



Capitol Hill Steering Committee on Pandemic Preparedness & Health Security



Transcript from March 30, 2022: Enabling Population-Scale Diagnostic Testing for COVID-19 and Future Infectious Disease Outbreaks

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We'll start in 2 min. Okay, great thank you welcome to today's webinar enabling population scale diagnostic testing for Kovat 19 and future infectious disease outbreaks our moderator

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Anita Cicero will now begin. Thank you. Hello and welcome all.

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Thank you for joining us today for the Capitol Hill Steering Committee on Pandemic Preparedness and Health Security.

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My name is Anita Cicero, and I am deputy director at the Johns Hopkins Center for Health Security.

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Our Capitol Hill Steering Committee is a bipartisan effort that was formed with support of 11 Congressional leaders and also former administration officials.

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All of whom are committed to making that this country in the world more prepared for the greatest health security threats.

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This committee is managed by our Johns Hopkins. center for health security, and we're able to host these regular webinars with a support of the open Philanthropy Project.

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This particular session today is co-hosted with our Johns, Hopkins Center for Health Security, Covid 19 testing toolkit, which is funded by Lida Hill, Philanthropies and the Gordon and

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Betty moore Foundation. Today we're going to be focused on diastic testing at the beginning of the pandemic.

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The Us. faced an acute shortage of covid 19 tests.

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I'm sure we all remember the times when tests were very scarce.

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Many people had to wait over a week to get their test results.

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So we did learn that reliable and affordable access to rapid at home tests, and also lab-based diagnostic testing across both rural and urban areas. In the Us.

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Is really a key component of our national pandemic response.

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Now we're happy to see hundreds of millions of tests on the market, and we know that making diagnostic testing and increasingly ubiquitous can empower people to make informed decisions to limit the spread of Kovan

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19. we are carefully watching the numbers of the the Ba.

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2 variant infections, and we know that future variance and future surges are still very possible. Throughout the pandemic.

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Public private partnerships have led to the development and wide scale production of new rapid at home diagnostics and expanded laboratory pcr based testing capacity.

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However, it's been an ongoing challenge to ensure that that long-term public access to testing, especially during time when demand wanes like right now so overcoming the challenges posed by market volatility and supply

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chain issues is, is crucial to ensure accessible diagnostic testing.

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For Covid 19. This pandemic also illustrates the potential value, and also some of the potential pitfalls for rapid diagnostic testing for other infectious diseases.

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In the future. So today, in today's session we're going to explore how policymakers can work to sustain the technological gains and diagnostic testing during the response to the covid 19

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pandemic, how we can avoid supply shortages for the remainder of the pandemic, and how we might be able to expand that effective and affordable at home diagnostic testing capacity against other infectious disease

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threats in the future. We are so pleased to be joined today by Representative Laurie Trehan, Dr.

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Tom Engelsby, who's the senior policy advisor for testing at the White House Covid 19 response team.

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Dr. Gg. Granville, senior Scholar at the Johns Hopkins Center for Health Security, and also Susan Van Meter, who's executive director at Advanced Dx.

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Our first speaker is Representative Laurie Trehan Congresswoman Tray hand proudly serves Massachusetts Third District.

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We're honored that congresswoman trayan is an honorary co-chair of our steering committee, and she's been very active in the policy debate around the government's response to covid 19

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and thinking about ways to improve our preparedness, going forward in the future. she's a member of the House Committee on energy and commerce, and is an advocate for expanding access to a affordable quality health care tackling climate change

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protecting kids, online fighting, disinformation, and much, much more representative tray hand.

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Thank you so much for joining us today. i'll turn it over to you now.

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Thank you. Thank you, Anita, for inviting me to speak here today.

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And good morning, everyone. it's great to be here I'm certainly grateful to my fellow panelists. Dr.

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Inglesby Dr. Gronball and susan denieder for joining me in what is going to be a very important discussion.

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For over 20 years the Johns Hopkins Center for Health Security has worked to protect the health of the public during epidemics and disasters through sound science policy and programs, and for this reason I was thrilled to be invited, to

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return today to explore policy solutions that will enable the United States to be better prepared for future pandemics and other health security threats.

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In particular, I look forward to hearing from our experts about the importance of maintaining and expanding our nation's testing capacity to help us prepare for future surges of Covid 19 as many of you know the American rescue

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plan was an unprecedented investment to aid Americans struggling during the height of the pandemic, and not only did it get much needed relief to families and small businesses struggling to make ends meet but it also played a

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pivotal role in getting shots into arms and making tests accessible in our communities.

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It allowed for school-based testing programs to keep our children and teachers safe, and it set up free testing sites for the uninsured.

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It also provided funding for rural hospitals for critical Covid, 19 testing and mitigation initiatives.

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So building on that progress. the administration successfully launched the at-home testing program which sent cost-free rapid tests to American households.

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A program that my family, my team, and thousands of the folks I have the honor to represent, have utilized personally.

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And of course, earlier this week, President Biden released his FY 23 budget request, and I was pleased to see this requesting robust funding levels to enhance the government's ongoing investments in

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emergency preparedness and response systems. The United States has made tremendous progress in our fight against Covid.

