



#WIGWednesdays

April 22, 2020

“Next Steps Ahead for COVID-19: Research and Development, Vaccine Manufacturing, and BARDA Partnership”

Featuring:

Lucy Gettman, Executive Director, Women In Government

Nevada State Assemblywoman Lisa Krasner, Western Regional Director, WIG Board of Directors

Dr. Clement Lewin, PhD, MBA, Associate Vice President, Head BARDA Office & NV Stakeholder Engagement, Sanofi Pasteur

Lucy Gettman: Welcome to WIG Wednesday, our weekly virtual series delivering timely information to help you better serve your constituents. I’m Lucy Gettman, Executive Director of Women In Government, a non-profit, non-partisan organization by and for women state legislators across the country. At this time you should see a polling question on your screen, asking “Is this your first WIG Wednesday?” Thank you for answering!

We are so glad you’re here for today’s virtual roundtable event, “Next Steps Ahead for COVID-19: Research and Development, Vaccine Manufacturing, and BARDA Partnership” with featured speaker Clement Lewin from Sanofi Pasteur. Sanofi has done two podcasts with WIG, and we hope you’ll check them out on our website and Soundcloud account. The first is [“Are You On the Fence About Getting a Flu Shot?”](#) and the second one is [“Don’t Hesitate, Vaccinate.”](#)

With that said, I’m honored to introduce today’s moderator, Assemblywoman Lisa Krasner of Nevada. A wife, mother legislator and college professor, Assemblywoman Krasner serves as Western Regional Director on Women In Government’s Board of Directors, a 14 state region, during this very critical time.

Assemblywoman Krasner, thank you. The virtual podium is all yours.

Assemblywoman Lisa Krasner: Thank you so much. Lucy. I was first elected to the Nevada legislature in 2016 and have served two terms as the Assembly woman for Nevada State Assembly District 26 and I’m currently running for my third term. I’ve been involved with Women In Government for several years now. I first served as a Women In Government State Director representing Nevada, and now I serve as Western Regional Director on the WIG Board of Directors.

Over the years, I’ve enjoyed being a part of a variety of public policy activities at Women In Government that yield important resources for legislators across the 50 states, and I encourage everyone on this call to learn more about how you can get involved with this great organization.

Before I introduce today’s speaker, I’d like to point out a quick housekeeping item. All participants are muted through the system, If you have questions or comments during the presentation, please be sure to write them in the Chat Box below in the Zoom Meeting Toolbar and make sure that you have selected “To Everyone” from the drop-down menu. We’ve reserved time for questions after the presentation and if you are a state legislator, please feel free to let us know in the body of your question who you are and from what state. This virtual roundtable event will be recorded and provided on our website once the event is over.



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Now, please join me in welcoming Clement Lewin, PhD, MBA, Associate Vice President Head BARDA Office & NV Stakeholder Engagement, Sanofi Pasteur. Clement is currently Associate Vice President Head BARDA Office and NV Stakeholder Engagement. He has been in the vaccines industry for over twenty years and joined Sanofi Pasteur in 2015. He is responsible for managing the company’s relationship with the US Department of Health and Human Services Biomedical Advanced Research and Development Authority BARDA focusing on pandemic preparedness as well as COVID-19 and supports engagement with external stakeholders.

Clem was the Biotechnology Industry Organization liaison to the Advisory Committee on Immunization Practices from 2004 to 2014. He served on the National Vaccine Advisory Committee from 2009-2012. He was on the advisory board of Bio Ventures for Global Health and a board member of the Alliance for Biosecurity. He currently serves on the Board of Trustees of Gaylord Hospital a long-term acute care facility in Connecticut.

With a very impressive bio, I am thrilled to welcome Clement to present on today’s WIG Wednesday topic.

Dr. Clement Lewin: Assemblywoman Krasner, thank you very much for the introduction. Thank you very much to Women In Government for providing this opportunity to speak to you about COVID-19, the company's response, and to tell you a little bit more in depth about vaccines. For me, as I was thinking about doing this, it's like coming full circle because I joined the vaccines industry about 25 years ago at Merck, and I worked on chickenpox vaccines.

