Podcast Transcript

Vaccine Administration

Date: December 21, 2020

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Run Time: 13:12

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Kattman: We have watched a vaccine come to market quicker than at any other point in history. This complex process is riddled with questions. Who can give the vaccinations? What does it take to store it? What went into the approval process? How does a vaccine get authorized? I'm Amy Kattman, and you're listening to BakerHosts.

On today's episode, we explore the complex life cycle of the COVID-19 vaccine and some common questions surrounding the authorization, distribution and administration of the vaccine. Lee Rosebush is the leader of the Pharmacy and Reimbursement Team and co-leader of the FDA Products Promotion and Defense Team at Baker Hostetler. He is a registered pharmacist with first hand experience in the pharmaceutical industry. He is also chairman and general counsel at the Outsourcing Facility Association. Welcome to the show, Lee.

Rosebush: Thanks. Thanks for having me, thank you for the opportunity. Great to be here.

Kattman: To begin, could you tell us what is the difference between FDA approval and emergency use authorization?

Rosebush: Sure. At the highest level, ultimately what it comes down to is the differences in the standards that are used by the agency for review. Specifically, for an EUA you actually have a little bit of a lower standard than you do under the standard approval processes by the agency. For example, when it comes to an EUA, which is what we have for the current vaccines, what you need to have is evidence of some sort of effectiveness. In other words, you don't have to prove

effectiveness, you just need to have some sort of evidence of effectiveness. Whereas, when it comes to an approval process, you actually have the risk benefit analysis where you actually have the burden to show that the benefit is better than, or worth, the risk in the situation with the specific product that we're talking about.

And that makes a difference when it comes to our current situation with the vaccine. Specifically, for example, if the pandemic were to end currently today or tomorrow, or we started to see that the differences that we were making were actually different in the situation for our products, and the agency, or in this situation, HHS, was able to remove the emergency pandemic declaration, then the EUA actually would be removed, and that company in the situation, if they wanted to continue to market that product, they'd have to go get FDA approval. So there is a difference between the two, and ultimately I wouldn't be surprised if each of the FDA sponsored manufacturers who have actually received an authorization for their vaccine, so Pfizer, Moderna, etc., moving forward, end up ultimately receiving FDA approvals after submission of additional data.

Kattman: Lee, how does the FDA review a vaccine?

Rosebush: So, the agency really uses two things. They really use clinical trials, which can be both a bench trial and a human trial, and then they use an advisory committee to help review those. In this situation, if we really look at what Pfizer went through, we've heard of the phase 1, phase 2 and phase 3 clinical trials. They used it in humans. In fact, it's been used in almost 70,000 people now across the world. And, we had an advisory committee. That was the big announcement last weekend, right, is that the FDA advisory committee had moved forward with their thoughts on the allowing of the authorization of this. Again, that's a little bit different than the approval process, where we typically see a bigger patient population and we have that approval standard, which is really looking at the more of the risk benefit, right, so is the benefit of using this vaccine, for example, outweighing the risks, where when we're looking at the authorization, that's different. It's really looking at whether or not there is any hint of effectiveness, right, and no lack of alternative.

Kattman: Now that we've talked about how to review a vaccine, who is eligible to receive the vaccine?

Rosebush: You know, that's the million dollar question. And the interesting thing, you know, the interesting thing here in this situation is that the federal government really doesn't have the authorization to say, you have to use it in "x" population, whether they be healthcare people, right, or providers, whether they be the long-term care population or the elderly. They issue recommendations. The million dollar question becomes is, what are the states going to do about this? And so now, what a lot of healthcare providers, and employers, and employees, and even the general population, are doing is, they're sort of quote-unquote lobbying, or they're reaching out to those state health departments to say, what's the next step? And if you really want dig into the weeds to figure this one out as to where the states are going to authorize, you have to look at their health plans, right?

Each state was required to issue a plan as to what they're going to do and how they're going to move forward with this vaccination. And so, the interesting thing is, is some states have said, look, we're going to use in healthcare providers and the long-term care, which is what the FDA and some of the other federal government agencies recommended. Some have said, we're going to use it in the broader population. And it's really up to the states to decide as to the right way to move forward with that plan.

Kattman: And where is the vaccine available?

Rosebush: Again that's, it's interesting, right? That's what's so unique in this situation, is that it's up to the states. So, the states in this situation could move forward with giving it to a pharmacy, like Walgreens or CVS, for example. They could send it over to a hospital. They could send it to individual nurses, where the nurses themselves could go out to residencies like long-term care facilities and actually vaccinate or inject. And so again, it's up to the individual states, and I would say, look, if I'm a, you're an individual who's very interested in receiving this or you're an employer who's wanting to make sure your employees have the opportunity to have this vaccination, that would be my first step, my first big recommendation. Make sure you reach out to the state and review that plan because, especially if you're located in multiple states or in all 50 states, you're gonna have to really dig in to figure out, what does a state want, where is this available and who can make sure it's taken care of.

Kattman: Lee, is there a cost to receive the COVID-19 vaccine?

