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ReachMD
www.reachmd.com
info@reachmd.com
(866) 423-7849

COVID-19 Vaccines & Considerations for Approval

Announcer:
You're listening to Perspectives with the AMA on ReachMD, produced in partnership with the American Medical Association.

Here's your host, Dr. Charles Turck.

Dr. Turck:
The recent approval of the first COVID-19 vaccine marked the beginning of one of the largest mass vaccination efforts in American history. And to learn more about it, we'll be diving into the approved and potential COVID-19 vaccines, as well as the review processes, followed by the FDA for authorization and recommendations for use by the CDC. Welcome to Perspectives with the AMA on ReachMD. I'm Dr. Charles Turck, and joining me today is Dr. Mira Irons and Ms. Shannon Curtis. Dr. Irons is the Chief Health and Science Officer of the American Medical Association. Dr. Irons, it's great to have you with us.

Dr. Irons:
Great. It's great to be here. Thanks for having us.

Dr. Turck:
Also joining us today is Shannon Curtis, who's the Assistant Director of Federal Affairs at the American Medical Association. Ms. Curtis, thanks for joining us.

Ms. Curtis:
Not a problem, happy to join you.

Dr. Turck:
So, let's begin with the FDA's process for reviewing the COVID-19 vaccine candidates. Would you give us a brief overview of that, Ms. Curtis?

Ms. Curtis:
Sure. I think a lot of folks have probably heard at this point, that there was a little bit of a new and different process, that the FDA used, and is going to be using, to review COVID-19 vaccines than the traditional review process for other medical products, like drugs and devices that folks, typically are – are used to coming out of the FDA. And that process is called the Emergency Use Authorization process. It's something that's utilized during public health emergencies, to get products, to patients and to the general public quicker than the normal, somewhat laborious, process of FDA review. Basically what happens is the FDA gets a dossier of safety and efficacy data from a manufacturer that comes out of their Phase 3 critical trials. They review that data. FDA decides if there's any deficiencies, or if that data looks good, and then they actually send it on to the Vaccines and Related Biological Products Advisory Committee – a committee of outside, non-governmental experts that also take a look at that safety and efficacy data, and then take a vote to suggest whether they think FDA should approve these products or not. So, the process seems a little quick, but mostly all they've done is cut out a lot of paperwork and kind of bureaucratic process. Full review has happened at FDA. Advisory Committee review will be a full and transparent process there, and then hopefully, if everything's satisfactory the FDA will go ahead and issue an authorization for those vaccines after all that review work is done. So, it's not quite the same as the typical biologics license application that a vaccine would usually get but in a lot of ways is very, very similar and we expect most of these vaccines will come back to do the full, BLA, application and approval process within a couple months after their EUA is issued.

Dr. Turck:
And if we turn our attention to the CDC, Dr. Irons, how have they reviewed COVID-19 vaccine candidates?

Dr. Irons:
So, thanks for the question. So, the FDA authorization is the first step in the process, but the next step then goes to the CDC, and specifically, the Advisory Committee on Immunization Practices, which is – everyone calls ACIP –to review the same information. They review the sponsor information, they go through their evidentiary claim for the framework and review, and then they make specific recommendations on use of the vaccine in the United States. And that's the standard that physicians look to, in terms of the ACIP's recommendation and specifically how the vaccine is – the vaccine will be used. And so, their recommendations are more clinically focused, so a lot of it has to do with the logistics of how the vaccines are administered – two doses, or one dose –whether you can administer it with other vaccines, they also specifically look at, special populations – pregnant women, women who are breastfeeding, immunocompromised, whether you can give the vaccine to people who have had COVID or had antibody, treatment. And also, information that physicians should be discussing with the patients, when they're getting the vaccinations, like, whether there are any, side effects, that people should watch out for. That's the second step of the process, and then ACIP's recommendation goes to the director of the CDC, to make that formal recommendation.

Dr. Turck:
Now with that background in mind, Ms. Curtis, would you tell us which COVID-19 vaccine candidates have been evaluated, and which ones are currently going through the process?

Ms. Curtis:
So, the first one that, has been fully vetted and evaluated, by the FDA and has gone through the CDC process as well is the vaccine that was a collaboration between Pfizer and BioNTech. That received the Emergency Use Authorization, last Friday, and went through the CDC process shortly after that. The first vaccinations went into arms, I believe on Monday. So that is out, available, and is being utilized as we speak. Moderna also, is going through the pipeline right now. The Advisory Committee at the FDA actually meets to review that evidence and have discussion tomorrow, and we expect an Emergency Use Authorization will come shortly after that, maybe this Friday, maybe this weekend. But we should see that very quickly. There's a few other vaccines in the pipeline that we're expecting to see probably apply for their Emergency Use Authorizations within the next couple of months, but they aren't officially in the system. Those will likely be candidates from, AstraZeneca and Oxford – that collaboration – and possible a candidate from Johnson & Johnson as well. Not sure on the exact timing there but, maybe in late January or February, we'll see some movement towards an EUA there as well. A number of others, in the pipeline, probably over the next several months we'll see coming up as well.