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19, however, the lack of Covid related funding in the FY.

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22 omnibus that just passed will make it difficult for our response.

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Teams to be properly resource, to continue to respond to the virus, and as we saw, all too clear with the emergence of the omicron variant waiting to provide funding.

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Once we are in a surge, will be too late. So the in administration has laid out the consequences.

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If Congress does not act to pass additional Covid 19 funding, including the inability to secure sufficient boosts, our shots, the inability to test, treat and vaccinate the uninsured the inability to maintain our

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testing capacity in order to fight Covid 19 in the future. The inability to purchase preventative treatments for the immunocompromised, and the inability to rapidly identify and assess new variants so in the

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coming weeks. The House expects to consider a supplemental appropriation bill to immediately fund our continued response to the covid 19 pandemic, so that we're better prepared for the next variant before it arrives and so that we

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can step up vaccination, testing, and therapeutic capacity both here and abroad. So there's no question.

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We still have a way to go as we continue working to respond to and recover from the pandemic and conversations like this key to ensuring that we're taking the appropriate actions to get there as quickly and as safely

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as possible. so thank you for the chance to be here today.

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Thank you so much, congresswoman for your remarks and if you have time for for a question before you go, I know you have to leave soon, but I just it.

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It's important that the points you raised about where we are right now with funding, and and it's it's good to hear that the talk of the supplemental is still alive, and and i've heard recently that maybe

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there's some cause to to be more optimistic than maybe a couple weeks ago about that.

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What do you think it's going to take to reach consensus on the way forward in terms of securing the funding that we need to make sure that we don't you know run out of tests for the public no

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it's a it's an important question I mean look it's hardly a secret that Covid 19 has become highly politicized over the last 2 years.

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I mean these days the the different perspectives on the virus seem to range from folks who don't think it poses any health risk at all to those who are hardly acknowledging the deeper understanding We have about it

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today compared to 2 years ago, and sadly the middle ground can often feel a lot like no man's land.

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So i'm not going to get into the specifics. on my colleagues views on covid 19, because we'd probably be here for a few days if we did.

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But there has been movement in recent days with republicans senators in particular laying out what they'd like to see in order to advance a covid funding package, and of course it's clear that we should be moving this

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funding without delay. but the reality is we have a slim majority in the House, and a 50 over 50 Senate. so there has to be enough of a bipartisan consensus to get this done I do believe we'll

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get there. Everyone is really pushing toward you know the end of this work period, which will be next week.

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So just as we have in the past, with the with the bipartisan infrastructure law and the omnibus package, it will definitely take some sacrifices from both parties to do so.

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But I I am not feeling as optimistic as as you are.

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The most important thing is that we get it done and that it addresses the core areas of need that the white house is laid out.

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That's testing and vaccination capacity protecting the immunocompromised and the uninsured, and certainly our ability to actively monitor and respond to future variants.

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So I look forward to keeping you all update on that progress and and working with you to ensure that our priorities get the consideration that they desperately need.

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Well, thank you so much. We will stay tuned and keep our fingers crossed on that one.

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But thank you so much for joining us. Thank you. And so now I will turn to our next speaker, Dr.

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Thomas Engelsby Tom it's great to see you Tom's, a senior advisor on the White House, Covid, 19 response team.

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Prior to this he served as a senior policy advisor for the Kovat 19 response in the office of the Secretary at Hhs a role that he held since February of 2,000, and 21 Tom is

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on leave as director of our Johns Hopkins Center for Health Security at the Bloomberg School of Public Health.

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His work is internationally recognized in the fields of public health, preparedness, pandemic and emerging infectious diseases and prevention of, and response to biological threats.

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Tom was chair of the Board of Scientific Counselors for the centers for Cdc.

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From 2,010 to 2,019. he has served on a wide range of committees and panels of the national Academies of Sciences, engineering and medicine, and during the covid 19 pandemic prior to Federal service

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he provided technical guidance to response efforts at the global Federal State and local level.

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So you've been so key and helpful in this response Tom, we're really pleased to have you i'll turn it over to you morning and thank you so much anita great to be with you all and a very special thank you

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to Congresswoman Trayan for her national leadership on the Covid 19.

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Response. You need to ask me to give you a sketch of where things stand and total testing efforts, and then and then turn to the testing work ahead.

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And so we start with where things stand on testing. Administration has been working towards 4 big goals.

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The first goal has been to increase the number of sites and programs for getting tested.

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At the start of the administration there were about 2,500 pharmacies offering free testing, and as of this week there will be about 16,000 pharmacies offering free testing in communities around the country in addition to that

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there are thousands of State and locally run community sites offering, testing, and generally that is, with full Federal support.

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And over the course of the past year. The Administration has also set up a range of free testing programs for specific higher risk communities, including a number of large testing programs for schools, long-term care facilities, community health centers and other other special

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communities just like the second big, has been to authorize a range of new tests for the U. S.

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Market, including over-the-counter rapid antigen tests as of January.

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In 2,021 there were. There were no antigen tests available in the Us.

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Market. And so to change this, the Fda created a streamline process for Otc test authorization and the fall.

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The Administration launched a new Nih program called Itap.

