



*Decentralization = Innovation:
The Case Against Reinstating
Government Management of
Federally-Funded Tech*

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Bayh-Dole
COALITION

Joe Allen (00:00:00):

Hi, I'm Joe Allen. I'm the executive director of the Bayh-Dole Coalition, and we've got a number of people registered today. So we're just going to give about another minute or so to make everybody get in line online, and then we'll go ahead and get started. So we have a great panel and I think we have a great subject today and we're looking forward to a good discussion and also, as we'll talk about in a minute, also getting questions from the audience. So we appreciate your time, being with us today, and we're going to get things rolling in about one more minute.

It's always hard looking at the camera for one minute while you're waiting for things to start, but we're doing the best we can. Okay, that's close enough to a minute as far as I can wait, so let's go ahead and get started. As I said before, I'm Joe Allen, I'm the executive director of the Bayh-Dole Coalition. And thank you for joining us for our program titled Decentralization = Innovation: The Case Against Reinstating Government Management of Federally Funded Technologies. This is a rarely-discussed topic, but the genius of the Bayh-Dole system, which unleashed the potential that federally funded inventions can make to our prosperity and well-being, is based on decentralizing the ownership and management of those inventions to their creating organizations, introducing authorities and centers for success, and then getting the Washington bureaucracy out of the way. Before Bayh-Dole, that was not the case. Federally funded inventions were taken from their creators to Washington where they were made readily available to any and all through non-exclusive licenses.

Since there were no incentives for the inventors to remain engaged or those who really understood the technology, very few were commercialized, much less even licensed. Only 5% were even licensed. So that was a pretty abysmal number. That all changed with Bayh-Dole, which made the US the undisputed leader in the development of government-funded research, but we're in danger of forgetting the hard-learned lessons of the past as Washington micromanagement is again on the rise. So we're going to discuss the issues of how our system works and again, some of the challenges that we're facing right now and we really have a great panel with us today. So we very much appreciate these folks being with us. I'm just going to do a quick introduction. Their more extensive bios are on our website.

Robin Rasor is the Associate Vice President for Translation and Commercialization at Duke University. Before that, Robin was the managing director of Licensing at the University of Michigan and the Director of Licensing at The, which we have to say in Ohio, Ohio State University. Jennifer Gottwald is the Director of Licensing at the Wisconsin Alumni and Research Foundation, WARF, where she's responsible for licensing life science and biotech discoveries along with green technologies. Jennifer is a trustee at the WiSys Technology Foundation and a founder and the leader of the AUTM Women's Inventors Group. Brooke Beier is the Senior Vice President of Purdue Innovates, which includes Purdue University's incubator in its Office of Technology and Commercialization. Under Brooke's leadership, Purdue has streamlined its technology commercialization process and enhanced its startup support services. Under Brooke's guidance, Purdue has been ranked as number six in the world for US patents according to the US Patent and Trademark Office.

Before we begin, if you have any questions for the panel, please submit them through the Q&A button at the bottom of the page. So with that introduction, let's go ahead and get started. As mentioned before, Bayh-Dole inventions made with federal funding, were taken away from universities and small companies to Washington where few were even licensed. Bayh-Dole cut out the Washington bureaucracy from the licensing process and introduced incentives and authorities from inventors and their academic institutions to actively engage in tech transfer. How important is it to have inventions managed by those who actually create them? So we'll throw that to the panel and then we'll go ahead and get started. So ladies, what do you think?

Robin Rasor (00:04:14):

I think I'll take this one first. Even though Wisconsin and Purdue have much longer histories in tech transfer, I think for this question, this experience the University of California system had is really useful to take a look at. So the University of California system started their tech transfer offices in the late seventies, they had it centralized for years and then determined that it just wasn't working. And beginning in it looks like 1990, they decided they would decentralize it to the actual campuses, with the first office formed at Berkeley in 1990, and then Berkeley, and

at UCLA and then later on at the other campuses. But I think I would like to read one thing from a working group from the University of California system back in 2012, and it said, “technology transfer operations should be faculty centric, service oriented, and user-friendly with a focus on sound business practices.”

The success of tech transfer depends on creating and nurturing an entrepreneurial culture on campuses where technology transfer personnel actively engage with faculty. Campuses should invest in staff with relevant commercial product expertise and product development experience and give them the resources and autonomy to be successful. And I think that’s a good example of what’s happened all across the U.S is recognizing that it’s incredibly important for the people that are doing the tech transfer activities, from looking at the disclosures, protecting funding, translational work, doing the negotiations, maintaining the revenue, et cetera, have to be located where the faculty and the inventors are because you can’t do this without a team approach with the faculty.

Joe Allen (00:06:12):

Okay, great.

Jennifer Gottwald (00:06:13):

I’d just add to that a little bit, Joe, in that Robin really summed this up well. I would also say we’ve got two advantages that come out of having this localized to our universities. At AUTM meetings, I often speak to European universities, Asian universities, who talk about how they don’t necessarily have the brand or the alumni following of their university. As silly as it might sound in this context, the Badger football team helps me license technologies, especially when they’re doing well. So I would say that having the brand around the university, people knowing who the university is, having your alumni spread out in companies and being able to champion your technologies is one small part of just getting a company’s attention who may become a licensee of your technology. So, that’s one thing that a centralized system would not have.

