Hello and welcome to “Our American States,” a podcast from the National Conference of State Legislatures. This podcast is all about legislatures: the people in them, the policies, process and politics that shape them. I’m your host, Ed Smith.

This podcast is one in a series NCSL is producing about states and the coronavirus pandemic. You can find links to podcasts, webinars and other resources at www.ncsl.org/coronavirus.

Today’s topic could hardly be of greater interest: the hunt for a Covid-19 vaccine. And at the forefront of that effort are the world’s pharmaceutical companies, which are pursuing multiple initiatives to find a vaccine. To discuss that effort is today’s guest, Clement Lewin, Associate Vice President for Vaccines, R&D Strategy at the pharmaceutical forum Sanofi Pasteur.

Lewin, who holds a Ph.D. from the University of London and has extensive experience in the field of vaccine development, will discuss the overall efforts to create a vaccine for Covid-19 and also explain the role state legislators and other policymakers can play in the vaccine process.

Today’s podcast is sponsored by Sanofi Pasteur, a member of the NCSL Foundation for State Legislatures.

Clem, welcome to “Our American States.”

Clem: Thank you very much, Ed.

Time Marker (TM): 01:37

Ed: Well, Clem, thanks for being here today. I can’t think of a topic of greater interest than the effort to develop a vaccine for Covid-19. As you know, our audience is primarily legislators and legislative staff and other policymakers. Can you give them an overview of where things stand with the efforts to develop vaccines for Covid-19?

Clem: Developing a vaccine is normally a fairly long process; it can take up to a decade. And what you’re seeing with this public health emergency to respond to Covid-19, the public sector and
the private sector have come together to try and develop vaccine candidates as quickly as possible to deal with this public health emergency threat, because without a vaccine, it will be very, very difficult to return to normal.

**TM:** 02:27

**Ed:** There have been a lot of different predictions for how long a vaccine will take to develop. Is there any sort of consensus in your industry on what a timeline looks like?

**Clem:** I don’t know that consensus is the right word to use because I think the different candidates are at different stages of development. You are seeing some vaccine candidates that are already in the clinic that are being tested in humans, which is a significant step forward. But when we look at the availability of a vaccine, one needs to accomplish two things.

The first is demonstrating that the vaccines are safe and effective in that they prevent Covid-19 in clinical trials. And then secondly, scaling up to manufacture enough doses so that you can go from, let’s say, the thousands of people or tens of thousands who might receive the vaccine in the clinical trial to the millions of people that would need the vaccine for an immunization program.

**TM:** 03:28

**Ed:** So, by many accounts, governments across the globe have tried to remove barriers as scientists rush to move potential vaccines through the approval process. Is that what you’re seeing from your vantage point?

**Clem:** That’s an excellent question, Ed. What you’re seeing is both the public and private sector are working to develop the vaccines as quickly as possible. So, work that might usually be done in sequence is being done in parallel to accelerate development.

Things are being done at risk, not risks in terms of patient safety or anything like that, because everybody is committed to a safe vaccine, but rather risking resources, both people and funds. We might normally wait for results to go into the next phase, but here we’re all going as fast as we can, so sometimes going ahead without fully having all the results available to make a decision as to the next step.

The other thing is that we are working very closely with regulatory authorities and other scientists such as scientists at the NIH and the CDC to share our learnings, best practices, as this is an evolving field. And then, finally, you’re seeing collaborations between companies in terms of sharing their information and technology.

So, all of this is combining to try and accelerate what the traditional timeline would be to get a vaccine out as quickly as possible in large quantities that we can actually use in people.

**TM:** 05:07
Ed: Now, you touched on this before, but assuming a vaccine is developed, what sort of plans are governments and pharmaceutical companies such as yours making to manufacture the billions of doses that will be needed worldwide and to distribute them?

Clem: Well, let’s break that answer into two things. The first is manufacturing doses. So, companies would normally wait until they had clinical results that showed the vaccine was safe and effective before scaling up to manufacture it.

What you’re seeing now is in parallel to developing their vaccines, companies are working on scaling up so that they can actually produce large amounts of doses as soon as the clinical results show that the vaccine works. So, that’s very different from how we might normally do things.

In terms of distribution, I think the manufacturers are really responsible for making the vaccine, both for making it and for demonstrating the safety and efficacy before it can be used. What we’re counting on is our public health partners to distribute the vaccine and prioritize who gets the vaccine and also to take over distribution to ensure that it’s equitable. So, I think that’s going to be a public/private partnership with the manufacturers supplying the doses, but the public sector taking over the distribution and administration as well as the decisions on prioritization.

Ed: This is certainly not the first infectious disease pandemic the world has ever seen. Even as a child I recall friends who had polio. Does history help us understand how this pandemic ends?

Clem: Ed, I wish I could say that it did, but I think every pandemic is different. I’ve only really experienced one, the 2009 H1N1 pandemic, but it was a very different situation; the disease wasn’t as severe; we were able to manufacture a vaccine within six months; and we knew a lot about the disease itself.

Here, we’re dealing with a new disease, Covid-19 – it’s very different from some of the coronaviruses that we’ve seen in the past and we don’t know much about it. So, it’s very difficult to predict how it will end.