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That provides free, technical and scientific assistance to companies to help them get through the Fda authorization process.

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And the result of all of this is that there are now 13 over the counter antigen tests with Fda authorization and many other testing companies seeking authorization for their tests. Of course, a variety of other tests have made it through

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the process as well. The third goal that we've been in pursuit of is to increase the volume of tests available in the Us.

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And to get there. The Administration has used large procurements and the Defense Production Act and advanced market commitments, investments, and automation to help drive the market for testing. forward.

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So we went from, for example, Otc. tests on the market in January of 2021 to 490,000,000 over the counter tests available for the Us.

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Market in January of 2,022 also made a large point of care.

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Nat procurement and strengthen the supply chain, including the consumables that laboratories rely on more than 200 or sorry, more than 2,000,000 laboratory tests, or performed a day during the omicron peak and that

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is outside of, and in addition to over over the counter testing that's that was done which brings me to the fourth goal which has been to reduce or eliminate the cost of Covid testing for people living in America at the start

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of the administration. Hhs issued guidance that all lab and point of care tests were to be covered by Medicare climate insurance, and Medicaid, and then in January of this year, 2,022

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Hhs required that private insurers cover over the counter.

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Energy and testing Medicare has committed to covering those tests by early spring, and then in January, as Congressman Trayan noted, we launched the Kovat test Gov program, which is distributed more than 300 and

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50,000,000 tests to households across the country via the U. S.

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Postal service with new orders now being shipped to people's homes within 48 h after order, so I mean just end by turning to some of the testing work going on now and the important work ahead.

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So we are set to complete the 1,000,000,000 over the counter test procurement that the President announced at the end of last year that will occur.

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Hopefully sometime soon. the first half of that procurement is dedicated to Covid. test.

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Gov. The second half will comprise the first ever Us.

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Testing stockpile. we're going to continue The Federal program for free testing and community pharmacies.

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This program is going to have to pick up a lot more volume now that now that the uninsured program for testing has unfortunate ended as of last Tuesday.

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Uninsured people are now going to have a lot fewer places and opportunities to get tested, which is a really negative negative consequence of where we are.

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One good announcement to share today If you Haven't already today is the role out of Covid Gov.

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Which is a new website for the public to get information on Covid.

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Specifically in their own counties, as well as to find places to get vaccines, masks, tests, and treatments, and as part of that, a new test to treat locator went online today or last evening.

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And this site will show the public and their health. care providers where they can get tested treatment, or whether with a prescription they can get a treatment prescribed.

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Those sites. They're more than now more than 2,000 one-stop test to treat locations in the Country, which include pharmacy-based clinics state run sites, community health centers as well as va

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Dod and any health service. and finally, the Administration has publicly committed to sustaining and building the Us.

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Testing infrastructure for the medium in the long term, so that we don't have to go through the constraints that we all experience from many experience during Omicron, and as part of that effort we released a request a

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formal request for information Hhs did to industry in February to get best ideas from industry on how to sustain and extend the testing infrastructure in the time ahead.

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We received very robust responses across the board and Hhs has been analyzing and development its plans to move ahead.

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But the problem now is that the Administration cannot move forward with those plans to fund best ideas and initiatives without additional Congressional funding.

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So Congressional support will be critical to maintaining what has been developed and what can be developed in the time ahead, and to create any stable infrastructure going forward.

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Let me stop there and turn it back to you, and I am happy to take questions.

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Okay, Thank you so much. I can speak questions coming in already.

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So. thanks very much. Our next speaker is Dr. Gigi.

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Granville Gigi is a senior scholar at the Johns Hopkins center for health security.

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She's also an associate professor in the department of environmental health and engineering at our Johns Hopkins Bloomberg School of Public Health, Gg.

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Is an immunologist by training and during kovat 19. During this pandemic she's led our centers efforts to track the development and the marketing of molecular and antigen tests and serology

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tests as well as the development of national strategies. for Covid, 19 serology Tests and Sars Kobe to Sarah Studies in the United States.

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Gigi launched and leads the Johns Hopkins Center for Health security.

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Kovat 19 testing toolkit. She is also written about the scientific response to the Covid 19 pandemic and implications for national and international security.

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Thanks for joining us today. Gg: The floor is yours.

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Thank you. Thank you very much. Nita. so as anita mentioned. I direct the Covid 19 testing toolkit, and just want to describe a little bit about it.

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It's a web resource that provides up-to-date information about all the Fda authorized tests.

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So it gives information about the accuracy of Pcr.

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Tests of rapid engine tests and serology or antibiotics that show that detect.

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If you had previously been infected. We give information on how to use the tests and when to use them, and we also provide information about testing services.

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So if you're an employer. and you want to contract with a company to do the testing for your employees, But you don't want to do it yourself.

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We have a list of the the testing services that use.

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Fda authorized tests. So you know that you're getting that they're using quality tests.

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We have feature conversations, so people can learn from leaders who have implemented testing strategies in their own industry. So that includes the entertainment industry, the travel industry.

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We have some upcoming conversations for for Hopkins that how they implemented their testing strategy for the university so big a big testing implementation plan.

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We have conversations with a couple of different school systems and how They've used testing, and we have an upcoming conversation about the Olympics.

