

“Bayh-Dole and the Coronavirus Crisis” Video Webinar

April 23, 2020



Stephen Ezell (00:00:00):

Good afternoon from Washington, DC, and thank you for joining us. I'm Stephen Ezell, the Vice President of Global Innovation Policy here at the Information Technology and Innovation Foundation. And we're delighted to host this event on Bayh-Dole and the coronavirus crisis, in collaboration with the Bayh-Dole 40 coalition.

Stephen Ezell (00:00:19):

As ITIF wrote in our report, the Bayh-Dole Act's vital importance to the US life sciences innovation system, the 1980 Bayh-Dole Act, by conferring the intellectual property rights stemming from federally funded research to universities, research institutions and small businesses, has since catalyzed a tremendous amount of American innovation in the life sciences and other sectors. At the time, it was in 1980, as The Economist wrote, perhaps the most inspired piece of legislation America had introduced in the past quarter century. It has since been emulated by some two dozen countries throughout the world, and it's going to be absolutely indispensable towards solving the coronavirus crisis we collectively face today.

Stephen Ezell (00:01:00):

With that, let me introduce our panel and turn the discussion over to our moderator Joe Allen. Joe Allen, now the president of Allen Associates, was truly the original architect of the Bayh-Dole Act, in his capacity as a professional staff member on the US Senate Judiciary Committee in the late 1970s for legendary Indiana Senator Birch Bayh.

Stephen Ezell (00:01:20):

In the years since, Joe has served as Director of the Office of Technology Commercialization at the US Department of Commerce, and as President of the National Technology Transfer Committee Center. Throughout, Joe has been a tireless advocate for Bayh-Dole and its catalytic impacts on America's world leading innovation ecosystem.

Stephen Ezell (00:01:40):

Next, we'll hear from Dr. Mark Rohrbach, who serves as Special Advisor for Technology Transfer at the National Institutes of Health, where he analyzes the interrelationships of NIH research with technology transfer, intellectual property, innovation policy and public-private partnership activities. Dr. Rohrbach previously served as director of the NIH Office of Technology Transfer and as Director for the Office of Technology Developments with the National Institute of Allergy and Infectious Diseases.

Stephen Ezell (00:02:10):

Next, we're joined by Wendy Holman, who is the CEO and founder of Ridgeback Biotherapeutics, a biotech company focused on developing treatments and diagnostics in the [inaudible 00:02:24] orphan and emerging infectious disease domains, including the coronavirus, for which Ridgeback currently has the only oral, direct acting antiviral treatments in phase one clinical trials. Wendy, thank you for your innovation. Ridgeback has also worked on Ebola treatments, and she serves on the presidential HIV/AIDS Advisory Council.

Stephen Ezell (00:02:46):

Last but not least, we're joined by Jon Soderstrom, who serves as Managing Director of the Office of Cooperative Research at Yale University, where he's responsible for coordinating the university's technology commercialization and faculty innovation activities. Since joining the office in 1996, he's helped Yale colleagues spin out over 25 new ventures that have collectively raised over a half billion dollars in venture capital. Jon previously served as director of program development at the Oak Ridge National Laboratory.

Stephen Ezell (00:03:18):

Lastly, let me note for those viewing that we welcome you to submit questions via the Slido application, which is available on our event webpage. And if you're watching on YouTube, you can follow the link in the event description to the Slido page to submit your questions, which we'll take in the last 20 minutes.

Stephen Ezell (00:03:39):

With that, Joe, let me turn the conversation over to you. Thank you.

Joseph P. Allen (00:03:43):

Thank you very much. I really appreciate it. I want to start this program by thanking Rob Atkinson and Stephen and Rachel and all the great people at ITIF. They've really worked hard to put this program on, and we certainly appreciate, I think it's an important topic particularly for what we're going through.

Joseph P. Allen (00:03:58):

As Stephen said, my name is Joe Allen, I'm the Executive Director of Bayh-Dole 40, which is a coalition of organizations and

individuals which have come together to celebrate the anniversary of the Bayh–Dole Act, which really has revolutionized the commercialization of federally funded inventions. It's hard to remember now, but before Bayh–Dole passed in 1980, very few inventions made with federal funding were commercialized, because the government took them away from the creators and tried to license them non-exclusively and they basically destroyed the incentives of the patent system.

Joseph P. Allen (00:04:32):

Bayh–Dole changed all that, because it allows academic institutions and companies working with the federal government to commercialize their inventions. It's made a tremendous impact on protecting public health. It's a driver of our economy. And it's one of the things now that the US is leading the world in, and in fact, Bayh–Dole has become a best practice internationally.

Joseph P. Allen (00:04:52):

It's hard to imagine now, but when we started by Bayh–Dole 40 Coalition before coronavirus just a couple months ago, no one could have imagined that we would literally be talking about public-private sector partnerships, perhaps not being too dramatic, defining how the welfare of the world is going to fare in the COVID-19 crisis. So what we thought we would do is take the occasion of bringing together some of our leaders in the federal government and industry and academia to talk about how these partnerships work, what each party brings to the table, and the role that patents and licenses play in taking a federally funded invention out of the laboratory and actually making them into a useful product. And in this case, particularly something that can help alleviate the crisis that not just the United States, but the whole world is facing right now with COVID-19.

Joseph P. Allen (00:05:43):

So I think I'd like to start with asking Mark Rohrbaugh a question. Since NIH is so prominent, we basically see you on NIH featured every day on the news, appropriately. Mark, could you just walk us through how NIH is partnering with the private sector, what each party is bringing to the table, and what the benefits are to not just the American public, but the world, which is actually waiting to see if we can do something to alleviate our current suffering?

Mark Rohrbaugh (00:06:24):

Yes, Joe, it's all hands on deck. NIH, with its extramural funding to universities and research hospitals, the NIH intramural program and companies are all working together on new drugs, vaccines, diagnostics and devices to address the pandemic. It's not just a one way street with NIH supplying the funds. Companies are offering up their resources, their intellectual property and expertise and taking on large, risky investments.

Mark Rohrbaugh (00:06:58):

For example, the recently announced Active program was developed to rapidly respond to the challenge. This is the accelerating COVID-19 therapeutic interventions and vaccine program. It's a public-private partnership between the Department of Health and Human Services. It's three operating divisions, three of its operating divisions, the NIH, the FDA, CMS, and a number of pharmaceutical companies with coordination from the foundation for the NIH.

Mark Rohrbaugh (00:07:29):

NIH funding has not only produced significant advancements in science, but also new inventions that are developed by companies under partnerships supported by the Bayh–Dole Act. This biomedical research and development enterprise is benefiting us now in the context of this new public health challenge.

Mark Rohrbaugh (00:07:48):

In partnering with companies, NIH complements industry by supporting areas of research that are too high risk, early stage or broad spectrum for private sector investment. NIH studies elucidate biological systems with published results that benefit the entire research community. Human Genome Project is a good example of this.

Mark Rohrbaugh (00:08:12):

NIH funded clinical trials involve first in human studies of potential new drugs and vaccines. They also involve studies of long-term progress of disease in populations and better ways of managing existing treatments. One field often leads to advances in another field. For example, what we've learned about the immune system in research for HIV/AIDS is now benefiting us today, as we design new treatments and vaccines for COVID-19.

Mark Rohrbaugh (00:08:49):

Issues of drug pricing have been raised for years and are of concern to the American public. Because of concerns in the '80s about the price of AZT, the first drug for treating HIV/AIDS, NIH I added a reasonable pricing clause for products developed under its collaborations with companies, and in its licenses of exclusive patent rights. By 1994, five years later, industry

partners had backed away from many agreements with the NIH. As a result, the NIH director at the time hosted public meetings to learn about the effect of the clause.