A second thing that you don’t have, and this comes out of some work I’ve been doing around inclusive innovation, is the trust factor. People are telling you their secrets, their inventions, what they’re very proud of, and also a bit unsure of what they’re seeing. If you don’t have that trust factor, your inventors who may already be a little bit non-confident because they are in a group where they’re the only in a room, a female inventor, a person of color, if they don’t have that trust factor, it’s going to be really, really, really hard to work with them on their inventions. And the teamwork that Robin’s talking about, that’s not just something where it’s interchangeable, and I’ll deal with whatever expert you want me to: trust is so important, and there’s been a new report that just came out this year supported by InvenTogether talking about the importance of trust and relationships in this technology transfer business. And I can’t say that enough, and that happens at the local scale.

Joe Allen (00:08:11):

That’s a great point.

Brooke Beier (00:08:12):

And I would certainly echo what Robin and Jennifer are saying and even amplify the relationship with the inventors. So it’s so important to have those constant touch points with the inventor to understand maybe if a specific application isn’t working for the technology, you have to make an improvement on it, and consulting with the inventor and having that knowledge in-house and that relationship on campus is so important.

Joe Allen (00:08:35):

Well, one of the things that Bayh-Dole did was before Bayh-Dole, the inventions were not only taken to Washington, but if they were licensed, if any royalties were back, they went to the Treasury Department, not to the inventor, not to the university. So, let’s talk a little bit about the nature of what comes in your door. You’re funding typically basic research. So when things come in the door, is it always obvious what the application could be? Could somebody in Washington do it just as well as you do, or do you really need the inventor and the research team and the department to really help you sort of figure out, “Does this have any utility? If so, where could be applied? Who could be potential licensees?”

Just talk a little bit about what your day-to-day life is. When an invention comes across your desk, again, is it important that it be managed by people on site or could somebody in Washington just look at the patent and get a sense of, “Hey, this is what it could do, and here’s who a potential licensee could be,” and that’s pretty much all there is to the process? So, just say a little bit about it: what really goes on in licensing? What’s your day like when inventions come across your desk, and how do you actually evaluate whether they’re important or not?

Jennifer Gottwald (00:09:46):

I can jump in first on this because I just came from a two and a half hour meeting that our office holds once a month where we evaluate all the disclosures, the innovation disclosures that come into our office over that month. You can imagine they are from a wide, wide, wide range of scientific disciplines. Each one of those starts with an online form that we don’t want the PI to spend too much time on because we want to get their attention and they have a million things to do, but then it’s at least an hour long meeting with our professional staff to ask some of those questions. What actually is the invention here and what does the faculty member or inventor think could be an application of it? Then it’s more staff research to figure out how likely is that what companies might be interested? Is this needed in the marketplace? What is needed to bring it to a product?

We just have ideas, they’re very important ideas and breakthroughs, but they’re not products. There’s much more work that has to be done and how would we protect this? Where would we protect this? We’re thinking about all of this upfront with a million unknowns. Then as a group, we get together about 15 people and really discuss each of these cases and decide where to spend our scarce resources and protecting these and our staff time and marketing them and finding industrial partners. So, all of that is so important to talk to have the back and forth with the inventor, and also to have the professional staff who can look into those questions.

Robin Rasor (00:11:19):

And I might add a couple of things. Those of us who are in the business know that it is incredibly rare and difficult to actually license something if the inventor is not participating. So first off, most of the technology that universities license is early. It’s very common for us to license technology before a patent issue. It is rare for us to be able to license something if the faculty member is not participating in the discussion with the potential licensee. We can bring the horse to water, but we can’t make the company drink until it actually meets with a technical person.

It’s very common also for licensees to fund additional research at the university because again, it’s an early stage invention and it’s hard for them to really know to evaluate it without additional research. So it’s very common that there’s additional research funded by the potential licensee, so I think it’s important to recognize that it is a team approach and without that inventor, it’s going to be very difficult to get anything licensed. And most universities obsess over their revenue sharing policy because they want to incentivize the inventors. If we don’t share any revenue with the inventors, why would they disclose an invention? So, if it’s going to a random place that’s not on campus and the inventors are not going to participate in the end result, the incentives really are different.

Brooke Beier (00:12:57):

I think a great example of all of that at Purdue, we had a technology that had the Guinness Book of World Records for the whitest white paint. It was a headline-grabbing technology, and the poor inventor, I mean that in a good way, the phone was ringing off the hook for this technology, right? It was in the Guinness Book of World Records. And so, you would think that as technology of that stature and marketing world, it would be really easy to license. Well, it was getting attention, and we do have a lot of NDAs and commercial eval licenses out there, but it takes the inventor for each of those applications, whether it’s painting roofs to airplanes, whatever that is, it involves the inventor having conversations with those companies to make that work for all those applications. So, it’s certainly a team effort.