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How testing was done there, and also a giant 500 person wedding.

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That was done. That was the wedding took place during Omaha, and they managed to have it safe.

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A safe gathering because of their testing strategy so we have been gathering this information and presenting it as best we can to people so they can make informed decisions using testing.

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We've been doing this since spring. of 2,020 thanks to the Lida Hill Foundation, and the Gordon and Betty Moore Foundation, and we have a few observations over that, time, and I have i'll present 3

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of them. So the first is that diagnostic testing has so much opportunity in the future, not only because of Covid, or not only with Covid, because we're not done with it yet, but because of Covid people have

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long wanted to have more information about their personal health and there's been. People have used fit bits and fitness trackers for some time, but this is the first time we've had an infectious disease where the expectation for getting

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that health data has almost been matched with reality not quite as seamless as we would like, but it's it's definitely getting in the right direction.

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So people have used tests to make decisions that are important to them.

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When do together, how to protect vulnerable people in their family, when to send their child to school, and when not to?

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And you know the question is, why stop with Covid?

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There are lots of diseases for which it would be really fantastic to have this kind of health information so that people can protect vulnerable family members and can make important decisions to stop the spread of disease.

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So influenza comes to mind wouldn't it be wonderful to have a test that you were that you could use at home.

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So you can make a decision whether or not to be you know around people.

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That question of whether it's allergies or whether it's something more serious.

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If you have small children at home, is it a Is it a chicken soup and rest?

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Kind of situation, or is it a good idea to send to go to the doctor?

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These are the kinds of things that people want. and this is why diagnostic testing will have such a great future, and we need to keep investing in it.

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The second point is about preventing fraud. fraud has not been part of our our pandemic preparedness.

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Strategy up to this point, but because of our experience through Covid we know that it really needs to be.

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From this point for it forward, I that's how we got into this actually in the beginning, because in the early days of testing there were no Pcr tests available.

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There were no rapid engine tests available. What we had were anti-tests or serology tests, so that people could tell if they had previously had Covid.

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But in the early days a lot of the tests that kind of flooded the market did not have the.

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They were not good, and in some cases they were they gave it about as much information as flipping a coin.

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And that's not the case anymore. But you know those are that was why we wanted to present present accurate information about about tests, because people were making health decisions based on the results that they got so those are early days more recently

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We've had problems where there are pop-up testing sites that are just really vehicles for for identity theft.

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We've had some incidents where people are doing double billing for insurance, so that you know there's So this is something that we just need to deal with going forward.

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There there are consequences to health, so we do need to do what we can to prevent fraud in the future, and it's unlikely that a future pandemic will not have these kinds of issues at stake my final point is that we

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have built this incredible testing system, and we have gotten a lot of great information.

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We have managed to prevent disease transmission. people have been able to make decisions that are in the best interests of their families.

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We really need to keep it going. The school testing programs are a wonderful case in point.

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My children go to school in the Baltimore City Public school system, and they manage to test more than 40,000 students and staff every week.

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And this is almost as much as the New York City. Public school systems have tested.

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This is an incredible resource that has managed to preserve in-person school for a lot of students, because we've been able to limit transmission and have school be a safe place.

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To be. This is something that is not just going to be important for Covid and future variants.

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Unfortunately, there are additional Greek letters that come after Omicron that we might get to all know a lot more in better detail.

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But it's. also important for future disease a flu is another as a disease that is whipped through school in the past, and has shut some of them down.

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And so I think it's important to think big and how we can help protect

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Schools are so that they can stay open. businesses have also used this.

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Large employers have had great testing programs that would be ashamed to see go.

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So just like in this pandemic, has taught us that indoor air, quality, and ventilation, all these things are super important to prevent disease.

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Transmission, so of is testing, to be able to make good decisions, to perform surveillance, and to to have a healthier place for people to gather.

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So. thank you very much for the opportunity to talk to you today, and I look forward to your questions. hey?

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Thank you, Gigi. I will move on now to our next speaker, Susan Ben Meter.

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Susan is executive director of Admir Dx, advanced.

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Dx represents manufacturers of in vitro diagnostic tests and technologies.

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Adventure avmed Dx Member companies create innovations which allow early detection of disease, facilitate evidence-based medicine, improve patient health and health care, and enable personalized medicine while also often lowering overall

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health care costs, adammed d axes, the only advocacy organization exclusively addressing policy issues facing diagnostic manufacturers in the Us.

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And around the world prior to joining admin Dx Susan was senior Vice President at the Health Care Association of New York State focused on hospital and health system, policy payment, quality and health information technology, priorities the Susan You've been

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quite busy during this pandemic and so pleased to have you join us today.

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I'll turn it over to you now. yeah thank you so much.

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I am really happy to be part of this panel, and you know certainly.

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Thank the congresswoman for hurried leadership and i'm optimistic to you that we'll soon see supplemental funding to continue the increase.

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Important work that has to proceed in order to ensure that Americans are as safe as possible, and that we are taking you know, a global view of obviously what is a global problem as well.

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So I'm hopeful there, and I want to thank you Anita and she she for your leadership at the Hopkins Center for Public Health security.