Mark Rohrbaugh (00:09:28):

The consensus of patients, companies, researchers, was that the clause, the reasonable pricing clause had not provided benefits, but it formed a wedge to reduce the collaborative opportunities to develop new products. NIH then removed the clause in 1995 and collaborations rebounded after that.

Mark Rohrbaugh (00:09:51):

Similarly, NIH has declined to exercise its march-in authority under Bayh–Dole, in response to several requests over the last 20 years to address the prices of drugs utilizing patented technology funded by the NIH. In each of those determinations, NIH directors have said that the march-in provision of Bayh–Dole does not authorize the control of drug prices by NIH. No other federal agency has disagreed with this interpretation since the beginning of Bayh–Dole 40 years ago.

Joseph P. Allen (00:10:28):

Thanks, Mark, actually, we'll get into the issue of march-in rights and some of the other things that have come up, because that's something that continually keeps arising.

Joseph P. Allen (00:10:38):

Wendy, we really appreciate you being with us. Wendy is actually working right now probably 24/7, other than the hours she's giving to us, to try to get her new product through the pipeline. And as Stephen said, it really is exciting. Could you tell us something about the nature of the virus that we're up against? Because you've actually looked at it as much as anybody. And also describe what it is that you're trying to develop now.

Joseph P. Allen (00:11:02):

And back to what Mark said, some people get the impression that when companies license a federal technology, they're from a university or a federal laboratory, they're getting a free ride. So can you address what you're bringing to the table and the kind of risks and expenses that your small company is undertaking?

Wendy Holman (00:11:20):

Absolutely. Thanks for having me on. I guess to start off with, to talk about COVID-19, as we all know, SARS-CoV-2 the virus that causes COVID-19 was only recently described in January. And if we think about the last three months, how much we've learned, we're still racing to keep up with ourselves.

Wendy Holman (00:11:41):

But the one thing that's very clear is that the disease has many stages. The virus, like all viruses, is starting to mutate, thankfully not too much. But the important features of that are that there will never be a one size fits all to this disease. What you use to help patients at early diagnosis will be different than what you use to help patients at later stages who are on ventilators.

Wendy Holman (00:12:07):

And what vaccine candidates you have, coronaviruses are weird viruses. There's a reason there's never been a vaccine for a coronavirus. My guess is that we'll have to have multiple platforms. And there will not be just one company that solves all these problems. This needs to be a collaboration of tens if not hundreds of companies to get multiple solutions. So that was the first part of your question.

Wendy Holman (00:12:32):

And then to talk a little bit about what we're doing, we have a license from Emory's drive group, EIDD-281, which is a potent antiviral against SARS-CoV-2. And the reason why we think of having an oral antiviral is important is because our goal is to keep people out of the hospital and off ventilators. And while tremendous work was done in Emory to do very early stage work on discovery of the compound, the real capitalists are being deployed now.

Wendy Holman (00:13:08):

I say that because we are spending a tremendous amount of time, energy and money in developing our clinical trial plan, getting clinical trials started, as well as developing manufacturing at risk. I say at risk, because manufacturing without any proven clinical data is completely at risk. We're working on not making tens of thousands of doses, but millions of doses to provide if the drug does in humans what it does in animals.

Wendy Holman (00:13:35):

Because the worst thing that you can do is get to a win and show a good effect and not have drug for people. So all these things are being done at the same time. And so while initial work was valuable and important, as far as dollars associated with it, it's a de minimis amount of money compared to what happens throughout the process.

Joseph P. Allen (00:13:58):

So just to follow up, if God forbid your technology doesn't work and let's all hope it does, is government or somebody going to step in and make your losses good, or what's the impact on your company if it doesn't work?

Wendy Holman (00:14:12):

Nobody's going to make those losses good, unfortunately. Those will be our losses to take. I say that, obviously, the financial sting is very real. But there's also a big, personal risk. I say that, we're in the midst of hiring a lot of people to get this work done, and we need the best of the best who are willing to be working seven days a week, around the clock with children at home that they're trying to get homeschooled, and all the other things that all of us are dealing with in this crazy scenario.

Wendy Holman (00:14:45):

And people are leaving various jobs, where they have longstanding and having to resign over a phone call in a very uncertain economic time. And so to get people to come over, they're investing a lot in us personally, because they believe in the mission, but they also want to have an answer to COVID-19.

Joseph P. Allen (00:15:09):

Great, thank you.

Stephen Ezell (00:15:10):

There's opportunity cost for you as well, Wendy, right? You've had to put other promising drugs you might be innovating, research aside, while you're trying to address the coronavirus.

Wendy Holman (00:15:20):

Well, absolutely, that is fair. But I as well as everybody within Ridgeback Bio believes this is the only thing that we should be working on. Because if we can get past this, we can move on to other diseases. But right now, this could hit everybody.

Joseph P. Allen (00:15:37):

Well, I think one thing that the public and private sector have agreed on is this is the number one priority. I think a lot of folks have basically shifted into overdrive to try to solve this crisis.

Joseph P. Allen (00:15:48):

Jon Soderstrom, almost every day we read about some exciting new technology coming out of academia. So can you describe, it looks like a real all hands on deck as Wendy described in our academic research institutions. Could you talk a little bit, what's going on there? And also what's going on at Yale to respond to the crisis?

Jon Soderstrom (00:16:07):

Sure, Joe. Wendy had it right. It's everybody's priority right now, is the singular focus of most all academic research. It's interesting, I've never seen the galvanization of the academic resources that we've seen in the last few weeks. It's really quite remarkable. And it's everything from engineering schools, not just at Yale, but across the country and probably throughout the world, who have come together to do things like design new types of protective gear that clinicians and frontline first responders can be using, from facial shields to face masks to respirators and alike, to actually dealing with shortages like ventilators. We're trying to figure out new kinds of designs for simplified versions to splitters off of similar lines. To repurposing drugs, to seeing what kinds of things we have on the shelf that we might be able to use.

Jon Soderstrom (00:17:05):

In fact, my team has spent the better part of the last month putting together an IND (investigational new drug application) so that we can actually do a clinical trial on a drug called subederone for which we got the active pharmaceutical ingredient from one of our venture partners, RA Capital. We've gotten gifts from various sources, including the Blavatnik Foundation to help us actually formulate the material. We've had regulatory consultants volunteer, this has been quite amazing to see this mustering of resources, not just at Yale but everywhere.

Jon Soderstrom (00:17:41):

And it's really exciting, because we know we have the best and brightest mind power focused on this right now and it is truly

amazing. And as Wendy pointed out, it's a partnership, it's government, it's companies, it's venture investors, it's academic researchers working together all for a common goal.

Joseph P. Allen (00:18:04):

That's actually really inspiring. Appreciate that. Stephen, you had mentioned in your opening remarks and ITIF did a really nice study about the impact of Bayh–Dole on the life sciences. Bayh–Dole is impacted a lot of technologies, but particularly in the life sciences. The Comptroller General testified in our hearing on Bayh–Dole that before Bayh–Dole when the government took inventions away from people that created them, and tried to license them non-exclusively, not a single drug had been developed from NIH funded research.

Joseph P. Allen (00:18:33):

So could you just summarize for us what you found in your study about what the impact of Bayh–Dole has been in the life sciences, and why that's really relevant to how we can respond to COVID-19 right now?

