

Center for Strategic and International Studies

Online Event

“Innovation, the Bayh-Dole Act, and March-In Rights”

Keynote Address by Congressman Ami Bera

RECORDING DATE:

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FEATURING:

Representative Ami Bera, M.D. (D-CA),

Co-chair, Health Care Innovation Caucus;

Commissioner, CSIS Commission on Strengthening America’s Health Security

WELCOMING STATEMENT:

John J. Hamre,

*President and CEO, and Langone Chair in American Leadership,
CSIS*

*Transcript By
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John. J. Hamre:

(In progress) – president of CSIS. I’m here to really just welcome. My role here is ornamental only. And it’s simply to welcome you all and say a sincere thank you to Congressman Ami Bera, who is going to be our keynoter today.

The topic we’re going to discuss – we’ve got a wonderful panel to review this – is what’s called March-In Rights. March-In Rights is a – is a curious term, but it’s a term that relates to one of the most foundational acts that Congress passed about 40 years ago called the Bayh-Dole Act. The Bayh-Dole Act is the reason that we all got vaccines within a year after COVID hit. It was because Bayh-Dole made it the law of the land where technology developed in government laboratories or in government-funded research must be commercialized, must be brought to the market. And within the Bayh-Dole Act there’s a very small provision that’s called the March-In Rights.

The original purpose of March-In Rights was to say if a company bought the legal rights to an invention and then just wanted to sit on it because they were trying to protect some other product they had, the government come could in to reclaim those rights and give it to another competitor. It was to make sure products got to the market. But now it’s being interpreted in different ways. And we want to discuss that.

We’re very fortunate today to have Congressman Ami Bera with us. He’s a medical doctor by training. But he’s also now a member of Congress. He’s a distinguished member of Congress that’s been serving in high-level committees throughout the Congress, and really pioneering, you know, a modern America, an America that embraces technology, embraces the future, and adapts public policy to accommodate that. I’ve seen him lead in so many different ways. And today he’s going to lead us in this conversation about Bayh-Dole and March-In Rights.

Congressman Bera, it’s such a privilege to have you with us. Let me turn to you, sir. Thank you.

Representative
Ami Bera (D-CA):

Yeah, Dr. Hamre, thank you for that generous introduction and, you know, for all the work that CSIS does. Obviously, I’ve had the pleasure of sitting on some of your panels and working groups. And continue to really appreciate the work that you’re doing.

And this is obviously a very timely topic. You know, as we think about the pandemic and can kind of see the light at the end of the tunnel, Dr. Hamre touched on, you know, could you ask me 12, 14 months ago – or, asked most of the medical professionals and the smart people out there if we’d have a vaccine to defeat Covid-19, most of us were saying 16-18 months at the earliest, more likely 24 months. And let’s hunker down and get this. But the truth is, we have three incredibly safe and effective vaccines within less than 12 months.

And much of the public probably thinks, well, they started working on these vaccines, you know, at the outset of the pandemic. The truth is, for the mRNA technology, this is something that the federal government, the NIH, has been investing in for years. And the return on that investment is that we have these remarkable vaccines that will help us end this pandemic. And in truth, as we look at our history in, you know, the latter half of the 20th century, it was the investments that we were making in the '50s, '60s, '70s in our academic institutions, our great research institutions, you know, in the NIH, in the NSF and elsewhere. And these are investments only the federal government can make because you're thinking about ideas and research that you don't know what that return on investment's going to be.

We don't have to guess what that return on investment was because we saw all the industries that came out of all of this R&D. You know, we built the pharmaceutical industry, cures for cancer. You know, helping us manage, you know, chronic diseases, but also developing the internet, you know, developing all this digital technology, et cetera. That at all came from federal investment but in partnership with the private sector, in partnership with academia, and, you know, it's hugely important for us to protect those federal investments.

And, you know, that's why this topic is so important because we're seeing a renewed debate over what those investments will be like in the context of what, truly, is a great power competition with China and others. And if we look at, you know, investment in R&D as a percentage of GDP where we used to be the top in the world, we now rank, you know, much lower than that, and China is top in the world, I think, spending close to 2 percent of their GDP on research and investment. The panel will correct me, but I think ours has now shrunk to about .7 percent of GDP, whereas, again, in the '50s and '60s we were probably closer to that 2 percent GDP number.

The reason why this is so important is when we think about, you know, issues of artificial intelligence, quantum computing, et cetera, whoever discovers and creates these industries is going to have a huge advantage as they go forward in the 21st century.

So, you know, I'm grateful that the Senate is having a debate as we speak right now on these investments in R&D. We're having a similar debate and we've seen, you know, in President Biden's budget and some of the requests that are coming to the House of Representatives a desire to increase research and development funding in these areas.

Now, the second piece of why innovation is so important is also protecting these patents, and that's where, you know, you're seeing the March-In Rights start to come in. Obviously, I understand the debate that will take place over some of these TRIPS waivers with regards to the mRNA vaccines and the technology that is uniquely American technology.

I think we have to be very careful that we limit that debate to the pandemic, and in – as opposed to there are some members of Congress who want to take these March-In Rights to everything, to all pharmaceuticals, et cetera. I think that would kill, you know, some of our innovative edge as well as some very important industries to the United States, and I think that that would set a dangerous precedent.

On the vaccine side of things, I also think we have to approach this with caution, and, in truth, it's not going to be very easy to build and develop the manufacturing capacity for mRNA vaccines. There are other vaccines out there that you, certainly, could license much as the AstraZeneca vaccines have been licensed to the Serum Institute in India and elsewhere. That could help us ramp up manufacturing capacity.

I also think, you know, Pfizer and Moderna could partner with other companies like Merck and others that have some vaccine through licensing agreements, et cetera, to help ramp up manufacturing to the extent possible. So I think that debate is still going to take place, but I would say with regards to the pandemic and vaccines, let's keep that debate very narrow and let's be very careful that these March-In Rights don't extend to so many other areas in industry.

And with that, Dr. Hamre, folks aren't here to listen to me. Let me kick it back over to you folks so they can learn from the panel.

Mr. Hamre: (Laughs.) Well, I think, Congressman, we heard exactly what we needed to hear from you, which was a thoughtful wise comment about the importance of intellectual property being a foundation for America's prosperity, and I want to say thank you.

You know, all members of Congress are elected to represent a region but also be a national leader. Very few of them are national leaders, but you are. Thank you for what you've been doing, Congressman.

Rep. Bera: Well, thank you. I appreciate it.

(END)