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Your work here has been critically important to help policymakers, and and the public really understand some of the key dynamics in the pandemic and gigg your leadership on the the testing toolkit has been

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tremendous. If thank you for your interaction. they're and for helping show schools and businesses. you know that they can do it right.

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That testing is possible and the values there, and certainly Dr. Angles be, you know, really appreciate your leadership for the Administration for some time now, and really moving forward and expanding public private partnerships which I think are really been core to

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ensuring that Americans have access to testing, and to that end, you know, I just want to say a little. A little word about admin Dx.

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Member companies is Anita pointed out. Adam and Dx represents men manufacturers that develop tests and technologies for the commercial market.

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So that actually includes everything, from sample collections to the instruments that laboratories use to run tests.

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These include high throughput instruments capable of running thousands of tests in a single laboratory shift smaller instruments for use of point of care. Dr.

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Engels be mentioned point of care, molecular testing, instrumentation. And then, of course, the tests themselves from screening tests, diagnostic tests, serology tests, and the like.

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So all of those technologies have been really critical throughout the pandemic, and I would argue that when we think about responding to large-scale public health circumstance like the Kovat 19 pandemic we really need to

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ensure policy is focused on maximizing all available diagnostic tools for all appropriate use cases.

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So we want to use lab-based testing there's high throughput lab-based tests that were so critical early in the pandemic in particular, to ensure the volume of testing could be done to face what was

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unprecedented demand. The first test for the commercial market was available in mid-march of 2,020, and we've had a massive scale up since then.

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We turn data for 13 of the largest diagnostics companies that make up about 80% of the molecular market.

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They've shipped well over 800,000,000 molecular tests.

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Their customers that are laboratory so public health, laboratory where he's reference laboratories, hospital laboratories, and then to doctor in those these points about antigen tests, including Otc.

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You know well over a 1,000,000,000 ramp up has been tremendous.

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The point that ties in here is about that ramp up has been that increased capacity for laboratories.

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I see i'm getting and notice my Internet connections unstable. I'm gonna be mindful there someone could just flag for me if I need to turn the video off to help preserve that connection.

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Like we've seen a massive increase in instrumentation for laboratories across the country before the pandemic.

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There are about 12,000 molecular instruments again. those big platforms on which laboratories run tests.

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We've seen a 110% increase in those instruments. So we now have well over 20,000 automate instruments in the country, including increasingly Hadn't had molecular instrumentation.

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So there's a great opportunity there to gigi's point about how do we take what we've built now?

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And really expand it. I also think it's important when we think about those use cases right to cheesy's point like this has been a great opportunity for the diagnostics industry to really help ensure that Americans really understand well

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the value of diagnostics is screening tools as tools to really effectively diagnose conditions. And certainly diagnostics.

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Are used every day throughout the the healthcare domain with patients, or any sorry to interrupt the

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We? There are little blips, so maybe turn your camera off, for now I hate to say that.

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But okay, no, no, not at all. And apollo apologies. right? I wish we had that kind of stability with the Internet that we really need right now.

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So hopefully, you'll be able to to need to hear me think you know the getting the clarity and the administration has done a terrific job of ensuring that. Americans understand use cases for diagnostic tests.

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You know, Looks like we might might have lost Susan to take some questions, and maybe Susan could dial back in.

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Yes, sure happy, too and and sorry about that there's so much to learn there, and and it's already been like an enriching addition to the panel.

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So, thank you. Maybe Tom, I will start with you if I could if we've heard about the test to treat program, and and this initiative. it's great to hear that you know it's moving forward can you say a little bit

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more about it. Well, you know what the aspects are that of the program Is it? live now?

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And if people go on Covid Gov. they they can figure out where to go for that.

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And also would you expect that? Not just for covid but maybe to you know, if it's successful to you know, stay in existence for other infectious diseases like the flu?

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Sure. So the test to treat program was first announced by the President and the State of the Union, and really has been ramping up since that time.

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So it is now. it is definitely now operational. There are more than 2,000 sites, and they represent a combination of predominantly pharmacy-based clinics, but also community health centers, state-based sites department of

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defense has is standing up. sites Va: Any health service.

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So those sites are all those are online, and there are more being stood up every week and to qualify as a test to treat one-stop site.

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You need to be able to provide testing, clinical evaluation and dispensing of an antiviral all in one place.

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It's been the case since december that if your doctor writes a prescription for you to get an oral antiviral.

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Then you can do that, and that still is that's still widely available.

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There are many thousands of more pharmacies, where, if your doctor prescribes a prescription for an Orland tomorrow, you can pick them up and Seeb's is Walgreens and many other pharmacies.

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I think the larger larger area of work around tests to treat is a more focused effort to educate the public about the availability of antivirals, and for people who have, underlying medical conditions, define very broadly the value in

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taking these oral antivirals early on after you have symptoms.

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So that's a public education effort separate from that There is a more robust, increasingly robust effort to reach health care providers.

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There's been information available since last year but for for a variety of reasons.

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They've been underprescribed so health care Providers haven't been prescribing at the rate that you might expect.

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So there's a real effort to try to reach health care providers with good information to help them understand these medicines, and be more inclined to prescribe them.