Stephen Ezell (00:18:45):

Absolutely. Well, what we really don't understand is that the United States used to be a global also ran in life sciences innovation. And in fact, in the latter half of the 1970s, European headquartered companies introduced more than twice as many new to the world drugs as did American ones.

Stephen Ezell (00:19:03):

And at that time, just about 10% of new drugs introduced to the world were introduced first in the United States. To address that, in the early 1980s, US policymakers implemented a concerted set of policies whose intent was to make America the world's innovation leader. That included policies such as dramatically increasing federal investments in R&D, channeled through NIH to the universities. Tax instruments like the R&D tax credit, the orphan drug tax credit, and the Bayh–Dole Act, which was absolutely instrumental in catalyzing the impact of federally funded research at universities, in terms of being able to license those technologies, so we can launch new companies.

Stephen Ezell (00:19:48):

And the data is astounding. In the first 20 years after Bayh–Dole was introduced, it led to a tenfold increase in academic patenting activity. Since Bayh–Dole was enacted, in fact since 1996 actually alone, and as a result of Bayh–Dole more than 100,000 academic patents, 420,000 invention disclosures and 13,000 companies have been launched as a result of university academic patenting licensing activity. And that all comes directly from Bayh–Dole.

Stephen Ezell (00:20:24):

When we look at life sciences specifically, discoveries resulting from Bayh–Dole have informed the research and development of more some 300 new drugs and vaccines since 1980. And in the context of the coronavirus crisis, we're seeing companies like Moderna, like Cepheid, who have credited have some of the key technologies like for mRNA messaging delivery technology, that they've licensed from universities or national labs, that have been instrumental to their development of diagnostics, therapeutics for vaccines for the coronavirus.

Joseph P. Allen (00:20:57):

Thanks. So it actually sounds like the current system seems to be working.

Jon Soderstrom (00:21:00):

Hey, Joe, can I just jump in? I just want to feed off of something Steve just said, which is, I'm going to just talk about my university, Yale. Over the past 15, 20 years, we have launched six new drugs with our industrial partners. But we've launched 35, 40 new ventures that are developing 40 more drugs, that are in various stages of clinical and preclinical development. Those companies collectively have raised \$1.7 billion in professional venture capital. And in terms of all-in capital from public and private sector, it's over \$7 billion that's being dedicated towards developing these drugs. That's the sheer size of what it takes to bring these things to the market.

Joseph P. Allen (00:21:50):

Well, that's a great lead in to my next question. We're going to start posing questions now for the whole panel. Actually, as Jon just did, we welcome anybody to weigh in, because this is a collegial discussion.

Joseph P. Allen (00:22:02):

The fundamental premise of Bayh–Dole is that rather than having Washington try to micromanage technologies, technologies are best managed by the people that create them either at universities, companies or federal laboratories. And when you're

licensing a technology for development, that license has to be based on the inherent risk and expense needed to take that technology from the laboratory and turn it into a useful product.

Joseph P. Allen (00:22:26):

Now, some people are arguing that during this crisis, that should be set aside and that any COVID-19 related technology should either be not patented or should be only licensed non-exclusively under the theory that's going to make it more available and it's more fair. I'd like to pose to the panel, if we took away the flexibility that Bayh-Dole gives right now, and says there's a one size fits all, that any COVID related technology there has to be not patented or it can only be licensed non-exclusively, what impact would that have on our ability to meet this crisis?

Wendy Holman (00:23:05):

I think that you kill innovation. I say that having licensed 280i from Emory, it would have been irresponsible of me to have licensed it, if I didn't think I could raise money around it. I say that because Congress did a tremendous act by pumping a lot of money into the system to help out drug developers. I have applied for federal funding and I haven't received a penny. I actually haven't even received a phone call back.

Wendy Holman (00:23:31):

And it's interesting, because we are the only direct acting antiviral that's being studied in humans right now. I recognize the system has, that they're trying to work through the kinks and trying to get money to companies at some point, but to have sat around and waited for that would have been a big mistake.

Wendy Holman (00:23:53):

If we want to get this country back on its feet, which we will, we have to run not walk. If I had licensed it in a non-exclusive way, there's no chance I could have raised money around it. So it would have been a nice little science experiment, I guess, without the possibility of actually making it into people.

Joseph P. Allen (00:24:17):

I think we're at the point now where science experiments are interesting, but this is no time for just having papers on the shelf.

Joseph P. Allen (00:24:23):

So let me ask a question to Jon and Mark, because you've been involved in this for a long time. Can you think of a single example of a successfully developed drug or vaccine that came out of a federally funded invention that was licensed non-exclusively?

Mark Rohrbaugh (00:24:38):

Joe, certainly not for patents on the composition, the core technology and the composition. So it can't be one size fits all. We all have research tools and standards and technology that can be used as is, and doesn't require a lot of investment and risk. And those are licensed non-exclusively.

Mark Rohrbaugh (00:24:58):

Whereas core technologies that are needed to bring an FDA approved drug, vaccine therapeutic to market requires some level of exclusivity by a company, as Wendy said, for investment. And more so than ever, in the last 40 years, new technologies are being developed by small companies that need venture investment, and less so than 40 years ago by big pharma, which then take on the later stage development after it's been developed at the early stages through small companies.

Jon Soderstrom (00:25:39):

Yeah, Mark's making a very important point, Joe, because Wendy's company represents the way biotech innovation is translated from NIH funded research academia into the marketplace, is we have to work with companies like hers, to actually move these things forward. And she's reliant on venture capital and venture capital basically has a fiduciary responsibility to its limited partners, that they're going to give them a return on their investment. And they would be in violation of that fiduciary responsibility to be simply investing it in things that can be copied and for which they would never be able to receive any kind of a gain.

Jon Soderstrom (00:26:19):

So, if I look at just all the different drugs that we have in our pipeline right now, almost all of them started with a biotech company, with a startup or a very small venture that became big, only because it was successful in developing a successful therapeutic treatment. But in order to do that, they had to raise hundreds of millions of dollars to take the drug through the preclinical development steps and into the market, into the clinic itself.

Jon Soderstrom (00:26:48):

A clinical trial today costs \$1 million a day. Forget about the indication, it's going to cost you \$1 million a day. They are not cheap to run. The government doesn't pay for it.

Joseph P. Allen (00:27:03):

So it sounds like despite the theory, that intellectual property is actually a key if you want to get drugs and vaccines developed in other technologies, as opposed to being a barrier, is that fair to say?

Jon Soderstrom (00:27:15):

Well, the patents are what give them the protection.

Joseph P. Allen (00:27:17):

Right. Okay. Well, listen, let's get into-

Stephen Ezell (00:27:22):

Joe, just on that point. You mentioned Elmer Staats previously the Comptroller General who looked at this issue for President Lyndon Johnson in the 1960s and as he said in his final report, quote, we found that hundreds of new compounds developed at university laboratories had not been tested and screened by the pharmaceutical industry, because the manufacturers were unwilling to undertake the expense without some possibility of obtaining exclusive rights to further development of a promising product.

Stephen Ezell (00:27:47):

We've been looking at these issues for over 60 years. And this is why we've put in place the Bayh-Dole system, an intellectual property system that has been so successful in underpinning the American life sciences innovation engine.

Jon Soderstrom (00:28:00):

So, Joe, I hate to jump in with an example.

Joseph P. Allen (00:28:03):

Please, please.