Joe Allen (00:13:43):

I think another thing that most people don’t recognize is universities pay the freight on this. The federal government is not paying for the tech transfer office, so your three universities and a lot of others, your schools are putting some serious money into this, and there’s no guarantee that money’s going to come back again. This is really a service as opposed to a profit-making center. So again, this is the hard thing to do. So, if you open your door

right now, are there licensees out there just begging to bid on licenses and compete against each other, or what's the reality of actually finding a licensee for one of your technologies?

Robin Rasor (00:14:23):

I think one thing that's definitely changed, and I'm the oldest of the crowd, so having watched the difference in the 30 plus years of doing this, where in the olden days, we did do a fair amount of licensing to existing companies or large companies like big pharma, auto companies, whatever. But that has significantly changed really in the past 10 years, where the vast majority of our licensees are small businesses, and in many cases, majority of our exclusive licenses are startup companies for whatever reason, and we could have a longer discussion about that. The people that are willing to invest and take the risk are the small companies with the idea that eventually they will get acquired by larger companies or they will go public.

So, most of what we're doing is a lot of investment, like you say, on our own part. Not only are the universities investing money on protecting the patents, but many of us have translational funds, we have mentors, we have new venture groups that are helping our faculty entrepreneurs start these companies who then have to go out and find investors, either angel investors or venture, which is more difficult right now, to move it a little bit farther. And it keeps on going, and we have examples of, for example, and I'll do it very shortly, one of our drugs that made out on the market started in 2003, took them 20 years to get a product approved. During that time, there was a startup, the startup got acquired. Then that startup, that acquisition, the acquirer put the money into the clinical trials, then it got acquired, then the drug got approved, and then it got acquired again. And unfortunately, the faculty member passed away happily. He got to see the product approve, but passed away with only two years left on the patent. So overall, it was about a 22-year process to get the original idea and then get it onto the market, so this is a long haul and very complicated often in this kind of a situation.

Brooke Beier (00:16:39):

And it certainly isn't for the faint of heart. And as Robin and Jennifer was going to say, it certainly takes a lot of effort from the startups to get the product out there. I have a similar story from Purdue. It was related to a problem that was identified by a local pediatric cardiologist and contacted a Purdue and center to help. And it was involved in the NICU where breathing tubes were coming dislodged from NICU babies. And so, they started this process back in early-1990s, came up with an invention disclosure in the late-1990s. Patent was issued in the early-2000s, and they started a company in 2004. And at that point they worked with our tech transfer office to get a license to it and put together a team.

And then in 2008, Purdue recognized they needed a little more technology translation funds. And so like Robin said, we have an internal fund that funded that commercialization effort. They finally got clearance from the FDA for adults in 2010. And at that point, the company almost went bankrupt and had to close 2012, a new CEO came on board and they worked for free for six months. This leadership team, they didn't take a single paycheck. They had family to put through college. It was a real struggle, but they persevered. They went back down there and they happily were eventually acquired by Medtronic. And now this is a product that's in NICUs and saving babies around the world. But that acquisition happened in 2020. So that's another very long, arduous process that has a great patient public impact, but it certainly wasn't for the faint of heart to take on.

Jennifer Gottwald (00:18:24):

I think what Brooke and Robin have said have just really, really outlined, at the end of the day, we're making an impact in the world. Our universities are, through these innovations, through patenting, we can protect these innovations and perhaps collect royalties on them, but the patent system will only allow you to protect something for so long and rightly so: you trade your explanation of your invention to the world for a period, 20 years, of being able to stop other people from using it, and that 20 years does not fit all technologies. So, with all of this work and bringing things to market, it's quite often that the universities are not getting much return on all the money they're putting into protecting these ideas and all the work that it takes to get them out there and support the innovations. And I just have to say, because I would be derelict if I didn't say it, my particular tech transfer office, WARF does not take money from our university and never has. But that's because we had some very smart people back in 1925

who recognized this mechanism and were able to establish an endowment that has been our support of patenting, licensing for our staff ever since.

Joe Allen (00:19:44):

Well, I think one thing that's become apparent from the three of you is there's a real passion that goes beyond a 9:00 to 5:00 job to do this. This is not just a cookie cutter kind of process. In fact, I remember Kathy Ku was talking about Stanford when they had a search engine disclosed and they couldn't find a licensee. Well, because of a couple kids in the dorm, that turned into Google. And I'll have to say as somebody who worked for Senator Bayh and worked with Senator Dole on Bayh-Dole, the whole startup model was not anything we envisioned when we passed Bayh-Dole. The universities have developed the startup model. That was not something that Washington mandated to you, universities have actually started doing the spinout.

So, let's talk a little bit about some of the things that people are proposing now. I think the biggest threat to the whole system is the administration's pending march-in framework, which is being posed as a guideline for all agencies to use. And you gave the examples, very compelling examples, about how it can spend decades to bring one of these to market. Again, people, let's not glance this over. It's not unusual to have entrepreneurs not take a salary for months and months and months to put their houses up to find VC. Those are the people that are driving the system, not the federal government. The government is funding early stage research: it's the inventors and the entrepreneurs that are putting money into it with no guarantee they're going to get that back again. So, what we're being faced with now is the idea that after you've done all this work — somebody's commercialized something, they've done everything you ask them to do, they complied with your license agreement — that anyone can file a petition to Washington to the funding agency and say they don't like the price of that, of a tube in the incubator, they think it's not reasonable, and ask the government to license a copier or force you to license a copier.