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So it's all part of a larger effort to try to move move, more of these oral antivirals to people who need them.

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In a short time period, because, as the fda is authorized, these medicines need to be taken within 5 days of symptom on set right, and your second question, and you, i'm sorry your second question about whether this would be a

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predicate for something in the longer term. I think a lot of the structures that are being set up now could be a predicate for the longer term, but really the they are funding dependence.

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And right now you know that we we aren't able to even find a continuation of of the testing infrastructure for Covid.

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But ideally we would create a testing infrastructure that worked for covid influenza and other respiratory pathogens at a minimum.

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Thank you that's good to hear and susan welcome back sorry about that, is it?

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If it's stable Now i'd love to invite you to finish the rest of your remarks, and then we'll pick it up from there.

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We still have time for you. I certainly hope so, and I apologize for that.

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Of course i'm trying to dial in on audio 2 to double down on the technology, you know.

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I think, really, maybe I can shift a little bit to talking about.

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You know the the key issue of sustainability? right?

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We have built so much right. We have massively augmented the laboratory infrastructure in the country.

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We've increased point of care infrastructure We've done terrific work in partnership with the Us. Government.

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Thanks again to Tom's leadership and the leadership of his colleagues on the Otc.

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Front. I've got to commend really very strongly the individuals at the Nih.

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Who are running the radics. itap program that's the program town mentioned, that has really helped facilitate and accelerate consideration and approval of rapid antigen tests.

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So so we need to take really significant steps to hold on to this capacity, not just to get us through the rest of the covid pandemic, but to think about the future in 2 regards one is beyond covid for all diseases, and

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condition. What can we do to maximize access to testing as appropriate for all diseases and conditions, so that excess is equitable.

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Right diagnostics are foundational to inform clinical decision-making, and we can ensure.

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Given this new expanded capacity that we are taking deliberate steps again to increase that access for all Americans.

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And then we need to think about 2 obviously future pandemic preparedness really hardened that the Administration, for example, has set up the first. You know, strategic national stockpile diagnostic tests. You know we don't know what that Next,

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new pathogen is going to be in the future. but we do know that there are core technologies and diagnostics that can help us in early stages.

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Take, for example, the covid pandemic. We knew that we were dealing with a respiratory pathogen.

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We were scrambling to get access to samples to develop tests.

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But in the meantime we know we could exclude certain respiratory ailments like flu.

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For example, Rsv. So having a certain stockpile of commonly used diagnostics, and then diagnostic raw materials to quickly help test manufacturers build up at scale so i'm really excited

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about what lays ahead of us. We want to really roll up our sleeves with the administration and dig in.

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We did take the opportunity to provide some robust comments to the requests for information on how to sustain manufacturing capacity, and we hit really on both again that short-term preparedness and then longer-term preparedness.

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But ensuring that we're taking a look at you know policies from coding coverage and reimbursement to ensuring regulatory oversight of all tests, All of our member companies are regulated by the

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Fda. We think that's the right bar we'd like to ensure that there is, you know, appropriate oversight of all tests moving forward.

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So happy to dig into any of those areas, but really, so critically important to hold on to this capacity through warm-based manufacturing, contracting the strategic national stockpile protein and then really looking to how can

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we continue it to extend the reach of testing for all diseases and conditions and for future pandemic emergencies.

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But thank you so much, and your connection's perfect now. So while we have you, I wonder if you could talk to, and Tom mentioned also I tap, or have there been you know one of the regulatory hurdles

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that your members have identified during this response. and and you know I tap be a primitive body to help address those going forward, or what what kinds of innovations from the regulatory front?

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Do you think we might need? Yeah, great question. A couple of issues come to mind right?

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I mentioned access to samples that's a key issue our manufacturers really need to be able to access samples patient samples, viral samples so that they can develop their tests.

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And they can validate those tests, so ensuring that we streamline access to samples when the Us.

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Government has access, ensuring that again diagnostic manufacturers partnering with the Government quickly have access to the samples needed in test development.

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We've had some robust conversations with the fda about that we're looking forward to improving that policy.

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We think the Fda did a terrific job once it developed templates for diastic test developers to really tell developers what it was.

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The agency wanted to see and test performance. Take, for example, the rapid antigen tests.

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You know once that template was in place giving developers the clarity that's tremendously helpful.

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So we'd certainly like to see that continue moving forward I think, because the icab program has been tremendous and absolutely serves as a very, very strong model for what is possible in the future.

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Gigi mentioned other infectious diseases, for which the benefit of rapid tests is, you know, very, very clear flu, being one of them.

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Rsv. Certainly there are any number of infectious diseases where you know wouldn't it be great to be able to have that test sent to yourself to your house to be able to perform that test and take the appropriate steps

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to best care for yourself with the oversight of a clinician.

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So we think there is great potential there we're always going to need very high throughput laboratory based testing that's the goal standard of testing. that's absolutely essential.

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But again getting back to that theme of using every modality we have as appropriate to extend the reach of testing.

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So certainly. I think there's great promise and icap and I really hope that that program is sustained and expanded.

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And then and then finally really big picture on diagnostics. you know we are eager to see there's a bipartisan legislation.

