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Establishing Approval Guidelines for COVID-19 Vaccines

(Sources: An article by Ben Westcott for CNN Health and an article by Paige Minemyer for FierceHealthcare)

Drugmakers from China and the U.S. are among the front-runners in COVID-19 vaccine development, and how regulators in those two countries decide to deem a product approvable could set the gold standard for any vaccines to follow. Weeks after the FDA rolled out its standards for green-lighting COVID-19 vaccines, its Chinese counterpart Friday released guidance for China with some similar criteria.

Specifically, China's National Medical Products Administration (NMPA) will require that a COVID-19 shot demonstrate in a clinical trial that it's at least 50% more effective at fending off the disease than placebo. The efficacy endpoint—and the statistical success criteria included in China's requirements—match the FDA's guidelines which were released in June. But the Chinese authority went one step further in that department, recommending that a shot's efficacy "preferrably" reach 70%. It is also asking that a shot protect humans for at least six months, though it said it prefers to see one year of protection.

In contrast, the FDA did not specify how long it expects a vaccine's defense to last, only saying that it wants to see safety assessments in all study participants for at least six months after completion of vaccinations

Both agencies said they would require post-marketing monitoring for long-term safety and efficacy data. The FDA has recently come under fire over its hasty emergency use authorizations for some treatments and diagnostic tests. These include the now-rescinded emergency use approval for anti-malarial drug chloroquine and its derivative hydroxychloroquine, both which came right after President Donald Trump advocated it as a potential "game changer." The drug was later shown to be ineffective at helping COVID-19 patients recover or prevention of the disease.

In its COVID-19 vaccine guidance, the FDA again left open the possibility that it would grant emergency use authorization for a vaccine before the completion of large phase 3 efficacy trials. Without giving specifics on that pathway, the agency said such decisions will be made on a case-by-case basis considering "the totality of the available scientific evidence relevant to the product." China's NMPA, in its version, also allows for conditional approval if an interim analysis finds "clear and acceptable" efficacy from an experimental shot before final readouts.

Given the FDA's history with hydroxychloroquine, in light of allegations of Russia's rushed approval for a coronavirus vaccine (without data from large-scale efficacy trials) have drawn concerns that the U.S. agency might once again yield to political pressure on its review of a vaccine. FDA Commissioner Stephen Hahn has said his agency will not "cut corners" in approving a shot in the U.S., despite the administration's Operation Warp Speed vaccine acceleration program.

Right now, AstraZeneca's University of Oxford-partnered

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- **Profarma Group** announced their financial results for Q2 2020 with consolidated gross revenue of R$1.4 billion (US$251.1 million), an increase of 9.5% year-over-year. Its distribution unit gross revenue grew 11.6% to R$1.4 billion (US$251.1 million) while gross revenue for its retail division was 24.2% lower due to COVID-related store closures.
- McKesson Corporation will expand its existing partnership with the Centers for Disease Control (CDC) to support the U.S. government's Operation Warp Speed as a centralized distributor of future COVID-19 vaccines and ancillary supplies needed to administer vaccinations. Vaccines and related supplies will be delivered to point-of-care sites across the country at the U.S. government's direction. "McKesson is committed to supporting public health in the U.S. and around the world," said Brian Tyler, CEO of McKesson. "Since the onset of the pandemic, McKesson has leveraged our deep expertise to help maintain the integrity of the healthcare supply chain, source and distribute personal protective equipment to frontline workers and stand up COVID-19 testing at Health Mart pharmacies, many in underserved communities."
- French pharma manufacturer **Sanofi** will acquire **Principia Biopharma** in a cash deal valued at US$3.7 billion. Principia's proprietary R&D platform for immune-related diseases will help Sanofi to build a more focused pipeline. Principia's platform so far has produced three promising drug candidates, one of which has emerged as a brain-penetrant BTK inhibitor in Phase III

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How COVID-19 is Changing the Way We Will Educate Our Medical Professionals

(Source: An article by Paige Minemyer for FiercePharma)

As the wave of closures swept across the U.S. due to the COVID-19 pandemic this spring, educators in the medical community are among those scrambling to totally rethink how school will work. That means rethinking going digital in an unprecedented way—both in terms of classes and in terms of the type of clinical care exposure necessary for student learning.

With COVID-19 showing no signs of letting up soon, leaders at medical schools are adapting their plans for education in the fall to meet the new demands of the pandemic. The delivery of medical education will use pre-recorded classes while lecturers connected with students participate in active discussions through online platforms like Zoom. It's the new normal, but it is going to need to be tailored to fit medical education curriculum and other health professions' education curricula to train students for that new normal," Stephen Spann, M.D., founding dean of the College of Medicine and vice president for medical affairs at the University of Houston (UH) said. At UH, Spann and his team have welcomed the university's first class of medical students in

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COVID-19 (cont.)...

July, saying they tried to strike a balance between the need for in-person clinical education with social distancing and the growing use of telehealth.