One of the first things I did was present at a Women In Government meeting – I think it was in Phoenix, Arizona – and took part in a panel discussion on Immunization focusing on chicken pox. It's something I always remember because the legislators have a great interest in immunization. Many of you are parents, and I know that you champion immunization not just in your own homes but also in the legislature. Legislators are excellent advocates for what's one of the great public health advances since pure water in reducing disease. So it has a tremendous impact, and thank you for all that you do.

Today I'm representing Sanofi, which is a large pharmaceutical company. We're a French company but with very big operations in the U.S. We do drugs against rare diseases, cancer drugs, cardiovascular drugs, and diabetes drugs, and where I work is in the vaccines division. We're one of the largest manufacturers of vaccines in the world and the largest manufacturer of influenza vaccine, but what I'd like to do today is tell you about how my company is responding to COVID-19.

While I'm talking about my company, I'd like you to take away the fact that Sanofi is no different from the rest of the pharmaceutical industry. We are working hard with our public health partners to respond to this public health emergency in whatever way we can and in a very collaborative way.



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So, what we have is a unique a portfolio to fight this public health emergency. Sanofi has a multi-pronged approach to combat COVID-19. I'm going to talk to you more about vaccines in a moment, but obviously vaccines are an important component. I don't think that we will really truly be out of this public health emergency without a vaccine, which will confer immunity to the population and enable us to return to our normal life, be it travel, visiting elderly relatives, going to baseball games, social events, and large social gatherings.

In addition to the vaccines, we also have some other things that we're working on. We have a licensed compound called Kevzara which is actually for the treatment of rheumatoid arthritis, but it works on something called IL-6 which is interleukin six. That is one of the things that is thought to cause the cytokines storm in people who are severely ill with COVID-19 and contributes to the morbidity and mortality of the disease. So we are looking into this as a supportive treatment.

It's not an antiviral, but it can help people recover from severe disease by reducing the cytokines storm. It's a very interesting story in the sense that there's now a clinical trial underway with over 1,000 people sponsored by BARDA, and I'll tell you a little bit more about what BARDA is in the next slide. Hopefully we will have results this month or next that will indicate whether this can help people recover from the disease. The company put this together in a matter of weeks - this clinical trial in partnership with Regeneron - and again it shows not only the partnership and how quickly we're moving but also the regulatory authorities.

The other area is you probably have heard of is hydroxychloroquine. We, as well as others, are doing trials to see whether this drug for lupus and an anti-malarial might be able to benefit against COVID-19.

We also recently announced a partnership with a diagnostics company to do an in-home diagnostic tests through your cell phone. I don't really know much about it, so I hope you won't ask me too many questions, but I just wanted to highlight again - that's another partnership, and that's the holistic approach that our company is taking looking at both treatments, diagnostics, and vaccines to help combat COVID-19.

Now I'd like to go a little bit more into detail on the vaccines program because that's really my area of interest and my passion. So we started out with one approach, which was the Baculovirus recombinant vaccine approach, which is partnered with BARDA, the Biomedical Advanced Research Development Agency. This is a part of a group that's part of HHS that is tasked with helping develop medical countermeasures that respond to either chemical or biological threats such as pandemic influenza and things like COVID-19 which are known as emerging infectious diseases.

BARDA was formed about 15 years ago, and Sanofi has had a long and productive relationship, mainly on pandemic preparedness, over the last 15 years. We maintain a year-round supply of eggs so that we can start pandemic influenza vaccine production at any time. We retrofitted a facility to extend production capacity in 2009. We produce - some of you may remember the H1N1 pandemic - we produce quite a bit of vaccines, along with other companies that BARDA uses.



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We’re making lots of different pandemic strains - just in case - to not only have a stockpile but also to make certain that we can make them. One of the differences between pandemic influenza and COVID-19 - both are pandemics, but with influenza, we have a vaccine that was licensed. We have the manufacturing infrastructure in place, so we were able to get a vaccine out in about six months.

COVID-19 is different because there was no vaccine available. Some vaccines that have been tested against SARS and MERS may be in early clinical trials, but there wasn't that much work. So we're really starting from scratch, which is one of the reasons why you hear people like Dr. Fauci say it'll take 12 to 18 months to get a vaccine available.

Sanofi is working on two vaccines. One uses a recombinant protein approach that's based on an existing flu vaccine that we use called Flu Block. The production system is the same, and Flu Block is the first recombinant DNA protein based vaccine. The traditional approach to making vaccines is that (1) you would grow the virus - let's say, in the case of influenza you grow the virus in an egg or cell culture; (2) you harvest the virus; (3) you purify the protein that you're interested in; and (4) then you make the vaccine.