Jon Soderstrom (00:28:03):

Back in the 1960s. Jerome Horowitz synthesized at the Detroit Cancer Center, a compound called D4T. And D4T, which goes by the generic name Stavudine sat in freezers everywhere from the '60s into the '80s because nobody really had any interest in doing anything with it.

Jon Soderstrom (00:28:24):

But in the '80s, during the AIDS crisis, the HIV/AIDS crisis, a couple of chemists in the pharmacology department at Yale, took it out of the freezer, tested it against HIV/AIDS and found out that it was one of the most active compounds ever. It was licensed to Bristol-Myers Squibb, which immediately got the very first fast track approval and it became ZERIT, which became the fundamental drug ultimately in the AIDS cocktail, which transformed HIV/AIDS from a death sentence to a manageable chronic disease.

Joseph P. Allen (00:29:00):

Good example. Well, let's turn now to one of the issues that we read about all the time. The Bayh-Dole Act provides that there's march-in authorities, where the government can compel a university to license others if good faith efforts are not being made to commercialize an invention or the developer cannot meet public health or safety needs.

Joseph P. Allen (00:29:20):

However, the Bayh-Dole Act does not give the government the authority to set the price of a successfully commercialized product. There seems to be some misunderstanding about that.

Joseph P. Allen (00:29:30):

But today, some are saying that in this crisis, threatening industry partners with march-in rights, requiring NIH to again impose reasonable pricing provisions are needed to protect the public interest. Mark, do you see march-in rights as an important tool to make sure that COVID-19 related technologies are actually being developed?

Mark Rohrbaugh (00:29:51):

March-in has a purpose as you said, and particularly when technologies are not being developed and for whatever reason are

being sat upon and sitting stale and to otherwise meet public health and safety needs. But it's a long, cumbersome process to use march-in. We need quick action in this crisis.

Mark Rohrbaugh (00:30:16):

Government has far more useful authorities if needed, to address public health needs than going through a march-in provision, such as contracting for development. It has limited... it has allowed patent owners that don't have NIH support to sue the government if they're using IP and receive a reasonable royalty in return.

Mark Rohrbaugh (00:30:46):

There also is a government use license, so the government could utilize technologies that were funded under Bayh–Dole for government purposes. It hasn't happened much in the biotechnology area, but it's possible if needed, but at this point, there isn't a sign that it's needed.

Joseph P. Allen (00:31:06):

I think the other thing that people don't... I don't think they've read the statute. If the government marches in, it's not an immediate that the technology is going to be licensed. The patent owner and the licensee have the ability to protest at the agency level, then they have the ability to go to court.

Joseph P. Allen (00:31:25):

So invoking march-in rights, even if they meet the triggers of Bayh–Dole is not a very fast method of trying to resolve things. Jon, but it's hard to imagine right now, but back in 1980, when we wrote Bayh–Dole, there weren't a lot of universities with technology management offices, and Congress was concerned to make sure that if we're going to allow universities to license and own federally managed technologies, that they're actually going to be effective in licensing them.

Joseph P. Allen (00:31:51):

So one of the reasons for march-in rights is to make sure that if universities are not enforcing their licenses or have unreasonable terms and license, the government can say, hey, look, you got a license other people, because we want to get this technology developed. Jon, could you say something about how universities monitor your licenses? And what happens in real life if a company looks like they're just really not moving forward on a technology for no particularly good reason?

Jon Soderstrom (00:32:17):

Well, I think that universities recognize their intellectual property as being valuable. And so for that reason, it doesn't lie fallow. In fact, one of the things that we do is we put in very stringent diligent clauses to make sure that people are doing things with the patents.

Jon Soderstrom (00:32:34):

But I'll say that by and large, you don't often get around to actually enforcing those clauses, because if you're really engaged with the licensee, particularly with the small biotechs that are springing up to take these on, you're attuned to what they're doing and some of the struggles they may be having with being able to advance the technology or raise money or whatever, and you're constantly working with them. But in those cases, where it simply doesn't work out, they either lose interest, the money goes, we have had tremendous amount of success being able to return, be able to reap the return from the licensee.

Jon Soderstrom (00:33:13):

And in fact, in some cases, we've had sort of a double benefit. We've actually seen one of the drugs that was being pursued, actually make it commercially available to the marketplace by Amgen, as Kymera. I'm sorry, Kyprolis. But at the same time, there was other technology that they weren't going to pursue, they gave it back to us. We actually used that intellectual property to start another company called Arvinas, which is one of the leaders in a very brand new mechanism of action called protein degradation. They've already got two drugs in the clinic.

Jon Soderstrom (00:33:46):

So we're actively managing these portfolios. It's not just you sign the deal and it's gone. It's actually working together with our partners and we look at them as being partners to help them actually advance and when it doesn't, then we'd have a mutual agreement, return it, we'll see what we can do with it. It works out very well.

Joseph P. Allen (00:34:07):

Well, that's a great point. I think what people need to recognize is march-in rights is a fail safe on the system, it means you're

in DEFCON three, something's really gone wrong that you didn't anticipate. And in real life, as opposed to where we were 40 years ago, universities have become very effective and academic institutions at actually managing their licenses. And one of the fears of Congress was, you're going to have a dominant company license the technology to suppress it.

Joseph P. Allen (00:34:33):

And again, 40 years ago, that was a reasonable fear. But I think in real life, that really doesn't happen. And if it does happen, universities and federal laboratories will not let that happen very long.

Jon Soderstrom (00:34:47):

We have no motivation to license it to somebody who's going to put it on the shelf. The only time we actually receive any benefit from it is when it's actually being commercialized. So we're not going to sign those kinds of agreements. The idea that it's going to lay on the shelf is crazy.

Mark Rohrbaugh (00:35:04):

Joe, the other consideration we need to keep in mind is if we put price constraints on only those technologies that are developed with government funded IP, it makes those early stage technologies less valuable to companies. They'll try to avoid them if they can, and it will make technologies that are not funded by the government without price constraints more valuable, including those from other countries. That would not be in our national interest, in terms of facilitating new innovative drugs for the whole scale of technologies, regardless of their source of funding.

Jon Soderstrom (00:35:46):

What do you think, Wendy?

Joseph P. Allen (00:35:52):

Let me ask you a question if I could, Wendy, because you're a company. You're a small biotech, you're in this thing right now. When you hear politicians and other people start to actually hold over your head and other developers the use of compulsory licenses, patents are bad, march-in rights, other punitive measures, does that make you more willing to get up in the morning and try to get these things developed? Or how do you feel when you hear that constantly being hung over your head?

Wendy Holman (00:36:17):

So the biggest thing that worries me when we talk about march-in rights and punitive measures and compulsory licensing is not actually that it's going to happen, because it's irrational for it to happen. But how much it detracts other people to come in and help the solution. So the implementation of it is ridiculous.

Wendy Holman (00:36:39):

I say that because it is the number one way to kill innovation. We need hundreds and thousands of companies coming in and trying to solve these problems. COVID-19, while absolutely awful for all of us, thank God doesn't have a 50% mortality rate. We need to be working not only on this pandemic, but ones that come in the future. And the more that the conversation tilts towards this, the less likely that you're going to have the best and the brightest are going to be coming here to solve the problem.

Wendy Holman (00:37:12):

So, that part of the conversation worries me, because I think it really limits the number of people who are going to come in here and try to help.

Joseph P. Allen (00:37:21):

Well, right now, as we've all said, we need all hands on board. So we want to make sure we get as many entrepreneurs in the public and private sector working together. Because of Bayh-Dole, US seems like it's uniquely positioned in the whole world to create the technologies we need to meet the current crisis. We've had a number of companies pledged to make their own technologies they've developed themselves available for COVID-19. Others like Wendy are working 24/7 now to develop new drugs and vaccines. It seems like our system is working.