So, what does that do to our system? Does that have any impact there? Or what would people think about the folks that have already got things in the market, they're still under contract and would be subject to this. There's no definition of what a reasonable price is because we never intended that in the law. And it's not even on the guidelines, there's no definition, so this would be up to some bureaucrat in Washington that anyone can file a march-in petition: people that don't like you, a foreign competitor, somebody who just wants to make mischief. What would that do to our system if in fact everything you've done now could be undone if someone says, "I don't like the price of something. I'm going to ask the Department of Agriculture or DoE or NASA to march in and license a copier to make it cheaper," would that have an impact or not?

Jennifer Gottwald (00:22:17):

Yes, definitely, in a nutshell. I think the US has done an experiment along these lines back in the late-80s and early-90s where NIH for company CRADA agreements collaborating with NIH researchers put in some provisions around reasonable pricing. I have heard anecdotes about people who are working in, say, large pharma companies at that point, whose job was to keep up with what's going on in academic and government labs. And when those went into control, they would have to go to their CEO to get permission to speak to an NIH researcher to even start any sort of talk of a collaboration, because that is so much uncertainty for the company that's going to be developing a product, especially a risky product like a human therapeutic. So, that just shut everything down, and the NIH and others recognized that and got rid of that policy.

I think we would see the same effect again if this happened. Every potential licensee that I talk to, a large company or venture capitalists who can fund our smaller startup companies, they have so many innovative ideas to choose from in the world. They're being pitched at all times. Every one of those carries a large level of risk, technical risk, product risk, market risk, safety risk, you name it. If there's also a risk that somebody can question your pricing, at the end of the day, that's just another red flag put against our technologies that we're supporting as taxpayers in our universities, that will probably move it down in the priority list of anybody even considering it to explore for licensing or funding.

Robin Rasor (00:24:05):

And I think the three of us have talked about this already: we're already seeing this concern by companies. So for example, we're seeing in consulting agreements where the companies are asking our faculty, who are the consultants to warrant that they are not going to take any federal funding, they're not going to use any federal funding for any of the work that they do with the company. We're also seeing it in sponsored research agreements where there's some requirement they want to know, is there any background intellectual property that had federal funding? So essentially we're devaluing our own federal funding inventions by, as Jennifer says, they're going to go down to the bottom. As a taxpayer, why would I want us to continue to fund basic research? At the end of the day, if it doesn't get commercialized, it's not going to help anybody.

Brooke Beier (00:25:02):

Yeah, well said, Robin and Jennifer. And I think just to put a final point on it, if these licensees have that uncertainty bottom line, they're not going to license the technology. And for those of us in tech transfer, we know that fewer licenses translate to fewer new products and that will create a less competitive marketplace. And the result, there'll be higher prices, not lower prices. So that's ultimately what we're trying to do is get licenses out there. So we do have a shot on goal to get a product commercialized.

Joe Allen (00:25:31):

Well, I think you all said it very well, because before Bayh-Dole, federal funding was considered toxic because the government would take inventions away. And I think we risk going back to exactly that situation where people are going to say, "If there's any federal funding involved, count me out." You talked a minute before about the role that startup companies play, and so say a little bit about what would be the impact or is there an impact if you're looking for the kind of startup person who's going without a salary or looking for early stage venture funding, if they come into you and say, "Okay, Jennifer, Robin, Brooke, what do you mean by this reasonable pricing? How do I know what a reasonable price is?", and you can't give them a definition of that, what you say is, "Well, the government will decide that after you commercialize it, depending on how they feel that day or what the political pressure is," would have any impact on the ability of people to fund early stage technologies?

Or would they say, "Hey, that seems like an acceptable risk to us. We're willing to roll the dice and see if we can...", And again, this doesn't just apply to drugs: this applies to any federally-funded invention. So, would they have an impact on our system? Would they have an impact on you forming startup companies or having people willing to, as Brooke said before, go six months without a salary or find early stage venture funding? Would people still be willing to invest in that, knowing that if somebody can make it cheaper, it could be taken away from them?

Robin Rasor (00:26:58):

Well, as Jennifer said before, there are lots of innovations out there to choose from. And especially right now, anybody who's trying to start up a company or trying to get investment funding realizes how very bleak the investment business is right now. And so a lot of the venture money right now, even a lot of the angel money, is going just in support of companies that they've already invested in so they can keep them going. If you've got a new invention and you're trying to get new funding for a new company, it is incredibly difficult right now.

I can just speak from my own institution. We are way down in terms of the number of startups that have gotten venture funding this year because of how difficult it is. So if you're going to add an added issue of somebody can just walk in and take the technology away, that's a significant added burden to being able to get investments. So there's same thing. Why are we devaluing federally-funded research if we don't need to?

Joe Allen (00:28:07):

You talked a little bit a minute before about who's actually funding the development, and some people really do believe that the government is funding research and development, that the public is paying twice when one of these things is commercialized because the government funded the research, and now the public's got to pay for a product. So just say a little bit about who's assuming the burden of commercialization: who's actually funding making these from the university into a product that actually be sold in the market? Under our system, who's assuming that burden and how often does that risk not pay off?

