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Realistic Planning Timeline for Return to Normality: When will vaccines and drugs get here?

Sorting out the ongoing tidal wave of reports concerning drug and vaccine trials with respect to Covid-19 is somewhat confusing, and the reporting comes with very little linkage to what the realistic expectations for the average business trying to open, stay open, and in all cases keeping employees and customers safe. This client alert seeks to add a little clarity to the potential timelines.

What is going on now? With respect to ***vaccines*** that might be available for US use, the next six months are going to have news about large scale trials of vaccine candidate efficacy across different doses and age cohorts of patients. There are six big trials at various stages of progress headed to final testing and approval ("Phase 3") in the US right now: Moderna Phase 3 is about to be underway; next month Oxford-AstraZeneca will start a large late phase trial; in September, Johnson & Johnson will start; in October GSK-Sanofi will start; Pfizer trials are scheduled to commence soon; and Merck trials should be underway by year's end.

For each of the three phases of trials for each of the projects, the media provides three levels of reporting for each trial segment. First, we get chatter from a CEO or Chief Medical Officer, second, SEC reports filed by the company are reported on, and lastly, headlines address peer reviewed scientific articles published in serious medical journals.

With six major trials in coming months (and over 18 other trials internationally, and an additional 142 pre-clinical candidates in development worldwide) and three levels of reporting on each step of each trial we have been and will be inundated with reports. Unfortunately, headlines from the first two sets of reports often cherry-pick a particular aspect of the results, or focus on a subset of data, and often don't offer the full picture. We just need to realize that reporters jump all over any little snippet and you get headlines all over the place that are often based on something like ten patients. Our take on all this is to place less weight on what you hear or read unless the report is citing as source material a peer reviewed scientific article from a top-level medical journal. Look for reporting citing Lancet, New England Journal of Medicine, Science, and the Journal of the American Medical Association, among others. Then pay close attention as to what that article says!

Where are we headed in terms of getting the vaccine deployed? Amazingly, with all of the fear of a potential novel virus that has driven medical research since the SARS outbreak in 2002, the architecture of a vaccine was already in place before Covid-19 showed up. Thus the big pharmaceutical companies had a big head start on developing a vaccine, and we are literally years ahead of where we could otherwise reasonably expect to be in terms of producing an effective vaccine. Most experts are guardedly optimistic that at least one of the six big projects will produce an effective vaccine, and maybe several of them will.

The task ahead nevertheless remains daunting. Getting the right recipe in such a short time would be a near miracle, but the ramping up to cook the vaccines is an entirely different, complex and lengthy process. Worldwide, vaccines need to be manufactured for 7 billion people, and as it is likely it will be a two-dose vaccine, thus potentially 14 billion unit doses will be required, per year (it is also likely to be like a flu shot that you have to get annually due to virus mutations). That level of industrial pharmaceutical production is going to take some time to put in place, and the big projects have been working furiously to put the manufacturing capacity online now, even as the final recipes are still to be determined.

As a result, several of the companies are contracting for manufacturing capacity in places outside of Europe and the US. For instance, the prime subcontractors in the Oxford-AstraZeneca project are in Italy and India. With the need so great in both Europe and India, much of the 1.2 billion doses to be produced in this project will likely stay in Europe and India. The US will get some of this production, but maybe only enough to cover 50 million people. We will be more reliant on the Moderna and Johnson & Johnson manufacturing supply chains for early vaccines, and later, on Pfizer, Sanofi, and Merck. (And regardless of who wins the election we should anticipate the federal government will want to materially intervene in the distribution process, although the exact plans have not been disclosed by either camp at this point.)

For planning purposes, the likely emergence of a vaccine that is widely distributed in the US is late Spring 2021, or

later. Thus, whatever Covid-19 precautions and safety orders are mandated by the various levels of government will likely remain in effect until the vaccine is widely available.

Where are we on medications to treat the illness? Aside from a vaccine to prevent one from becoming ill, there is a great deal of research and development for drugs that can curtail the illness, or at least limit its severity. One drug, Gilead's Remdesivir, has been deployed sparingly since April, and has had some beneficial effect in limiting severity of illness. In the middle of July, a small English company, Synairgen, announced that its new drug SNG001, based on Interferon proteins, had a very significant effect on hospitalized patients, preventing 79% of hospitalized patients from worsening to the point of needing a ventilator in a random blind trial. Also worthy of mention is Regeneron's 'designer' antibody therapeutic, REGN-COV2, comprising of two antibodies selected from their extensive library that has shown promise in curtailing progress of the disease in early testing. REGN-COV2 is headed for Phase 3 trials both as a medication to curtail illness and as a potential short term prophylactic against contracting the illness (through a direct presence of injected antibodies, which is a different mechanism than the vaccines, which are developed to spur the body's own immune response including neutralizing antibodies and T-cell response.) Merck is reportedly in early development stages of an oral antiviral.

If one or more of the therapeutics is shown to have a substantial impact on curtailing illness or limiting severity of illness, deployment of such a drug would likely accelerate and enhance the ability of businesses to open again to customers and employees.

Current mask wearing and handwashing, combined with rigorous testing, contact tracing, and isolation programs have worked; just not in the US where adherence to common sense measures has become a political issue. The proof is Hong Kong. With a dense population similar to NYC, Hong Kong has had 7 Covid deaths, while NYC has had 17,000.

So wear your mask and wash your hands, and keep watching for updates on vaccines and therapeutics!

For more information about regulatory guidance on COVID-19 related FDA requirements and permissible uses and disclosures of protected health information please contact our firm.

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