Joseph P. Allen (00:37:50):

From your perspective, how well are our public and private sectors responding now under our patent driven system? Does it seem like the system's working or does it seem like there's some other system somewhere else, which is actually being more affected than we are?

Wendy Holman (00:38:05):

Just to try to attempt to answer part of that, if you go on clinical trials.gov, and you type in COVID-19, it's I think in excess of 50 clinical trials now ongoing. And this is for a disease that we only really categorized in January. So that's amazing. The

American innovation system is working. And it's evident in all the hospitals around the country who are now using different technologies to try to answer the problem.

Wendy Holman (00:38:37):

It's a global issue, and it's certainly a US issue. And the more that we can do to help innovation the better.

Jon Soderstrom (00:38:46):

Joe, can I just add something to what Wendy just said? If you look at the system, and let's just take one drug Gilead's Remdesivir. And what's really interesting is they own all the patents rights, they hold everything. Yet they're making it available at cost through the clinical trials, and they have pledged that it's going to be made the same if it's successful in the trials that they're doing. At least the early preliminary data looks very promising. Don't know yet.

Jon Soderstrom (00:39:14):

But that's just an example of a company that's doing the right thing for the right reasons, because we know it touches the core of who they are, and the business that they are in.

Joseph P. Allen (00:39:26):

Can anybody think of examples of countries that don't protect intellectual property particular for drugs and vaccines? Are any innovations coming out of those countries? Is anybody challenging us as far as who's really stepping forward right now?

Jon Soderstrom (00:39:45):

No.

Stephen Ezell (00:39:45):

I'd find that to be highly unlikely. We were very fortunate in the United States that the effective system we have put in place over the past three decades to support biomedical innovation has allowed our industry to come with such alacrity, with such an incredible response.

Stephen Ezell (00:40:06):

Wendy mentioned the 50 clinical trials. I understand that there's over 155 novel coronavirus treatments and at least 80 vaccines under development. We look at an industry where the private sector has invested about \$130 billion in R&D over the past year, an industry that invests 20% of its sales into R&D every year, 22% of its workforce is in R&D. We're incredibly fortunate that we have put in place a system that enables us to respond to this level, and now would be the absolute last time to look at undermining intellectual property rights that have been foundational to that effective system.

Stephen Ezell (00:40:43):

And your question, Joe, just look at the US versus Europe. Europe, obviously, is a strong environment for innovation. But from the years 2014 to 2018, US headquarter companies introduced more to the world drugs than did all European headquarter companies combined. Part of the reason why is they put in place policies like in Europe to control pricing, breaking the link between the ability to earn revenues that can then be reinvested into future generations of innovation. And it shows you how tenuous the system is, if we don't get it right.

Stephen Ezell (00:41:15):

So the last thing policymakers should be thinking about now is undermining the very effective policies we put in place.

Joseph P. Allen (00:41:22):

Well, listen, I've got a couple more questions. But Stephen has been monitoring some of the questions we've gotten from the great folks who are online now. I'm going to defer to you for a few minutes. And let's see if we got some questions from the audience, the panel can talk about.

Wendy Holman (00:41:35):

If I could say one thing, Joe, to what Stephen said, which is, so right now for our clinical trials, we are trying to operate at the speed of light. And so whenever we're told that there is going to be a two day delay because of some label needs to be processed somewhere or what we view as a esoteric thing that should be fixed overnight, we start bringing in battle analogies constantly. Did your forefathers do this when this happened?

Wendy Holman (00:42:00):

And in this situation, we need our tippy, tippy top to be focused on this problem. So it's our Navy SEALs, it's our Green Berets.

But when you're talking about changing the platform and shifting the foundation, you're not going to bring the best to the table.

Joseph P. Allen (00:42:20):

That's a great point. Stephen, have you got some questions from the audience that we could take a look at?

Joseph P. Allen (00:42:30):

I've got one here that says it appears-

Stephen Ezell (00:42:34):

Go ahead, Joe.

Joseph P. Allen (00:42:35):

Okay. One that I can see is it appears there's some confusion between Bayh-Dole and 1498 compulsory licensing. They'd actually like to have the panel just talk about that. Does somebody want to talk about march-in rights under Bayh-Dole and the government's authorities under 1498?

Mark Rohrbaugh (00:42:53):

Certainly. So under Bayh-Dole, we have a government use license for inventions that are made with government funding. This government use license can be used by any agency for research purposes or other activities that are authorized by its statutes and mission.

Mark Rohrbaugh (00:43:17):

If the government chooses or needs to procure something for its government use, it can produce those, for example, under a contract and make them and utilize the technology without a license, necessarily from the patent owner. If sued in federal court for infringement, the defense would be either, we have a government use license because it was made with government funding. Or, if it was not made with government funding, there are limited ability for the patent owner to seek compensation for its use.

Mark Rohrbaugh (00:44:09):

So for example, the patent owner could not stop the production, they can't get an injunction like they might normally in a private sector lawsuit. They can get a reasonable royalty. So the government if found to have fringed, the government would pay a reasonable royalty to the patent owner.

Mark Rohrbaugh (00:44:30):

Whereas with march-in, it again applies to government funded technology that meet one of the four statutory criteria and there's a long process for doing that. Including if the government finds that this may be the case, it holds a administrative hearing, hears from both sides, there is a degree of due process. And then if the patent licensee or owner disagrees with the decision, they can appeal it through courts up to the Supreme Court, before it could be implemented by the federal government.

Mark Rohrbaugh (00:45:06):

In which case, the federal government could either force them to license to another party or step in and license it itself to third parties.

Joseph P. Allen (00:45:15):

Okay. Stephen, do you have any other questions that you wanted to pose to the audience?

Stephen Ezell (00:45:24):

We had a question from Michele Forzley. She is a reporter with UN Health Update. She writes, quote, activists demand that government funded products be available at no or low cost to all. Many argue R&D organizations should promise equitable access to discoveries. What if any elements should shared access plans include, how can implementation be monitored?

Stephen Ezell (00:45:54):

So a couple questions that I'm hearing from her there, but I think getting at this broad question of how we can be certain that coronavirus therapeutics are brought to the global population and at affordable cost. If anybody would be interested in taking that question.

Jon Soderstrom (00:46:15):

Well, first of all, the companies are pledging that already. J&J has already said that they will make it affordable, globally affordable. Other companies have stepped up and made similar pledges. I mentioned Gilead before. But this is an unusual circumstance. This is a crisis. And it is focusing people in a way, because it touches our very existence.

Jon Soderstrom (00:46:44):

And so for that reason, I think people are going to act in a much more altruistic fashion. They are acting in a more altruistic fashion. But eventually, we're going to get back to normal and we're going to be back to other things and we're going to have to require... there's going to be a profit that's going to need to be made.

Jon Soderstrom (00:47:03):

Because federal governments, philanthropic organizations and others aren't going to be able to pay for every medicine that is made, at least not in the United States, not in our system. I don't know how you're going to do that without having some sort of profit motive. It incentivizes innovation.

Joseph P. Allen (00:47:26):

Does anyone else have thoughts about, because I think, again, how you get access to make sure that these technologies are accessible is a question you hear all the time. So do other people on the panel have thoughts about how we can make sure that people can actually use the technologies that are being developed now for COVID-19?