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The valid act that would create a modernized regulatory apparatus for all diagnostic tests that would mean developers for the commercial market laboratory developed tests to ensure ensure that clinicians and

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patients have transparency, and to test performance and those tests are already reliable.

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So we're really here to work with Congress to improve and advance the valid act as well.

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Good, Thank you and in in terms of innovation for future tests.

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And Gg: We know that that you and the tracker have been looking very closely at all the new tests that have come out on the market over the course of this pandemic.

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What do you see in terms of this? You know the future of improved testing?

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What kind of scientific or technological innovations can can you imagine?

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And and you know, how do we get there? Well, there are a few different types of testing that that are not yet available for purchase.

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Are available that haven't been fda authorized yet, but there are a couple of Dna based or or Crispr based approaches that could have give you more potential to test for more diseases, and and and very rapidly so

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it's combining some of the benefits of pcr and some of the benefits of of the raption test.

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But it's you know there's a there's a lot of innovation and great ideas.

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There. I just know that the the demand is there and we saw that during Omica, and that people really wanted to have tests they couldn't get them.

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And you know that that was I think that is not going to go away and in, just even if there there will always be problems when there's high demand.

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But I think there's now this expectation I mean people this is new.

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I mean, if people forget. It was not that long ago, when we had the 2,009 a flu pandemic, and was not nearly as terrible as Covid.

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But nonetheless, you know, there was no nobody was like.

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I need to have a test to be make sure if I have flu or not like it was not a possibility.

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Now It's a possibility it's reality I think it's, you know it's now an expectation that it will keep getting better.

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Tom, one of our viewers, has asked if there's an effort to renew the funding for providing service, testing services for uninsured patients, and and what the rationale was for ending the program.

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So supplemental request that the administration sent down to Congress funding for the unshared program and there's certainly is strong interest in continuing that effort.

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But are no more funds in that program than, or that that fund ran out last Tuesday for testing and treatment, and is soon to run out for uninsured people who are seeking vaccination.

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And so yes, the administration is is very continuation but It's it's completely dependent on additional funding from Congress.

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So we need that in the supplemental yes, I mean that's that would be, I mean, certainly would be up to Congress to decide how to do that.

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But that would be. I think the proposal would be to have that be part of the rest of the supplemental funding request.

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Okay. Great. Thank you. And another question that, Susan. you might want to take on.

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What what can the Us. do to support development of lower cost tests like rapid tests for a dollar?

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Well, I think it's always important for to bells test performance with lowering costs right? We want to make sure that we're making available to Americans.

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Tests that we can stand behind that are high quality tests that have great test performance.

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Right. Gigi mentioned that early in the pandemic under the prior administration there was a policy that lifted a requirement for Fda, authorization for rapid serology tests.

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And so the market was indeed flooded with many tests to her point that were really no better than a coin flick.

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You know that policy was closed, that so-called loophole was closed.

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So all rapid antigen tests all over the counter test.

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Do you have to get fda authorization so I think that's a very important standard to maintain right it is in the public's interest and the interest of patient health to ensure that test performance is high caliber so that that's a really important

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thing, the role of the Fda. and ensuring that test performance.

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And I think once there is policy in place that that really supports the coding coverage and reinforcement, the clinical guidelines for usage of tests.

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And certainly, you know coverage not just by public payers, but by private pairs as well.

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Then, I think you'll see the market respond right There are certainly a number of manufacturers currently able to manufacture and are at scale high quality.

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Rapid tests, we can see a circumstance where that policy shift does change again to support that market, so that you'll see more economies of scale be able to come into place.

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But really important to ensure. We've got that really robust test performance. under the Fda.

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Thank you, and you get. Can I just add just a few words on it?

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So just to to note that Radx program which we talked about before, which is the which really runs the itap program for helping helping manufacturers get through the Fda operation process their intention is to move ahead with

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a program at Nih, exclusively focused on helping to bring down costs, either through production or cost of goods or packaging, or other approaches.

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But that also is subject to additional support from Congress. That was part of the supplemental request to continue to fund that and need The other thing to note, I think just is kind of a point of clarification.

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There is a lot of, I think anecdotal stories about how other countries had tests that work extraordinarily cheap.

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I think it's just important to compare apples to apples aren't just to oranges some other countries did provide free testing or very low cost, testing, but somewhere along the way the governments were we're making the

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purchases. so if this, if it was entirely subsidized, it was still the case.

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The Government was doing the subsidization and in the uk they're kind of moving through a different transition right now.

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They're actually moving away from providing as much free testing to try to create a market which they didn't have before.

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So they're kind of moving towards having people do more cost sharing of testing.

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Thank you so much for that. and There There are also some you know anecdotal things.

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We're hearing about, you know, Do rapid at home tests really work with Va. 2?

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Are they gonna work for a future variant, and that I see a question in the Q.

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And a from Madison Muller, from Bloomberg, and she asks the

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Some States are scaling back testing centers as our independent testing companies. at the same time.

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More at home tests are available. Is there any concern that we could miss rising transmission rates as more people switch to testing at home, and they may not report infections.

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I could, I could start with that. So at this point we still have, on the order of 850,000 laboratory-based tests reported every day.