Brooke Beier (00:28:43):

I can jump in here. A federal agency — and because of that, the American taxpayer — may fund the earliest stages of the work at a university, the results from the creation of a new drug. And just to put it in perspective, in 2023, the average size of an NIH grant was \$609,790. So, that total amount of award is often allocated over several years, so if you just play out that example, and if a new drug is conceived in year one, maybe after a \$125,000 taxpayer investment, that drug's considered to be federally-funded and it's subject to Bayh-Dole forever for its entire patent life.

A 2020 study estimated that the median cost of developing a new therapeutic agent approved by the FDA between 2009 and 2018 was \$1.1 billion. So yes, the taxpayer did fund that early stage research, maybe a couple hundred thousand dollars of seed funding, that's ultimately 0.011% of the total investment in that final FDA-approved project. So certainly, the licensees that are putting that hundreds of millions in the pharma world and the billions into this is taking on that risk. And it's that risk of protecting the IP that the university takes on, then it doesn't get commercialized, or the dollars that it's putting into the de-risking of the technology, if that never gets commercialized, we're taking on that risk and there's no insurance clause to say we get those dollars back.

So, licensees take on a large financial risk to bring it to the market. And at the end of the day, if it doesn't make it there, it's a sunk cost. And I always say that you have to have 1,000 things right to get that product commercialized, and only one thing go wrong for it not to happen. So it's a risk, and that's why having any type of uncertainty out there just makes it that much harder to attract the licensee.

Jennifer Gottwald (00:30:34):

And if I may add, I think drug development is the best example of all of this because it is something that is so fraught with risk and so expensive to do correctly because we want safe and effective drugs for our people. That makes a lot of sense. I've got some examples from working in renewable chemicals. So innovations where we're going to derive some of the things we currently derive from petrochemicals, from biomass, from renewable sources. This is incredibly important as we look at climate change, what's happening in the world, and also innovative new products that can work much better, and maybe bio-compost on their own.

We have relationships with our inventors obviously, but as we're licensing things, we also develop relationships with our licensees, and I learn a lot from negotiating with my licensees. Bringing a bio-renewable chemical to the market, while not quite the drug development process, involves building a lot of hardware, plants, processes, engineering, still with that level of risk, is this going to scale up? Are we going to get the product we need at the end of the day? Are we going to be able to supply our feedstock to keep this coming? And will anybody buy it by the end? And what I've learned is through that scale up process, our licensees for these types of technologies are sometimes selling products for maybe two, three years where they are losing money on everything that they are selling because they are trying to get their customers to trust their product, to test it out, to get used to it, to use them as a supplier.

And they cannot charge the prices where they can actually recoup their costs at that point, much less paying us for the use of the patent. We have to think creatively in a business sense of when people are making money, when our licensee is making money, and what a fair share back to the university it is. But I think that just emphasizes what a risk all of these are and what our licensees have to put into taking our incredibly groundbreaking ideas that the federal government funds, but actually turning them into a tangible product that I can go to a store and buy and that helps make my life better.

Robin Rasor (00:32:51):

And Joe, if I could add something. I know that a lot of the press about march-in rights has been very focused on this is to reduce drug prices, but in reality it's going to impact more non-therapeutic kind of products like what Jennifer's talking about. At Duke, we have quantum computing, we have some energy technology, other things like that. And I know Purdue has the same thing. Those may be more significantly impacted because in many cases our patents are very important to these end products. In a pharmaceutical product, it's often that the university product, the federally funded one in this case, may be a very small portion and they may not even need that patent at the end of

the day. So the thought that, “everybody, stop worrying, this is just about reducing drug pricing,” the fear is that it’s going to have significant impact on things other than drugs that have federal funding.

Joe Allen (00:33:55):

That’s an excellent point. And just to go back to that a second, I think it’s beyond dispute now. There’ve been a number of studies which has shown the least impact of march-in rights for drug pricing because for the very reason you said. Most drugs are not susceptible. March-in rights only apply to federally funded inventions and very, very few drugs you can practice just by the federally funded inventions. However, when you get to energy, environment, other agriculture, those would be subject to it. And the other thing that people gloss over is anyone can file a march-in petition. I think this is going to start a cottage industry of people harassing innovators saying, “Hey, Jennifer, really would be a shame if somebody filed a march-in petition against your nice little company. Maybe you should make it worth my while or maybe you should let me infringe on your patent.”

Or maybe, the other thing is, you just talked about how hard it is to get development money. So these small companies now are going to have to divert their R&D money now into hiring lawyers to go to the agencies to defend their inventions. And it’s going to be very much what has happened to our patent system now, where these post-grant procedures are being used to grind down innovators. And so a large funded entity can come back and say, “Hey, Brooke, I can do this for years. Can you?” So you really have a way of intimidating entrepreneurs. And the final thing is a copier can always make things cheaper than the entrepreneur. You know it’s going to work, you know what the market is. The entrepreneur knows none of that.