For the recombinant DNA protein based vaccine approach, what you do is you (1) take the DNA that codes for the protein – the map, and (2) you put it in cell culture - you produce the protein, not the virus. In the case of COVID-19, you are producing the spike protein of the coronavirus. It's known as a coronavirus because on the outside it has these proteins that look like spikes. (3) Then, in this case, to ensure that we have a good immune response, we add an adjuvant. That does two things – first, it enhances the immune response, and second it may be antigen sparing, which means you need less protein to make a vaccine. This allows us to make more vaccines.

Having more vaccines for COVID-19 available as quickly as possible is critical. It's not going to be enough to license the vaccine and prove that it works. You're also going to have to make certain that you have enough vaccine to potentially vaccinate everybody in the United States or most people as most people have not yet been exposed to COVID-19.

Now the story with the adjuvant is interesting for me because it highlights the difference in how companies are responding to this pandemic. We've partnered with GlaxoSmithKline to use their adjuvant ASO3 that's also used in pandemic influenza vaccine. The partnership came very quickly. It took us a few weeks to agree at least to start working together and for them to supply us with the material that we needed to start work.

Why I think this is a great example of collaboration is that GlaxoSmithKline is also one of the large vaccine companies, and while we are rivals, what you see here is two companies saying, “We may be rivals, but we need to work together, and we're working with BARDA on this.” We all came together to work as quickly as possible to make the vaccine available.



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What's the technology? Why is it attractive? It's a licensed platform that makes Flu Blocks, so it's something the regulatory agencies are familiar with. There is a safety experience in that there's been millions of influenza doses used, so you know that it's fairly safe. As with all vaccines, safety is important. We're collaborating with BARDA. They're now funding early stage development, and there is manufacturing capacity for Flu Block at Pearl River, New York that already exists.

So where are we now with this? We need to do some non-clinical work which is testing prior to going into manufacturing, and we're making the proteins as we speak. The teams are working hard. It's a large exercise now as part of the company. We have the product is being made in Meriden, Connecticut. I have colleagues in Swiftwater, Pennsylvania; in Europe; in Canada; and in Cambridge, Massachusetts that are working on the non-clinical aspects and then putting together the plans for the clinical trials. We hope to be in clinical testing in the fall and have a product available, assuming all goes well, in 12 months after that.

Recently, we also announced a second approach which is mRNA, messenger RNA - and I'm certain many of you read about it because this is the first vaccine to have gone into clinical trials against COVID-19. mRNA is a new technology. We are partnered with a company called Translate Bio. We were working with them before on vaccines against other diseases, but as the emergency and the magnitude of this public health emergency became apparent, we decided that we would like to have two shots on goal or multiple shots on goal - that it deserved a second approach as well.

And we believe there's synergies in the development of two vaccines in terms of the clinical trials and the non-clinical work on it. There's a similarity. So in terms of the assays we need to measure whether the vaccine is working and other things that make it attractive. So this mRNA approach is very new, and there's never been a vaccine that's been licensed using this technology.

The mRNA approach is different – as opposed to the recombinant vaccine approach where you make a protein, you inject the protein into the person, they mount an immune response to the protein, and they're protected against the disease. In the case of mRNA, your body is the factory. So what you do is (1) you take messenger RNA, which is essentially the blueprint for the protein; (2) you package it in a delivery system which is lifted nanoparticle - for those of you are scientifically inclined; (3) you inject that into the person; (4) the person then uses that blueprint to make the protein in the human body, and (5) that protein made in the human body produces the immune response. It has a different mechanism of action to what we were discussing before, the recombinant.

It's considered that because the protein is made like the virus would be - in man - that it might mount a very good immune response. It increases manufacturing capacity, and it has, as I mentioned, some synergy. So this is our second approach. I would say it's somewhat more risky because the technology is unproven, but if it works, it's extremely fast. It will provide good protection and more doses. If we think about this as a global problem, there will be a need for a large amount of doses. One technology or one facility or one company won't be able to supply the world demand.