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So we do have a a strong system in place to be able to detect friends and testing in terms of overall numbers percent tests that are positive.

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It is true that there is a larger shift now to switch over to counter testing that's definitely happening, and there are various efforts under way to try to assess whether people might be willing to voluntarily report some fraction of those

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tests that are being performed at home. but we do.

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I think Cdc. still does have confidence that they will be able to detect trends.

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Certainly trends of rising. Va. 2 placing prior strains.

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We certainly want local testing programs to continue. to the extent that they are needed.

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Certainly the Federal Government hopes that State and local programs will for testing will continue and are not are not scaled down.

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There is support continues to be fema a 100% reimbursable fema support for local testing efforts.

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And so we're certainly hopeful that that state and local programs will continue.

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And now, more than ever with the end of the uninsured funds, I think people will rely on those programs.

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Jump in, Andita: Yeah, yeah, and I totally agree with everything that Dr.

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Angles B. right to help ensure that we're maintaining that capacity.

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And I think the question is really an important run. like How do you really ensure that we're doing it.

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We can't either of everything you can to track transmission There is a strong sequencing program that is in place.

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There was, you know, a pretty robust funding policy put forward for sequencing, so we can track variants for sure.

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But we we have seen in the past right when the demand for testing declines, as it did before Delta, so early summer of 2021, we saw a precipitous their decline in demand.

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And then we saw a contraction right of sample collection sites.

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Some companies curtailed some degree of manufacturing capacity right?

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There was really just not those demands signals in place.

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So I do have concerns about that I worry about a constriction of sample collection sites. Well, we've got the lab capacity.

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Now we've got the manufacturing capacity for laboratory-based, testing.

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We should expect to see a contraction there again because of the lack of demand signals.

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So another reason why We're really encouraging you know members of Congress to please support that supplemental to ensure that capacity is maintained, and and to Dr.

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Ingles fees, point You know we're hopeful also that states and localities that have sample collection sites that maybe are also vaccination sites.

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You know, maintain that infrastructure because that's so critical, right?

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If there is a shortage of sample, collection sites the backup, the capacity to be able to really leverage laboratory volumes that we know we can hit.

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We've done about 3,000,000 a day at the height of omicron and laboratory-based testing.

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So just another, you know, plug for our colleagues on the hill who are listening today to please, you know, work as swiftly as possible, and thank you To ensure the supplemental is move forward thank you I just add

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one more thing. This is another reason why it's really valuable to have these like the these constant surveillance like the in the school system.

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You know, these kids are getting tested on a weekly basis. And so we saw, at least in Baltimore City.

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We saw a trend of, you know, upward for our ownicon cases, and we realized we were able in retrospect to see that you know it was.

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See it coming. and and so we this kind of kind of constant surveillance is really helpful to detect trends, which is really all

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All you're able to get because of the people using it. rabbited at home tests and teach you another quick question for you.

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I know you've been looking into environmental monitoring too, for Kovat.

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So what role do you anticipate for widespread environmental monitoring?

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For pathogens, for instance, from wastewater and air sampling.

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It seems critical to distinguish diagnostic tests from monitoring, widespread presence of pathogens.

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Yeah wastewater monitoring is so it's a really exciting area.

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And About 80% of Americans can use their Their sewer system is is connected to, you know, can be connected to surveillance.

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So this is a great opportunity for more development. we need there's a lot of work that needs to be done to to support public health.

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To be able to collect this data. This is a new method of surveillance, and and to support public works which, you know, has not really had much of a role in the public health infrastructure.

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Before, So they operate on razor thin margins. and we need to think of new ways that we can help to make this kind of surveillance even more powerful because it's it's it's got a

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lot of potential, because not only for covid but for a lot of infectious diseases, and also to track antibiotic resistant bacteria as well.

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So it's really an exciting area, air sampling as well has a lot of potential for for detecting new pathogens as well as once we're looking for.

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Thank you good to hear and i'm we're really at the end of time.

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But so, Tom, I maybe i'll just give you the last bite, and if you talked about how the administration put out the request for information for manufacturers, what are you learning any like highlights that are helping to figure out how

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to manage the the surgeon waning of demand in the supply chain.

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Well, I think it's still in in process so only a couple of maybe a couple of observations.

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People have asked why some people would say Well, why can't we make the transition for the transition to commercial market more quickly.

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I would say that in this case testing is some extent in the commercial market, but it is extremely vulnerable to demand changes. So we have heard very consistently from your manufacturers. that without you more stability.

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They can't afford to keep producing tests at the level they would produce them sufficient for any kind of uptick or search.

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And so it's just it remains, clear that this is a problem that while it can be well, we can have pharmacies and businesses buying tests on the market, the market alone is not going to work to make the testing available We

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need for surges or emergencies, or consistency or to keep them market stable.

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So that's a very consistent theme and I think as as Susan has said, we, we just need to have a really strong working partnership between industry in the government that's clear from the responses that that's what companies

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are seeking. Thank you so much. Thank you to our panelists for an excellent discussion today.

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Thanks to our viewers for joining us today, our next session of this Capitol Hill Steering committee will be on May the 20 fifth, and more information about that session will be sent out soon.

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We're taking April off so you can do your taxes.