So just on that theme, let’s just, for a second: you’ve talked about how hard it is to get venture funding and what the odds are against commercialization. So when these products fail, does the government come back and tell the innovator or the DC, “Hey, you really did a nice job, appreciate what you did. We’re going to pay you back for that.” Or do people lose their jobs and lose their homes and lose years of their lives when these things go down? Who’s actually taking the risk in our system? Are the feds subsidizing all this or are somebody in the private sector putting their life and livelihood on the line with a remote chance this is actually going to hit and actually make them money?

Jennifer Gottwald (00:36:02):

I mean, if there is a federal program that does that, I would love to hear about it because, no, the feds do not reimburse this. And I don’t think they necessarily should either. I think we are America. We’re a risk-taking society and we want smart people to put their money where they think good innovation is. And I hope it works out for them, but, yes, all of those. It’s so hard. I encourage entrepreneurship all the time in my job with the right people. And I think it’s amazing when I see somebody in their mid-20s out of a graduate degree and a postdoctoral stint who’s going to go six, 12 months without a salary when they should be starting to build up their career, build up their nest egg.

They may be wanting to start a family. How hard is that to do when you’re putting all of your time and efforts and resources into a startup? But it takes that effort and, no, they will not be paid back and we also won’t be paid back. We talked about our tech transfer offices invest in protecting ideas and in supporting these ideas through translational funds, in helping to fund the companies through venture funds. All of these things exist across many universities and we’re not going to get that money back either.

Robin Rasor (00:37:21):

And in reality, as much as we wish we could say our numbers were better, in reality for most universities, we’re fortunate if we’re able to license 30% of the inventions we get. And even then it’s probably a smaller percentage that actually bring revenue in, actually make it all the way to a commercial product. So you talk to a venture capitalist, same thing. I mean, they’re investing in many things and hoping that one out of 10 actually make it. Which is why the risk is so high, because you’re having to fund nine things that don’t make it to get that one. And so we’re all, especially venture investors, the universities as investors, we’re in the risk business and that’s just the way it is. If they all turned into products, we would be having different conversations.

Joe Allen (00:38:19):

It doesn't sound like this is a great get-rich-quick scheme, if you want, which people allege. I mean, people are saying it's de-risk by the government. "You're just giving stuff away. It could be done by Washington." I mean, it's hard. That's the reason we're having this webinar, to really talk about would that really work. Let's talk about another issue, which is being thrown up now as far as reestablishing Washington micromanagement. The Bayh-Dole Act was one of the first laws to emphasize the importance of making products based on federally funded inventions in the United States. And some are now implying that universities are really not taking that seriously, that you're giving technologies away to our foreign rivals. Talk a little bit about when you're trying to license these. What's really involved in finding a domestic manufacturer and does the government do anything to help you find somebody? What do your licensees go through? So just talk a little bit about, again, are you giving stuff away, you really don't care who makes it? Or is it a little bit more to this than just, going out and looking around the corner and there's easily somebody found who could make this and could sell it around the world. So just talk a little about domestic manufacturing, if you don't mind.

Jennifer Gottwald (00:39:32):

I think like you said, Joe, we all know the basic tenets of Bayh-Dole. They guide all of my work and I will always be looking for domestic manufacturers, companies who will manufacture domestically, if I can find them. The truth is we live in a global world and a lot of things are distributed and specialized throughout. I brought up this topic in a room of pharmaceutical executives within the past year, that there may be more expansion of manufacturing products based on federally funded research only within the U.S. for sale throughout the world. And they were saying how some of the components they need to put into our human therapeutics, there are maybe three groups in the entire world who can manufacture them for them.

And those groups may have contract business lined up for the next year or two. So they don't have the liberty of saying that's easy or we'll just build another plant next to what we have and make this incredibly specialized peptide, or this particular viral vector, or whatever it's going to be. I think we have the incentive to find domestic manufacturers. If we are licensing and it's not domestic manufactured, that's because that's what the market will bear and that's how we're going to get products out there. In my mind, having a product based on our University of Wisconsin technologies manufactured not in the U.S. is far superior to not having it manufactured at all. And I feel like that's the tradeoff we're looking at here.

Brooke Beier (00:41:12):

I think with startups, it especially hits them hard because of certain tech domains. Like Jennifer was saying, we all kind of know them, but if they don't have manufacturing facilities in the U.S. or it's priced to the point that a startup would be upside down if they actually did engage in that manufacturing, the alternative is for that technology to sit on the shelf, unless that government grants that manufacturing labor. So we certainly all try to find those domestic manufacturers and I think it doesn't hit industry maybe as large, except maybe in pharma, because large industry players may be able to create their own manufacturing facilities, or pay premium prices, or those manufacturers may put them at the top. Because manufacturers don't necessarily have an incentive to help out the startups. So it's certainly a challenge for the small startups, which I think in university licensing probably 70% or so goes into those small startups.

Robin Rasor (00:42:07):

Another comment, we're forgetting that not everything that comes out of university is a widget or something that's manufactured. There's a lot of research right now, let's face it, in AI and software of patient management, improving processes. When we say manufacturing, it's kind of complicated to figure out what that means. All of us have language in our licenses just by definition that says you have to follow Bayh-Dole, you have to get a waiver, all that kind of thing. But again, in many cases when we're licensing, it is still very early. I'm not sure that for a lot of the things that we license, anybody even knows how it's going to be manufactured at the end of the day. So some of this ends up getting pushed farther along once they actually know what the product is, what the components are, how it's going to be manufactured. It's really hard to define that for a lot of technologies that come out of universities at the time of license.