Rosebush: You know, that's interesting, right? We hear an awful lot about the millions and billions of dollars that have been available from the current administration, and that even today, right, there's talks of the next COVID stimulus package and there's gonna be money put forward for vaccinations. But what they don't tell you is that there's more than just purchasing the vaccine. So for those that receive the vaccine that's been purchased by the federal government, in other words, the federal government laid out tax dollars to purchase that vaccine, that vaccine is technically free. But what's in addition to that is, obviously, the costs associated with actually administering that vaccine, and those aren't always covered. So you could see costs associated with actually receiving this vaccination different than for the vaccine itself, it would be the administration cost.

Now don't get me wrong, a lot of insurance plans are paying for this, right, and particularly those from large players or the more gold and Cadillac standard plans, for sure, most are covering this, but I would not be surprised if there are individuals out there who, as they move forward, or employers who want to do this for their employees, who receive costs, especially with those costs associated with the administration factor.

Kattman: We all talk about returning to normal. Can you tell us what that looks like?

Rosebush: You know, whenever I hear that, I often think it's going back to the way that we were. In other words, being able to go the beach, being able to travel, being able

to have our meetings, and being able to go back in the office and see each other face to face without our masks and without our social distancing, and in order to get back to that, it's going to be interesting because we really need to have what they call herd immunity. In order to get to herd immunity, what you really are looking for is that approximately 70% or so of the patient population has some sort of quote-unquote immunity for the disease state. So that could be, in this situation, they've actually had COVID-19. It could be that they've received the vaccine for COVID-19. The interesting thing is, and we don't really quite know this as medical practitioners yet, right, I'm putting on my pharmacy hat here, is, if somebody has had COVID-19, do they have long-term immunity?

And often times what we're hearing is, no. It's possible, at least in certain patients, to actually get COVID-19 again. And so, in order to get to that 70% you're likely going to need a vaccination of approximately 85% to 90%, just because it may be possible that you're gonna have a few people who could receive the vaccine and still get sick, or who may ultimately have a little bit of a mutation and therefore could get sick again, and so, in order to get to that 70% you're probably looking at 85% to 90%. In order to get there, it's important that we continue to have masks and social distancing until the vaccinations are able to reach there, but it's also important that we take a look at factors tied to these vaccines. You know, one of the interesting things that we have as a pharmacy practice, we see those who are actually doing the vaccinations at this point, is a little bit of a nightmare, because the situation currently is, the Pfizer vaccine for example requires two doses. The Moderna vaccination requires two doses.

Now you would think, okay, well, those are about the same. The interesting thing is, from a record keeping perspective and tracking of patients when they have to come back, the Pfizer vaccination is you receive the vaccine today and you get your second shot three weeks from now. The Moderna actual vaccination is you receive that shot today, you get it four weeks from now. We actually have a couple of other vaccination programs, or vaccines, that are moving down the pipeline. One of them, knock on wood, is a one time, another one is a separate, either three or four weeks. So you could image as we get three, four, potentially more of these vaccines that come through, the record keeping nightmares that are gonna happen for employers if they're trying to keep track of their employees, or for healthcare providers if they're trying to keep track of patients as they move forward.

And interestingly, for liability purposes, for employer/employee relationships, the question then becomes is, if somebody were to miss that three weeks for the Pfizer or four weeks for Moderna, etc., depending on the what the vaccine is that they're receiving, what ultimate issue are we going to have? Is somebody going to have to restart and take two shots again? Is that second shot, if it's four or five or six weeks out, still as effective? We don't quite know the answer to that yet, and obviously that makes a difference whenever we start to talk about herd immunity, coming back into what is quote-unquote normal, and what that means from a liability perspective, both for those employer/employee programs and for patients as we move forward.

Kattman: As a closing question, Lee, could you tell us, what are the next steps?

Rosebush: Sure. You know, as all of the health recommendations from our federal government continue to roll forward, whether it be through Dr. Fauci, whether it be through the FDA, whether it be through the CDC, obviously, and our state boards who continue to push it, the big thing is continuing to wear your mask and maintain your social distancing until we really do have that herd immunity. I do think what we'll start to see, as the vaccinations continue to start to pile up or move forward, I do believe you will start to see a slowing of the movement of this disease across our country, and the reason being is, obviously as more people get sick they have immunity, as more people receive the vaccine we'll have immunity, as more people have that immunity the spread starts to slow down and therefore we'll start to see better numbers as we move forward.

I really do think, personally, in looking at some of the materials and data that have come out from the federal government, we'll start to see a drastic reduction probably end of March, beginning of April. And that is what many people are pushing for from the federal government as we continue to move forward. The other thing that I would tell you that is extremely important, right, is that we continue down that testing route. What I'm afraid of, is going to likely happen, is, is that people start to feel more comfortable. Because the vaccine is out there, we start to see this spread start to slow down again and we start to ease up on our social distancing and our masking and other things that do have an impact. And so, it's important that we continue down that pathway until we really do start to achieve that herd immunity.

Kattman: Thank you, Lee.

Rosebush: No problem, thanks for having me. It was great being here.

Kattman: If you have any questions for Lee, his contact information is in the show notes. As always, thanks for listening to BakerHosts.