Jon Soderstrom (00:47:43):

Well, many of us have already signed pledges to do that. There's one that was put together by the Association of University Technology Managers. There was another one that was led by Friends at Stanford, MIT at Harvard, which essentially we have made that pledge, that we're going to try to do our utmost to make these things available broadly, affordably, as rapidly as possible.

Jon Soderstrom (00:48:12):

But we also recognize in so doing that, in some cases, there's going to have to be substantial investment that's going to come from the private sector, and it's going to have to get recognized.

Joseph P. Allen (00:48:23):

I think other people have speculated that when you have a crisis like this particularly for a vaccine, that typically it's going to be made available to public health services. So in other words, the company is going to be negotiating with the government and the government has tremendous leverage when it's negotiating. Very much like when you had the polio vaccine in the '50s, so this is not going to be the kind of situation where you have to go to your doctor to get a prescription, to get a shot. It's going to be where governments worldwide are going to be saying we need to make these things available. So this is not your typical situation.

Jon Soderstrom (00:48:56):

I can see this being, I remember the polio vaccine when I got it as a child. I lined up in the high school auditorium with hundreds of people from my hometown and we all just stood in line until we got our sugar cube. We took it and we were gone. This is going to be the same.

Joseph P. Allen (00:49:14):

I was glad it was a sugar cube and not a shot when I took mine. Somebody else?

Mark Rohrbaugh (00:49:18):

Joe, yeah, there are historical examples like polio, but also smallpox, where the population was, those vaccines were made available to the entire population. They were not like typical drugs, in which you had to go get a prescription and pay through it, pay for them at a pharmacy depending on your insurance.

Joseph P. Allen (00:49:42):

Well, again, I think in the current crisis, what we need to focus on it seems to me is actually getting the vaccine first, because that seems like the biggest need, but again, it's certainly a legitimate question to make sure these are going to be accessible, but this will be done through a lot of means which are traditional, just because of the nature of the crisis.

Jon Soderstrom (00:50:00):

Correct. This is different.

Joseph P. Allen (00:50:01):

The current system is actually working [crosstalk 00:50:04] to make it affordable.

Stephen Ezell (00:50:06):

Go ahead, Wendy.

Wendy Holman (00:50:07):

What I was going to say is that, I think Jon said it well, which is the industry has completely come together, and everybody wants to have a solution to this problem. And while the one thing that has not been thought about is the technologies that the government or at least that I can see has supported the most with big dollars has been what will be the most expensive cost of goods, technologies.

Wendy Holman (00:50:33):

And so outside of vaccines, vaccines are critical, and you can get vaccines to be cheap over time. But for example, for Ebola, we have an amazing treatment for Ebola that was used in the 2018, 2020 outbreak in the Congo and it's an antibody and antibodies are expensive. And thankfully, we had tremendous support from the US government and WHO and all international groups to make sure that every single patient who had Ebola was treated with either after the clinical trial was finished, and the results came out with the two winning drugs, which was our drug and Regeneron's drug.

Wendy Holman (00:51:11):

But these are expensive drugs, these are expensive... antibodies cost a lot of money to make. And so when we're looking at something like a global pandemic, I think that there should be a big emphasis on things that could be made cheaply, like oral pills. Obviously, vaccines are critical. But if the coronavirus vaccines look anything like natural occurring coronaviruses, they'll likely need to be done, you'll have to get a booster every year.

Wendy Holman (00:51:40):

And so you will have intermittent need for treatment when vaccines are having breakthroughs or people are not getting vaccinated. So just I wanted to add that which is that for some technologies, the cost of goods just out of the gate is very expensive.

Jon Soderstrom (00:51:56):

Wendy is on a very important point, because first of all, making a pill, a small molecule, just a tablet is actually fairly straightforward chemistry. But the biology that's required to actually make active biological material is not simple, nor is it straightforward. And it's why there's only a few companies in the world that do it really well. They tend to be very large corporations, as opposed to small corporations. But it has to do with the technical sophistication it takes to actually make it and to make it active, which is a critical component.

Joseph P. Allen (00:52:30):

And what's the failure rate of new drugs and vaccines going through the system?

Wendy Holman (00:52:35):

I don't know.

Jon Soderstrom (00:52:39):

It's high.

Stephen Ezell (00:52:40):

The majority fail.

Jon Soderstrom (00:52:42):

The vast majority fail.

Joseph P. Allen (00:52:44):

So that's a problem. As we discussed earlier, for the people that fail, under our system, those companies are taking the hit. Nobody's coming in to say, hey, you really tried hard, we feel sorry for you. Here's some money to make it up. There are real consequences. So the under the Bayh-Dole system, while the government's funding the initial research, it's the companies that really are stepping in to turn it into a product. And that's not being done at any cost to the taxpayer. So there really are risks in that system.

Joseph P. Allen (00:53:12):

And as we said before, there has to be some kind of reward for the risk, but at the same time, under the current crisis, everyone's focusing on getting these technologies out and making sure they're as widely available as possible. Stephen, do you have any other questions we got from the audience?

Stephen Ezell (00:53:27):

I do. First, I would just add, there have been those that have suggested that intellectual property rights represent a barrier to access new medicines, because they can increase their cost potentially. And you see policymakers in countries like Chile and

Ecuador and Israel who have talked about issuing compulsory licenses in this case. But it doesn't make any sense to issue a compulsory license against intellectual property that doesn't actually exist.

Stephen Ezell (00:53:56):

The problem with the coronavirus is not intellectual property, it's that we actually don't have the intellectual property yet that we need. And the fact of the matter is that the access to medicines question presupposes the very existence of medicines in the first case, which springs into stark relief. We have to innovate to have the intellectual property.

Stephen Ezell (00:54:14):

And then in terms of the pricing, if you look at the United States, Congress with the coronavirus preparedness and response, Supplemental Appropriations Act, CPRSA has said this is an exceptional, extraordinary case. And if the government purchases vaccines, therapeutics or diagnostics for COVID-19, it's going to do so under Federal Acquisition Regulations guidance on fair and reasonable pricing.

Stephen Ezell (00:54:34):

I think you'll see countries putting in places those types of policies in this case, and again, this is an exceptional case. It shouldn't represent a new norm for how we look at the process of drug innovation, in my opinion.

Jon Soderstrom (00:54:44):

Steve, can I just add one thing to what you just said about compulsory license? One of the things history has shown is that if countries start using compulsory license as a vehicle by which they can make drugs affordable, they will not get the next generation of innovation as rapidly as they would otherwise. It just isn't going to happen, because companies won't introduce it there.

Joseph P. Allen (00:55:08):

And you also don't find new technologies coming out of the countries that use compulsory licenses.

Jon Soderstrom (00:55:13):

Correct.

Joseph P. Allen (00:55:15):

All right, so Stephen, do you have other questions for us?

Stephen Ezell (00:55:18):

I covered a couple that are somewhat related. One was, and Mark maybe addressed this earlier, but has the federal government taken any actions to better coordinate the process of drug discovery and approval policies across the administration?

Mark Rohrbaugh (00:55:34):

Absolutely. Certainly. The example I gave was the partnership, public private partnership with the NIH, CMS, FDA and pharmaceutical companies. So that's a good example of how we're moving forward on that front.

Stephen Ezell (00:55:52):

Great. Another question. Can you discuss the cost of both time and investment that it takes to bring in FDA approved therapy to market, after it is licensed from a university? And there was a related question to that, which was, I'm curious if the Bayh-Dole framework enables innovation and IP management practices, like the new COVID-19 technology access framework from Stanford's OTL.