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I'd like you to take away a few things. One, the company's working extremely hard on a vaccine. What you're seeing is a partnership between companies to address this issue. Vaccines are always a public private partnership. We always work closely with stakeholders such as the CDC and your state and local health departments to deliver the vaccine and monitor things, so this isn't new to us.

But what's I think unprecedented is how we're all working as hard and as quickly as possible and sharing information to come up with a solution to this problem. So it's not that we're acting in a different way, but we're all working together to accelerate things and move things forward as quickly as possible. We're building on the spirit of collaboration that always exists, but there's an even higher sense of urgency because we all recognize the importance.

I'd like to switch gears now because, as I mentioned, it's going to be a while for a vaccine, and then we're going to need quantities of vaccine before we can truly control the COVID-19 pandemic. There will likely not be a vaccine available and in quantities this fall when influenza season starts. Influenza is a respiratory disease with a high morbidity and mortality. The difference is that we do have a vaccine available now that's universally recommended. The vaccine has been available for 40+ years, and around half the population gets vaccinated.

I think this fall it's going to be particularly important to get vaccinated or encourage people to get vaccinated for two reasons. One, from a societal perspective - as Dr. Redfield, the CDC Director said yesterday, vaccination against flu can reduce the number of people utilizing the health care system emergency rooms, but also intensive care. Flu season brings people in, and the utilization of healthcare services becomes particularly important if we have a surge in COVID-19 infections in the fall, as many people think will occur. So whatever we can do to reduce the burden on the healthcare system will allow the healthcare system to cope better with COVID-19.

Second, on the individual level, if you get influenza, particularly if you're elderly, it can cause respiratory problems and other complications. It can leave you in less better shape to respond to COVID-19 if you should unfortunately be infected. If you're healthy, COVID-19 will have less of an impact, hopefully. We know that risk conditions for severity of influenza - like cardiovascular disease, diabetes, and obesity – are similar risk conditions for severity of COVID-19.

Getting a flu shot and preventing yourself from getting flu as an individual can also help your chances should you get COVID-19. I don't think anybody wants to get it, but if you get it, you want to make certain that you're as healthy as possible. I've certainly seen people or heard of people - my daughter is a master student in Paris, 26, and very healthy. She came down with COVID-19, and it knocked her out for a month. So it's no joke. I would encourage even healthy adults to make sure that they get their flu shot this year. It's recommended every year, but this is a particular year to make certain that you do that.

Hopefully I leave you with two messages. One is that we are working as hard as possible to develop a vaccine. Sanofi and other companies are working on diagnostics treatments and vaccines in an



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accelerated manner. This is unprecedented. We are all committed to working together and to working with our public health partners to deal with this.

Secondly, as legislators, I would encourage your constituents to get vaccinated against influenza this season in particular because it's important and of societal benefit for themselves and their loved ones. Finally, please advise people to listen to Dr. Fauci, to the CDC, and your local public health for guidance on how we manage this epidemic and public health emergency. They are doing a great job. They have a lot of knowledge, and I encourage you to trust them.

I'm happy to answer any questions if that'd be helpful.

Assemblywoman Lisa Krasner: Thank you, Dr. Lewin, very much for this important and timely presentation. Before we take question and answers from the audience participants. I wanted to let you know that we can see that 67% of the polled participants are joining with Wednesdays for the first time. So welcome!

Dr. Clement Lewin: One quick thing I forgot to mention! I encourage you to listen to the podcast that Women In Government produced on flu shots. It's a great resource, and it's available on Women In Government's website.

Assemblywoman Lisa Krasner: Thank you. On your screen, we would really like it if you would answer the polling question “Have you conducted a flu shot clinic in your district?” if you see that right there in the center. Thank you.

So now we'd like to take this time to have Dr. Lewin answer a few questions from the audience participants. If you haven't submitted any questions, please submit them by using the chat box below, and then please be sure to select “To Everyone” from the drop down menu.

Okay, so the first question I see here is can the vaccine give better protection than having the actual illness, the natural immunity you would have?

Dr. Clement Lewin: That's a really good question. I think the target of vaccines is to provide as good protection as natural immunity. I think one of the questions here that's the unknown is we don't really know how long having the actual illness protects you for. There's been some literature – I think it's out of Korea - that some people had been re-infected, although it's not really clear whether they had been or not. It's not clear how long, if you have had the disease, how long you'll be protected. You're protected for certain period of time, but how long is not clear.