Jennifer Gottwald (00:43:08):

And, Joe, you asked with all of this what could be helpful. How could the federal government help us with this? And I can think of two very easy things off the top of my head. One, we've mentioned this waiver process, which does exist. You can present compelling evidence to the funding agency, whoever funded the invention explaining why your licensee has to manufacture not in the US. And it gets reviewed and sometimes these waivers are granted, but that process has no timelines to it. While the people we work with are very helpful giving feedback, it can be a long, long, long discussion that can take years and never get to an answer one way or another. Maybe as a university I've got a little bit of patience for that, but the company who's putting money into this, it does not. They need to know within a reasonable amount of time will this work or will this not work?

They can't wait around indefinitely wondering can we start manufacture here? Do we have to build a plant? What are we going to do? That's not going to be a successful product at the end of the day. The other thing is I think we're all in this together, and I love efforts like the CHIPS and Science Act, where the United States has recognized that there are certain manufacturing capacities that the United States maybe doesn't have in the level we need and will support it. That's wonderful. And anything the funding agencies can help us with with ideas of who could manufacture within the US, we'll take all the help and collaboration we can get on this, both for support of companies who are manufacturing in the U.S., a more transparent and straightforward waiver process and also the knowledge and the sharing of that knowledge of where we could manufacture or our licensees could manufacture domestically.

Joe Allen (00:44:57):

Yeah. Right now the whole burden is put on you and your licensee to find somebody and then Washington clobbers you if you don't. And in fact, the Department of Energy has now expanded that beyond Bayh-Dole, which I don't think is legal, but they did it, to say even if you want to have a non-exclusive license for sales abroad, it has to be made here or you have to get a waiver. And there's been a survey by AUTM of its members have found that most times the agencies never even respond to your waiver request. They never even reply because they're scared to death. They're scared to death if they say yes that they're going to get beaten up politically.

So we're back to the pre-Bayh-Dole era where things just sit on the shelf or your licensees now got venture funding, they got their house mortgage, they've got a plan they come to you with, they applied to everything and nobody even gives them an answer. Nobody even replies to them. What kind of system is that?

Robin Rasor (00:45:46):

Well, and the few waivers that I've gone through in my lifetime often are short term. And so can you imagine, here's this company, they go through all this, they finally get the waiver and then three years later the government comes in and says, "Okay, well, you set up all this, but now you can't do it like this anymore." You can't run a business with that kind of a hammer hanging over your head.

Joe Allen (00:46:14):

Well, I think that's one thing that Bayh-Dole for 44 years has been. It's predictable. And now we're getting to the point where it's not predictable because the agencies now have this march-in thing, have this domestic manufacturing thing, which they're expanding to non-exclusive license. If you want to sell a product in Thailand, you have to find somebody in the United States who could actually make it at a competitive price, to have some poor guy export it there. They don't understand that people have to make sales and make money. And it seems like we obviously need to build up our domestic manufacturing capability, but making it harder to license doesn't seem like it's really doing that. But I think, again, people need to understand that even if Washington said, "Okay, here's a database of potential manufacturers. We'll help you find somebody. See if this will work," there's none of that.

It's basically, the burden's on you, and then you're bad people if you can't find a domestic manufacturer because obviously you don't care about developing the United States. So all these things kind of undo the whole Bayh-Dole system now by putting uncertainty back in your system that are going to come back to haunt you. We actually had one question here, back to an earlier discussion where we were talking about march-in rights and drug pricing. And I'll throw this out. This is sort of outside of our topic, but if you want to address it, that's fine. Is there something

else that we should do to focus attention on alternative ways to better achieve reasonable pricing in healthcare as opposed to march-in rights? That's, again, outside of our topic area, but if you want to comment on that, somebody did ask it. And if you have thoughts about that, we'd be happy to hear them. You should win a Nobel prize if you solve this one because no one so far has solved it. But if you have thoughts about that, please share them.

Robin Rasor (00:48:01):

Well, perhaps because we have this debate tonight, there've been multiple articles in both the Times and the Wall Street Journal just this week on the whole process of how a patient ends up paying for something and these pharmaceutical benefit associations. I am not going to get involved in it, but I would recommend anybody to read any of these and familiarize yourself with the whole process of how drug pricing is determined in the U.S. It's fascinating, it's complicated. People have been trying to change it for many a year, but it is not as simple as, "Oh, we'll put a clause in a university license and miraculously the drug is going to cost 25% less." It's just not going to happen that way because of the way the United States insurance and Medicare and Medicaid and all this kind of stuff. So some of those articles have been really interesting the last couple weeks.

Jennifer Gottwald (00:49:06):

And I just want to emphasize something Brooke said before, this is not as direct as we would like it to be, but the more innovations we can get into companies' hands and the more products they can bring to market in human healthcare, the more competition there is and that can drive down those prices. If there's an incredibly pricey treatment for a certain indication, it will go down when a competitor comes up that is just as effective or more effective. That's the way the market works. If you make it easier for us to take this incredibly complex process that has a lot of risk and not a lot of winners and let us do our job, maybe some of our innovations, maybe somebody at my university right now is going to have something that's going to bring down the price of Alzheimer's drugs. I don't know yet. But if they do, I want to be able to give it the best shot it could get.