Stephen Ezell (00:56:22):

So essentially, some questions about the process of moving technology from universities in the private sector, in the context of this crisis.

Mark Rohrbaugh (00:56:31):

The Bayh-Dole Act, as I think Joe was talking about it earlier, gives the universities, the recipient of funding, of government funding, with the authority and the responsibility to enter into, to hold title two inventions that it makes with government funding. And then the responsibility to ensure that they make reasonable attempts to license those to companies to bring them to market. They're free to set the standards and the conditions in which they do that, as long as they reach that general goal and principles of the Bayh-Dole Act.

Mark Rohrbaugh (00:57:12):

So AUTM has also come out with a set of principles too, that are a little different, but the same goals as that from Stanford, MIT and Harvard.

Joseph P. Allen (00:57:22):

Wendy, did you want to say something?

Wendy Holman (00:57:24):

I was just going to add that a few years back, the top center for drug discovery did that paper which basically said it cost \$2.7 billion to bring a drug to market and the criticism on that paper was, well, that also includes some of the failures. And so whether you include the failures or not, I don't know what the accounting is.

Wendy Holman (00:57:41):

But my point is that this is tremendously difficult work. It takes meticulousness, it takes organization, it takes collaboration, it takes dedication, patience, but most importantly, it takes resources. So whether that's \$2.7 billion or I think another group came out and said the answer is \$2 billion. The point is, it takes a lot of money.

Jon Soderstrom (00:58:04):

And it's a lot of time, and the answer is bimodal. It works or it doesn't. And you don't find out until the end. And right now, I don't know how long it's going to take with Wendy, how long you've been at it or how long it's going to take. But a typical pharmaceutical takes 10 years from beginning of preclinical development, lead identification, do all the work, get it into the clinic, and then six plus years of clinical trials. You've spent 10 to 12 years developing this, spending money, not getting reimbursed, just investing, investing, investing. And then to find out it doesn't work. That's 12 years of your life lost.

Jon Soderstrom (00:58:51):

That's why in the biopharmaceutical industry, people take great pride in how many drugs they've gotten over the FDA threshold. Because it's not very many. You can look at Wendy and you can tell, she's just anxious to get there.

Wendy Holman (00:59:08):

Exactly. I also [crosstalk 00:59:11] my costs at some point, so that's also the plus here.

Stephen Ezell (00:59:16):

A related question, please explain the difference between a promising innovation in a university laboratory versus a practical treatment for patients and why the private sector is needed to develop it.

Jon Soderstrom (00:59:26):

I think I just talked about that, but I'll take another shot at it. The point of fact is, we can come up with lots of interesting things that look like they'll work in vitro, trying it on an assay, trying it in a test tube. And given the nature of the biology, we think it will work, but eventually that thing has to be turned into a drug. And that drug has a very, there's a very prescribed process for taking it from the point where you think you have a drug, to go to the FDA to get permission to put it into human beings in a phase one trial to see in normally healthy human beings, whether it is safe or has adverse effects. To put it into a phase two trial where you try to start beginning to test for efficacy, to a phase three trial where you take all comers in the disease state, and see if it has broad efficacy.

Jon Soderstrom (01:00:20):

Each one of those things adds zeroes to the amounts of money you have to raise. And so whether it's 2.7 or two, or even if it's a billion, it's a lot of money. And it doesn't come from the government. It comes from private sector investors, human beings who are willing to bet that this is going to change the course of the disease.

Stephen Ezell (01:00:47):

Mark originally talked about the role of NIH funded basic biomedical scientific research, trying to understand biomarkers, disease pathways, biology of humans. But then it's really about the private sector that does the applied R&D activity to actually bring a drug to market. And studies I've read in the past suggest that the private sector may invest as much as \$100 for every \$1 of public investment into a new drug.

Jon Soderstrom (01:01:15):

Actually, I think that number is actually pretty close, based on... I've been involved in 20, 30 companies that have taken drugs, and six of them actually made it into the market. That number sounds about right.

Stephen Ezell (01:01:31):

And it highlights the complementarity of public and private investment in biomedical research has been so critical to US leadership in the sector.

Jon Soderstrom (01:01:39):

Correct.

Stephen Ezell (01:01:41):

Another question from our viewers, John Wilkerson asks under Active might companies make competitors drugs ramp up production of COVID-19 candidates? If so, are there regulatory changes or exceptions that will allow that?

Joseph P. Allen (01:02:00):

Mark?

Mark Rohrbaugh (01:02:02):

I'm sorry, can you repeat that? Companies...

Stephen Ezell (01:02:04):

I'm reading the question as it is, under Active might companies make competitors drugs ramp up production of COVID-19 candidates?

Jon Soderstrom (01:02:15):

There are companies that have already pledged to do that. To work in collaboration to do that. Pfizer, for example, is making its production capabilities available to anybody. The first vaccine candidate that looks like it's going to be successful, they've already pledged that they'd make theirs available.

Joseph P. Allen (01:02:32):

I think the Gates Foundation is doing something. There's really a-

Jon Soderstrom (01:02:34):

Seven, they're ramping up seven.

Joseph P. Allen (01:02:38):

It's pretty remarkable what's going on. And these are all things that are voluntarily coming up forward without people being compelled, that are just... It really shows American ingenuity is alive and well and responding to the crisis.

Stephen Ezell (01:02:53):

A question, may a panelist explain what BARDA is and what its relationship to the Bayh-Dole Act is?

Mark Rohrbaugh (01:03:03):

So BARDA is an office within the Department of Health and Human Services that is responsible both for setup, to be responsible for biodefense and in homeland preparedness for various disasters or offenses that the US might suffer from biological or other types of weapons that are used against the country. So it has also been involved in pandemic flu and other public health crises, and is poised to help and has been working with companies to help to address the needs for industry in developing these new treatments and vaccines.

Mark Rohrbaugh (01:03:51):

They're more involved on a later stage and a preparation and distributions phase, whereas NIH were involved in the earlier stages of research and development.

Stephen Ezell (01:04:01):

Okay, great. Thank you. Several additional questions coming in. One, what are the pros and cons of the government offering to share the financial risk of building out pre-approval manufacturing for promising priority products? And a related question, quote, given the expertise of big pharma, wouldn't it make more sense during this COVID crisis to attempt to license exciting leads to large pharmaceutical companies rather than startups?

Jon Soderstrom (01:04:39):

So let me just answer the last part and we can talk about the other part. But the things that are going to address the COVID crisis right now have already been licensed. They're already out there. They're in Wendy's hands. They're in the hands of others, that are going to be developing these things and many of them are being done in the typical biopharma partnership mode, where you have large pharma collaborating with smaller biotechs, to advance their technology or technologies for scaling up production, for example.

Jon Soderstrom (01:05:19):

That's already happening, that's already in play, that's been going on since this thing was first identified.

Wendy Holman (01:05:27):

I think I could try to answer maybe part of the first one, which is the government can do a lot to share risk with companies right now. And one mechanism is the SARS-CoV-2 is not recognized as a material threat to Homeland Security. So to have material threat designation allows for the government to pre-purchase drugs that could be approved in the next 10 years.

Wendy Holman (01:05:56):

And if anybody wants to ensure that risk is shared and prices are kept low, that is an easy market mechanism to do that. So take some of the money, the tremendous amount of money that was given by Congress, very generously given by Congress to help with this crisis, puts SARS-CoV-2 on the material threat designation list, which would then allow the government to buy early. And of course, they're going to get great pricing, because they're setting the price themselves.