So, for example, your natural immunity for influenza or other respiratory viruses doesn't last that long. It's going to be very interesting to see since other diseases like measles or chicken pox have lifetime immunity. So that's one of the things that we're trying to understand and figure out, because as we



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learn more about the disease and as we control it, it'll help determine how often vaccination might be required.

Assemblywoman Lisa Krasner: Thank you. Here is another question. What are some suggestions to ensure that the eventual vaccine is distributed equitably?

Dr. Clement Lewin: The way I like to think about it is based on precedence. I think that initially the distribution of the vaccine will hopefully be similar to the H1N1 pandemic, where BARDA and the U.S. government purchased the vaccine and managed distribution. I think that in terms of equity that has a lot of benefit because public health is well placed to prioritize and ensure that the people at the highest priorities - let's say usually recommended by The Advisory Committee on Immunization Practices (ACIP), the recommending body that advises the CDC as to who should get the vaccine - and then also it ensures equity and distribution nationally as the doses come out since we're not going to get 600 million doses at once. It would be nice if we did but I think unrealistic. They can then determine where the vaccine goes. So that would be the first wave, a national immunization program.

I should also mention while public health will do the distribution, I think they're going to need - just like the H1N1 pandemic - to work with their private sector partners, including doctors, pharmacists, and nurses such as a visiting nurse association and school nurses - to make certain that the vaccine is administered because it's going to be difficult for them to do it all on their own.

Once that happens - and assuming it becomes a routine immunization - I hope that we follow the standard practices that we do for vaccines because we have a very strong infrastructure in the U.S. There's the Vaccines For Children (VFC) program for children 18 years and under that provides free vaccines to the non-insured and Medicaid eligible, Native Americans, and Native Alaskans. I think that's a program that has eliminated a lot of the socio-economic disparities that existed.

I think that for the elderly and other groups at risk, Centers for Medicare & Medicaid Insurance (CMS) should put the coronavirus vaccine in Medicare Part B, the same as with the influenza vaccine. So again, it would be first dollar coverage and insurance provides first dollar coverage. I think hopefully the vaccine, if needed, will be recommended by the ACIP, covered by insurance, included in Vaccines for Children, and covered by CMS so that people will have access to it. Does that answer your question?

Assemblywoman Lisa Krasner: Thank you, Dr. Lewin. We do have another question. Is there any evidence that pneumonia vaccines have been helpful in deterring or lessening the effects of COVID-19?

Dr. Clement Lewin: I'm not aware of that, but like the flu vaccine, I should have also said to get your pneumonia shot if you're eligible. One of the complications of COVID-19 is pneumonia, so presumably you're less at risk of getting pneumonia, but that's just off the top of my head. I'm not aware of any evidence of it.



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And there was a question about tuberculosis (TB) vaccine. There is this theory that a form of TB vaccine, BCG, because it generates sort of a broad immunity, may provide some protection. I think it's anecdotal. I'm a big fan of Dr. Fauci, and I'd say we have to wait for the evidence there.

I've heard it anecdotally. I have a friend from Singapore who thinks it helped them, but I honestly don't know. I think the explanation, though, is that it's one that induces and strengthens your immune response to a pathogen in general. So it may render people less susceptible, but it's not specific to COVID-19. It just gives you a stronger immune response.

Assemblywoman Lisa Krasner: Thank you. So I have a question. How is Sanofi working with caregivers to document and/or disseminate any information of new protocols currently?

Dr. Clement Lewin: Are you referring to clinical trials or protocols for COVID-19?

Assemblywoman Lisa Krasner: Yes, both.

Dr. Clement Lewin: For COVID-19, I can give you an example with vaccines. We have a group of what we call medical science liaisons to call on a doctors and academic people. We've created materials so that they can educate and answer questions on the disease and engage in discussions with them. They are looking also to try and identify sites for clinical trials for vaccines. For Kevzara I'm not that familiar, but I would assume that there are people enrolling in the clinical trials.

Because it's not a licensed indication, our sales people would not be going into doctors' offices and telling them. If the doctor inquired, they would go to our medical information liaisons and we would provide information. But it's not something that we can for want of a better term “promote,” Where we're focused on at the moment is just trying to understand whether Kevzara can help, and we should have the results soon. They'll be reviewed by the FDA, and then we'll go from there.