But the one thing I think everyone agrees on is that it’s likely that a vaccine will be required to achieve herd immunity and to get everyone back to the life as we knew it, for want of a better term.

Ed: We know that drug approvals are a federal function, but are there steps states can take to help with distributing and administering vaccines? What is the state role?

Clem: Ed, I think first of all, you’re correct, that the states aren’t going to be the regulators deciding whether the vaccine is safe and effective, and they probably won’t decide on the prioritization. I hope that will be the advisory committee on the immunization practices.
But states will play a critical role in the distribution and administration of the vaccine because state and local health departments are critical to routine immunization, to influenza immunization, to routine pediatric immunizations, and the annual influenza immunization. And I think their role will be just as important, if not more so in this mass immunization program.

So, I think the role that state and local health departments will play both prior to in preparing people and preparing for the administration of the vaccine, educating both the public and providers about the vaccine, and then implementing the programs will be critical.

**TM: 08:50**

**Ed:** Are there any other things legislators and other policymakers at the state level should be planning for in the months ahead?

**Clem:** Again, a great question, Ed. I think legislatures and legislators can play a very important role in immunizations, as they always do, and I’d encourage people to think beyond the Covid-19 vaccine. A couple of examples...

First of all, we don’t know whether we’ll have a vaccine available this fall. There’s a lot of concern about influenza cocirculating with Covid for a couple of reasons: one, there’s some evidence that coinfection in an individual person could increase the mortality; and then secondly, because influenza could utilize healthcare resources that may be needed to deal with Covid.

So, we know that we have an influenza vaccine that will be available this season and getting immunized will be very, very important this year, even more so than normal years because the influenza vaccine is known to prevent influenza, which is something that from a public health perspective we will be striving to do this year to, as I mentioned, hopefully reduce the morbidity and mortality if there’s coinfection with Covid, but also to reduce healthcare utilization so that the healthcare system is better able to cope with the Covid surge if it arrives.

Support for that from state legislatures is critical, support for an influenza immunization and clinics and the education activities that states carry out will be very, very important.

The second area where we’re seeing potentially... I don’t want to say they are issues yet... is the impact of social distancing and states closing down has left some children unprotected – they’ve not received their routine pediatric immunizations. State legislators can work to help support their health departments to ensure that catchup does occur and that hopefully would prevent outbreaks of disease and not leave children unprotected from the disease, ensure that they get protected, caught up with their vaccinations as quickly as possible.

So, I think those are the two areas in addition to thinking about how a Covid vaccine might be administered, so preparing for that, is leveraging what we already have to make certain people get vaccinated against influenza this fall and that we make certain that our children are caught up with their routine infant immunizations that have been unfortunately disrupted by the public health emergency.

**TM: 11:35**
Ed: Well, those are excellent points for state officials to consider. Now, we want to be realistic about the situation, especially as we see infections spiking in some parts of the country. But I wonder if there’s room for hope as well. Is there anything you’ve taken from this experience that makes you optimistic or gives you hope that we might be better prepared for the next pandemic?

Clem: Oh yes. I think there are a lot of things that give me hope. First of all, vaccines, we always work in a public/private partnership with our federal partners and state partners to make certain that we have both in terms of vaccine development and distributing existing vaccines and generating data on them.

So, we’re used to working together, but I think that this pandemic or public health emergency has made us work even closer together, both in the private sector and the public sector, and I hope that we continue to leverage what we’ve learned on how we can work together.

The second thing is I think hopefully some will learn from the way we’re developing vaccines; I think it’s a little too early to tell whether that’s been successful or not. But assuming that we are successful, this could be applied to the development of routine vaccines and also leave us better prepared to develop vaccines for the next pandemic.

And then the third thing that gives me hope is that this public health emergency has made us realize the importance of the public health infrastructure, the need for that infrastructure to be able to respond to Covid-19 or other emerging infectious diseases, and hopefully that lesson will remain with us and we will continue to invest in strengthening and reinforcing our nation’s ability to respond to public health threats when they emerge.

TM: 13:28

Ed: Well, I certainly hope your optimism is proven out as we get on the other side of this thing. So, before we wrap up, is there anything else you’d like to share with legislators and policymakers and other folks listening today?

Clem: Yes. What I’d like to share is that for me, this has been a really interesting experience because what I’ve seen is people really come together with a single mission to develop a vaccine or vaccines against Covid-19. My colleagues globally are working extremely hard to move the program forward or programs forward as quickly as possible.

I’m really impressed with the dedication of my partners at the Biomedical Advanced Research Development Agency and NIH who are literally working 24/7 to get the programs forward, and that we are all in this together working as quickly as possible to make a safe and effective vaccine that allows all of us to return to life as we knew it.

Ed: Well, Clem, thank you so much for sharing your expertise on this topic. I can hardly think of one more important to be talking about right now and thanks again. Stay safe.

Clem: Thank you, Ed, same to you.
Ed: And that concludes this edition of our podcast. We encourage you to review and rate our episodes on iTunes, Google Play or Spotify. You may also go to Google Play, iTunes or Spotify to have these episodes downloaded directly to your mobile device when a new episode is ready. For the National Conference of State Legislatures, this is Ed Smith. Thanks for listening and being part of “Our American States.”

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