Wendy Holman (01:06:27):

So that to me is such an easy market mechanism to make this happen, and that would help share the risk.

Joseph P. Allen (01:06:34):

Hey, Wendy, I see we have a reporter question for you. It looks like Karen Longheiser for Pharma Manufacturing asks, Wendy, is there anything companies like Ridgeback can do to protect acts like Bayh-Dole, or perhaps in general to encourage productive private public partnering? Other than what you're doing right now.

Wendy Holman (01:06:53):

So my only hope is to lead by example and to work hard to accomplish solutions and to be very collaborative. So other than that, I'm open to suggestions.

Joseph P. Allen (01:07:05):

I'll tell you one thing you've done, which I appreciate is you've taken time out of what you're doing running a company to spend an hour and a half with us today. I think that really shows that you obviously feel strongly about getting the message out and we deeply appreciate that.

Wendy Holman (01:07:19):

Thank you. This is a very important message. So I appreciate it.

Joseph P. Allen (01:07:21):

Stephen, got any more? One thing I'll throw out there while we're waiting is, Mark Rohrbaugh, you've done some really interesting studies about the public impact of some of the drugs and vaccines that NIH has funded before. And obviously, that's made a huge improvement for public health, not just here, but around the world. Could you say something about some of the work you've looked at as far as how revolutionary some of these drugs are and what they've really done to make lives better around the globe?

Mark Rohrbaugh (01:07:58):

So Ashley Stevens formerly of Boston University and I have worked on and published some studies and continuing those studies, looking at the products that have come to market in the US and now abroad, in the US, in FDA approved therapeutics and drugs, with intellectual property from US nonprofit institutions and more recently foreign nonprofit institutions. In the study we published in 2011, we were able to show that while these products represented about 10% in the drug category, represented about 10% of the drugs, they were twice as likely to represent first in class, new technologies, new treatments for diseases and conditions that were otherwise not available. So they're really having an important impact.

Mark Rohrbaugh (01:08:53):

Most of the vaccines that have been brought to market have a component that came out of federal laboratory, NIH or research universities and hospitals.

Joseph P. Allen (01:09:06):

I think one of the things that Stephen mentioned earlier that we had the Comptroller General say not a single NIH funded drug had been commercialized when the government before Bayh-Dole took the rights away and tried to license them non-exclusively, and now I think your work is, we're probably up to over 250, almost 300 since Bayh-Dole passed.

Mark Rohrbaugh (01:09:26):

Over 300.

Joseph P. Allen (01:09:28):

You can either have papers, interesting papers or you can actually be helping to treat people and actually under Bayh–Dole, you're doing both. You're getting the papers done and getting the research done. But the research is not just sitting in the laboratory, not just sitting on a shelf, it's actually turning into something useful. And not just here, but around the world. The US is the leader in, in fact, life sciences, largely because of the alliances between our public and private sectors driven by Bayh–Dole.

Jon Soderstrom (01:09:53):

I just want to add one additional thought to that, Joe, is that one of the salutary effects of Bayh–Dole is also to increase the collaboration between academia and industry, and so that there isn't a handoff, per se going on. But there's actually a collaboration that begins early on and continues through to the early drug identification stages within a biotech company.

Jon Soderstrom (01:10:17):

And because there is this vested interest in getting these things done, you see faculty much more actively engaged. And over the course of my career, it's gone from faculty asking, should we be doing this, to why aren't we doing more of this? And I think that that's one of the little remarked upon features of this.

Jon Soderstrom (01:10:39):

But I know that most biotechs benefit greatly from just having those interactions.

Joseph P. Allen (01:10:45):

And the other thing is, Bayh–Dole didn't create any new bureaucracy, it didn't require any new funding. It just said let's better utilize what we're already doing. I think the results speak for themselves. Stephen, have you got any other? We're running out of time, but we have probably-

Stephen Ezell (01:10:59):

Maybe one final question. Okay, from Patrick Kilbride of the Global Innovation Policy Center, is there any credible public sector capacity to produce a safe and effective treatment or a vaccine, absent private sector leadership?

Jon Soderstrom (01:11:16):

Not that I'm aware of.

Stephen Ezell (01:11:19):

It kind of gets to the question of should the government be the one developing this vaccine or the private sector or both?

Jon Soderstrom (01:11:26):

Well, I think that once you get to production, it has to be the private sector, because it's the only place that the skillset exists to manufacture it at scale.

Mark Rohrbaugh (01:11:39):

And the facilities as well are available in the private sector. That's why NIH partners with, the Department of Health and Human Services partners with companies in these efforts.

Joseph P. Allen (01:11:50):

And there are people pushing internationally in here to just basically say that the government should really should be the people in charge of drug development. I think if you look how the system is working right now, that's going to be a very risky experiment to undertake.

Jon Soderstrom (01:12:06):

But the expertise doesn't exist. It doesn't exist in academia. It doesn't exist in the government. It exists in the private sector. It exists in companies like Wendy's and Pfizer and Merck and others. It doesn't exist in those places. Could academia do this? No. Could the government? The skillsets don't exist. Not at scale.

Joseph P. Allen (01:12:29):

We might have time for another question. But I actually want to recognize two people in the audience which are very

important to me. One is my former boss, Senator Birch Bayh's wife, Catherine is watching this. She's become a real keeper of the flame and really appreciate that.

Jon Soderstrom (01:12:43):

We all love her.

Joseph P. Allen (01:12:44):

She's great. The other is Niels Reimers. Niels is actually one of the fathers of academic tech transfer. He's the one that did the licensing of the Cohen Boyer invention, which actually put the US biotech industry on the map.

Jon Soderstrom (01:12:56):

We all owe our careers to Niels.

Joseph P. Allen (01:12:58):

I just want to make sure we give a shout out to Catherine Bayh and Niels Reimers because but for what you have done, we wouldn't be having this conversation today.

Wendy Holman (01:13:06):

Thank you.

Stephen Ezell (01:13:07):

Thank you.

Joseph P. Allen (01:13:09):

Stephen, anything else? We probably have about another minute or two, I think.

Stephen Ezell (01:13:12):

Joe, I think we've been able to very comprehensively get through all the questions that have been posed on Slido. So Joe, any closing words from you or any of our fellow panelists?

Joseph P. Allen (01:13:26):

Well, I'd just like to thank the panel, because you're all busy people. You all have day jobs, even in COVID-19 you have day jobs, and you're really working on solving this problem right now. These are not theorists that we have on the panel. These are people that actually have their fingers actually working, try to solve solutions. So I deeply appreciate you giving us a lot of your valuable time. I think this has been hopefully helpful to the audience.

Joseph P. Allen (01:13:51):

But my bottom line is the system is working right now. The fate of the world may literally depend on what we're coming out with. This is not a time to come up with some new experiment to try something which has already failed in the past. Bayh-Dole works, patents are important, decentralized technology management beats centralization all the time. And let's just keep on doing what we're doing. And again, thank you for your time.

Joseph P. Allen (01:14:15):

And Stephen, is there anything else you want to say? Appreciate your help from ITIF also.

Stephen Ezell (01:14:20):

I would just like to thank our panelists, Wendy and Mark and Jon, say that we appreciate from ITIF the collaboration with the Bayh-Dole 40 coalition. I want to thank our audience for joining us this afternoon. I want to say that video of this event will be available online, on the event webpage subsequently, in case you would like to share it with others, for their viewing. Thank you all very much for being with us today.

Mark Rohrbaugh (01:14:47):

Thank you.