The challenges facing UH are emblematic of the same hurdles that medical schools across the country are navigating. Alison Whelan, M.D., chief medical education officer at the Association of American Medical Colleges, said that the pandemic has forced medical colleges to get back to basics and really glean out the key competencies that students must learn in reshaping the education experience. "It's taken a lot of sort of creative jimmying," she said, balancing Zoom versus in-room learning. Medical schools were not alone in moving to remote learning in the spring as the novel coronavirus first began to spread in the United States. As schools move into the fall, coronavirus continues to be a difficult challenge. Medical students in their first two years are largely engaged in more classroom-based activities so going online was a logical transition. However, students miss something in being able to get together for a conversation so looking ahead to the fall, greater emphasis will be placed on active learning opportunities.

The bigger challenge is effectively providing the hands-on clinical care for third- and fourth-year medical students, who engage more directly with patients. Students were pulled out of clinical sites in the spring, a decision was very difficult for medical schools. There are ways to conduct such training remotely—such as talk-through sessions or simulations—but it is far less effective than conducting a physical exam in-person. Schools are providing additional coaching and advising to students at all levels to help them through the shift to virtual education.

David Muller, M.D., dean of medical education at the Icahn School of Medicine at Mount Sinai, explained that Mount Sinai students have continued to conduct clinical education in-person for its third and fourth year students, as there are few viable alternatives. He said that these students must realize that COVID-19 will be something they need to prepare for as physicians themselves. "COVID is here to stay," Muller said. "Even once we're all miraculously vaccinated, this is going to become part of their clinical practice." The telehealth transition will take on an outsized role in navigating the pandemic and will also become a focal point in medical education.

At UH, for example, nursing students that predated its first class of medical students were shadowing nurses on virtual visits as part of their clinical training, said Tray Cockerell, director of strategic relationships at Humana. Humana and UH co-founded the medical school together, and it is under the UH's Humana Integrated Health Systems Science Institute. Cockerell said that nursing students would join Humana nurses on in-home visits, so transitioning that experience to the virtual space was the logical step. He said there is an interest from students in learning more about this kind of care. "I think that's something that is emerging and has been certainly an interest of all the clinical colleges to learn more about how we bring telehealth into education and leverage opportunities like this," he said.

Even as COVID-19 subsides, the telehealth revolution will continue. Interest in telehealth extends to the new class of physician trainees as well. Much of their educational journey has been influenced by the digital demands of COVID-19, starting with their admission interviews in the beginning of the year. For the 170 applicants who made it to the interview stage, only 48 in-person interviews were conducted before the pandemic forced UH to take the interviews virtual. And, as more practicing physicians expand their use of telehealth, it will become a critical piece of curricula moving forward.

Vaccine Approval (cont.)...

adenovirus-based candidate, AZD1222, as well as mRNA products by Moderna and a partnership between Pfizer and BioNTech, are in late-stage development and could be among the first to be approved in the U.S. In China, an adenovirus-based program by local vaccine player, CanSino Biologics, is already allowed for military use. The company has secured a deal to conduct a phase 3 trial in Saudi Arabia, and it just began late-stage testing in Russia, Reuters reported, citing a Russian registry.

China's state-owned Sinopharm has launched a phase 3 trial of an inactivated vaccine in the United Arab Emirates. Fellow Chinese company Sinovac picked Brazil and Indonesia as its phase 3 testing sites for its inactivated vaccine.

In Brief (cont.)...

trials for multiple sclerosis.

- **Takeda** is in the final stage of talks to sell its Japanese consumer healthcare business to U.S. private equity firm **Blackstone Group** for an estimated US$2.8 billion. The planned sale comes as part of Takeda's efforts to liquidate US$10 billion in non-core assets following its Shire takeover. Takeda continues to narrow its focus on prescription drugs in core therapeutic fields, including oncology and GI.
- The **U.S. Food and Drug Administration (FDA)** has issued an emergency authorization for convalescent plasma treatment for COVID-19 patients. Under an expanded access program, approximately 70,000 patients have received the plasma treatment. The U.S. government's Biomedical Advanced Research and Development Authority (BARDA) funded the early access program, and the Mayo Clinic served as the lead healthcare institution. Convalescent plasma treatment has shown a 35% improvement in survival rates for COVID patients.
- **Johnson & Johnson** has reached a supply agreement with the European Union for 200 million doses of its coronavirus vaccine candidate, pending successful testing and approval. This follows J&J's US$1 billion deal for 100 million doses with the U.S. government's *Operation Warp Speed*. Financial terms of the EU deal were not disclosed. Meanwhile the EU has been negotiating with other pharma giants, including Sanofi and GlaxoSmithKline.
- The Japanese government is considering participation in COVAX, the global pact for the joint procurement of COVID-19 vaccines. Senior Health Vice Minister Hisashi Inatsu stated "We'll discuss what to do with (the COVAX facility) while keeping a close eye on the progress of vaccine development in Japan and negotiations with overseas companies." Japan has already entered into deals with Pfizer and AstraZeneca to receive a supply of 120 million doses of their vaccines if successful.
- **Abbott Lab's** new rapid COVID test has received **U.S. FDA** approval. The antigen test, which is the size of a credit card, can be used at home with a 15- minute results turnaround and has a 97% accuracy rate. The test is anticipated to revolutionize COVID testing.

(Sources: Company Press Releases, FiercePharma, Fox Business, Pharma Japan and Scrip)