supply chain in the US is healthy and robust. **Dr. Douoguih** said she is not an expert in this area.

(2:33:00) Rep. Upton asked if Mr. Young could walk through the manufacturing process. **Mr. Young** said that the supply chain is unique for an mRNA vaccine. One site will be responsible for developing a DNA template. One site will be responsible for creating mRNA from this DNA. Then the final site will put this product into vials and distribute it. **Rep. Upton** asked when is the earliest that an Emergency Use Authorization may be used. **Mr. Young** said if all goes well the data will be given to the FDA in October. From there it will be up to the FDA.

(2:39:30) Rep. Eshoo asked how Astra Zeneca plans to meet the standard of both the British government and FDA. **Dr. Pangalos** said that as a multinational company this is a challenge they face regularly. The product that will be available in the US will be approved by the FDA. **Rep. Eshoo** asked how manufacturers are preparing to handle the fact that doses may be different for different populations. **Dr. Pangalos** said the first step is ensuring efficacy. Beyond that more data will be needed. **Rep. Eshoo** asked why Pfizer chose not to accept any government money. **Mr. Young** said that Pfizer decided not to take any money so they can operate on their own timeline.

(2:45:10) Rep. Tonko asked what steps are being taken to ensure that enough ancillary supplies are available to equitably distribute a vaccine. **Mr. Young** said that Pfizer made early investments in securing these supplies. **Rep. Tonko** asked if Astra Zeneca is coordinating with other companies to procure vital supplies. **Dr. Pangalos** said since companies are using different technologies they are not competing for the same materials. Early investments have also been made to secure supplies. **Rep. Tonko** asked what guidance has Moderna received from the federal government related to the production of ancillary supplies. **Dr. Hoge** said that they have worked with BARDA directly in providing transparency related to the purchasing of ancillary supplies.

(2:50:40) Rep. Carter asked how much of the material used in an individual vaccine comes from overseas. **Dr. Pangalos** said that 100% of the ingredients come from the United States. **Dr. Douoguih** said that 99% of the materials come from the US or Europe. **Dr. Gerberding** said that she will have to submit an answer for the record. **Dr. Hoge** said that the vaccine will be made entirely in the United States. **Mr. Young** said that the raw materials are procured and manufactured in the United States. **Rep. Carter** asked if the FDAs guidelines are fair and achievable. **Mr. Young** said yes.

(2:56:30) Rep. O'Halleran asked what is being done to ensure that there is broad representation among participants in clinical trials. **Dr. Pangalos** said that studies are being run all over the world to ensure equitable representation. Within the United States, diverse communities are being

recruited to participate in trials. **Dr. Douoguih** said that J&J is still in the planning phase, however they plan to launch a community outreach program to recruit a diverse testing pool.

DM_HC 1256836-1.PG0610.0010