And the hydroxychloroquine - I should have mentioned it's not a product that we have in the U.S., so the trials are actually outside of the U.S. that we're involved in.

Assemblywoman Lisa Krasner: Okay, thank you very much. So it looks like we are right up to our last question. If anybody wants to type a question into the chat room, please do so now. Otherwise, I'm going to ask a question that I have here.

Dr. Lewin, you mentioned that there's going to be about a 12 month timeline projected for a new vaccine. What do you recommend we do in the meantime?

Dr. Clement Lewin: I'd say 12 to 18 months, and what I would say is I would follow the guidance. You know, I always listen to Dr. Fauci. I think the CDC has excellent guidelines, and then at a local level, I would talk to your local public health officials because they know the situation on the ground far better



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than I do. So I would take their advice because I believe they're the best place to tell you what to do and how to proceed.

Assemblywoman Lisa Krasner: Okay, so, maintain safe social distancing, stay home, and don't go to work when you're sick.

Dr. Clement Lewin: Yes, all those things. Absolutely. I see there's a question. How do you suggest messaging the speed of the vaccines? It's an excellent question. I think what I would say is everybody - the CDC, NIH, HHS, the FDA, and for our company - safety is a primary concern for us. We are not going to do anything that would risk - any shortcuts that would risk the safety of the vaccine. That's paramount for everybody. So we are taking the steps. That's why it's taking 12 to 18 months.

What we are doing, though, is trying to accelerate and do things that risk that we might not normally do. By saying do things that risk I don't mean take risks in terms of safety, but doing things in parallel so that if - let's say if a vaccine failed, we would have invested a lot of money needlessly. But to get to do things fast, normally we would do things sequentially, one after the other. Here, things are being done in parallel. But I would assure you that none of us wants to take any risk on safety.

Assemblywoman Lisa Krasner: Great. Thank you, Dr. Lewin, and thank you so much for presenting during today's Women In Government “WIG Wednesday.” I'm wondering if you could please give us some closing remarks.

Dr. Clement Lewin: I would like first of all to thank you and all the legislators for what you're doing to help your constituents through these difficult times. Thank you for your support of immunization. I hope that you continue to do that. The third thing is to encourage you and your constituents to follow the guidance of public health in these challenging times. And finally, I hope you and your families and your constituents all stay safe.

Assemblywoman Lisa Krasner: Thank you very much, and thank you to everyone who joined us today for “WIG Wednesday.” Resources from all “WIG Wednesdays” and registration links for upcoming events are on WIG's website at www-dot-Women In Government-dot-org. And if you haven't already, please follow Women In Government on [Facebook](#), [Twitter](#), LinkedIn, [Instagram](#), and [Soundcloud](#) to stay connected with WIG and fellow state legislators nationwide.

Please stay tuned for upcoming WIG Wednesday sessions:

April 29, 2020: “What the CARES Act Means for Small Businesses, Individuals and Non-profits” moderated by Tennessee State Senator Becky Massey with featured speaker Katie Vlietstra Wonnenberg, Principal, Public Private Strategies

May 6, 2020: “Disparities in COVID-19 Among People of Color” moderated by Maryland State Delegate and Speaker Pro Tem Sheree Sample-Hughes and Georgia State Senator Gloria Butler with featured



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speakers Dr. Sandra Ford, CEO of DeKalb County Health Department of Georgia, and Dr. Leana Wen, Visiting Professor at the School of Public Health at George Washington University

More sessions will be announced in the coming weeks, so keep an eye on your inboxes and on WIG social media **#WIGWednesdays** for more!

This week we are recognizing WIG’s Board Treasurer Hawaii State Representative Lauren Matsumoto for a Good Deed Done. Representative Matsumoto found a new way to connect with her constituents during the COVID-19 pandemic by sewing masks to give to those who need it. She is also supporting various communities in Hawaii by donating them to frontline workers.

[Click on the link here](#) for Representative Matsumoto’s mask tutorial!

If you have done something to connect with your constituents during COVID-19 and would like to be featured, be sure to reach out to the WIG staff. Their contact information is available on the current slide.

We greatly appreciate your support of Women In Government and look forward to seeing everyone again next Wednesday!

Thank you all again for joining us, and stay safe.