Dr. Turck:
For those just tuning in, you're listening to Perspectives with the AMA on ReachMD. I'm Dr. Charles Turck, and with me here to talk about the approved and potential COVID-19 vaccines is Dr. Mira Irons and Ms. Shannon Curtis, from the American Medical Association. Now, Dr. Irons, considering the deluge of information coming at physicians about COVID-19 vaccines, where should they turn to get reliable and educational information?

Dr. Irons:
Well, you're absolutely right about the deluge of information. It's coming fast and furious and physicians are also seeing more and more patients every day. So, what we have done at the AMA, is created a COVID Resource Center. We did that, going back to February, and it's on the AMA public website, where we post all current information about the pandemic, but also any treatment information, CDC guidelines or information about vaccines. Given the focus on vaccines over the last few weeks, we've actually created a page on that website that is really devoted to vaccines. That page includes, FAQs that physicians would ask information from the CDC, the MMWR that went along with the CDC's recommendations last week, and also FDA information. And the most recent post on that was a tool kit from the CDC, that could help guide physicians in talking to their patients about the vaccines.

Dr. Turck:
And if we consider our patients, Dr. Irons, many may be hesitant to receive vaccines, so what questions do you think we're going to hear from patients about the new COVID-19 vaccine, and how would you plan on addressing their concerns?

Dr. Irons:
So, you're absolutely right. I think that, you know, we're seeing a higher degree of vaccine hesitancy in the country than we have previously, and, not just patients, but physicians and health care providers have a lot of questions. And so on that same site, we actually have created FAQs for patients, and, they're really grouped in specific subject areas. The vaccine safety and the speed of vaccine development, natural immunity versus the immunity from vaccine side effects, a specific, section on mRNA vaccines and, vaccine administration – just the logistics of a vaccine administration and also some information on herd immunity – to try to answer their questions about the process, and, also about vaccine safety.

Dr. Turck:

Finally, Dr. Irons, even with the COVID-19 vaccine, we still have to maintain preventive measures, like social distancing and mask-wearing, especially in light of the coming holiday season. So, what advice do you have to help patients stay safe and healthy during the holiday season and beyond? And does the AMA have any related resources available for patients and physicians?

Dr. Irons:
So, I think we'll all agree that this holiday season is like no other that we've experienced before. And even though we're seeing light at the end of the tunnel, with the vaccine, the vaccines being introduced, we're still going to have to continue the public health measures of wearing a mask, social distancing, and washing your hands, until we can get enough of the population vaccinated, to start to round the corner on this pandemic. And obviously, things like that become more difficult during the holidays. You know, the recommendation is that people should, celebrate with their immediate families – those within their households, this year, which is difficult for a lot of us to do. But it's really the safest, for most people, however, if you need to expand outside of, your immediate household, either kids coming home from school, or other family members, you need to think about some things, to try to protect yourselves and others. So, first of all, if you've been exposed to anyone with COVID, if you have COVID, or if you're symptomatic do not attend any gatherings. And certainly do not attend any gatherings with people who are at increased risk of severe disease. When you're starting to think about, attending a gathering, or expanding individuals into your bubble, there are some considerations to think about: the community levels of spread of COVID-19, where you are and where they came from, exposure during travel if you have to travel, the duration of time that you'll be together, the number of people involved, and also the behavior of the people that are getting together, both before the gathering and also after a gathering. So that can kinda help mitigate some of the increased risk that you might be exposed to.

Dr. Turck:
And, Ms. Curtis, do you have any thoughts to add about how patients may stay safe and healthy during the holiday season and beyond?

Ms. Curtis:
Sure. You know, I think it's just really important for all of us to keep in mind that as difficult as all of this has been, you know, put far and large, it would appear from the data that we're seeing, you know, most people are getting COVID in situations when they are gathering with their family and friends. We know it's hard to stay away from those folks, and to limit the gatherings, with your family and your friends over the holidays, but that really is the biggest thing that we can do to keep people safe, to keep our families, our loved ones, our friends and ourselves safe, as we come into this probably difficult next couple of months, when case numbers are gonna be high, we're all gonna be stuck inside – things like that. You know, as difficult as this is, we do understand that some people probably are considering maybe expanding their bubble or maybe are going to plan to see some limited family members over the holidays and over this winter. And I think just one thing to keep in mind, that is, if that is something that you are choosing to do, one of the most important things that you can do to ensure that you're not going to transmit virus is to think about isolating or quarantining prior to opening up your bubble, prior to visiting with any friends, prior to visiting any family. If you can just stay home for that seven days, ten days, before you're gonna see anybody else that will give you the best chance to ensure that you're not going to get anybody else sick. So, something to keep in mind, as hard and as tough as this all has been, I think everybody should be hopeful that we do have a light at the end of the tunnel. We have some really excellent-looking vaccine candidates coming through the pipeline, or are already out, and hopefully over the next couple months, we'll be in a much better place, so, you know, take care of yourselves now, but keep the faith, keep the hope. There is light at the end of the tunnel, and hopefully this time next year we'll be moving on and be into a much better place.

Dr. Turck:
Well, with that, I wanna thanks my guests, Dr. Mira Irons and Ms. Shannon Curtis for speaking to us today about the latest COVID-19 vaccine developments. It was great connecting with you both today.

Dr. Irons:
Great, thanks very much.

Ms. Curtis:
Thank you.

Announcer:
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