Joe Allen (00:50:01):

Right. The other thing which I don't think people realize is before Bayh-Dole, the U.S. was not the leader in life sciences. We were a follower and in biotech we were number three. It's only because of the alliances with industry, which again has taken the risk and our universities and federal laboratories, we are now the undisputed leader in life sciences of biotech without any question. That doesn't seem like something we should just take for granted because we can easily go back the other direction.

Let's talk about one other thing now, as we are rounding out our discussion, that we really haven't talked about. I think one of the most remarkable things about the Bayh-Dole system — this is actually a credit to the three of you who have been actually very active in this — is universities share best practices. You teach each other. This is not the kind of thing where if you get a really a great model on startup formation, you keep it proprietary. Can you talk a little bit about what it really means to the profession that this has been self-regulating, that you really do get together as colleagues, you really do share best practices, assuming you do, and what impact has that made on our ability to really be far and away the most successful country in the world on commercializing publicly-funded inventions?

Robin Rasor (00:51:18):

Well, that's why we have professional associations, but I think we should also remember too that while the universities have professional associations and we all talk to each other, interestingly, our partners. Even Big Pharma but also the venture world, they also participate in helping us with best practices. A good example is the BOLT joint term sheet that was done between AUTM and the Venture Capital Association to try to help move some of these complicated negotiations a little faster by having some definitions that everybody can use and some systems that everybody can use so we can move things forward.

I think what's really interesting about it is I'm not competing with Purdue or competing with Wisconsin. We're all colleagues and even, I would say, we're colleagues with the venture world because we all at the end of the day want to get these products moved forward. Yes to make money, but also to make an impact. And so we do all talk

and work together so we can make the process smoother and more beneficial to all of us. To me, it's been a great profession because of that camaraderie and how much we all interact with each other.

Jennifer Gottwald (00:52:46):

I think another thing that comes out of this is I... Totally Robin is correct, and I do love that, that I'm not competing with any other tech transfer office. By definition, what we all have is unique. That's why it's patentable. So we all can work together and help each other and that's so important because every university culture is different. Starting a spin-out company in San Francisco is much different than doing so in Madison, Wisconsin. I need different tools than my colleagues at University of California, Berkeley, do, and I can talk to Brooke because we've got more similar situations and we can talk about what works here in the Midwest. What can we be doing within this area to support entrepreneurship?

We create toolboxes so that any office can look at which of these particular processes, programs, ideas is going to work in my office. And it's incredibly effective that way, that we are all so open and sharing of our processes and that no matter where you are or how big your office is or if you're dealing with medical innovations or engineering innovations, you can find ideas and colleagues at other offices to help you out.

Brooke Beier (00:54:04):

Yeah, I was going to say we just learn from each other's successes and failures and we build off of it and we improve and we share best practices and it's going to be dependent on each university, just like Jennifer said. Geographically, maybe strategic alignment of tech area and tech focus, but certainly if one institution has a great program to de-risk technologies or have seen certain funding things make a big impact, schools are willing to share that, and all in the name of trying to get those technologies out there.

Joe Allen (00:54:36):

Well, I have to say, as one of the people that's actually old enough to have worked on the original Bayh-Dole Act, all Bayh-Dole does is say there's a potential for commercializing and making this stuff real. But that potential is only realized because of people like you. And I think it's really something we really should take a lot of pride in to see how decentralization has really blossomed across the country that you sound like one model fits all. You've actually developed models that fit in with your university and your section of the country.

Before Bayh-Dole, universities were not economic development engines. You didn't have state governments looking to you as places for start-up formation and that's become a fact now. In our closing minutes, anything else you want to add about how our system's working and particularly should people appreciate why? Well, one thing about Bayh-Dole, we didn't create any new bureaucracy. We didn't create any new federal funding, so we don't have any cheerleaders in Washington. There's no Washington bureaucracy that's pushing Bayh-Dole. But having said that, shouldn't there be a greater recognition of what this has really done to the country for a little law that most people have never heard of, that suddenly made trillions of dollars of federal R&D and economic benefit as well as a scientific benefit?

Jennifer Gottwald (00:56:03):

Definitely. And I think we need to get the stories out more of the products that people are using in their everyday life that had their origin. Again, a lot of development and a lot more going into it, but their origin at universities and how the Bayh-Dole Act has allowed us to make that transition. AUTM has a Better World report that publishes these stories and that is such a great investment of resources. This is what we can use to tell our friends and families what we do for a living and why we are so passionate about it. Because it kind of gets dry when you start talking about patenting and prior art and things like that. I think when you actually look at what an impact this has made in everyday life, it's amazing. We've got the simple examples like Honeycrisp apples, everywhere to — Brooke was talking about monitoring, breathing tubes in the NICU. These things are so important and they help us in so many ways, and that's what we want to do. We want to take the great research happening on our campuses and get it out there to help everybody.

Robin Rasor (00:57:15):

I'm just laughing because for those people who are listening who are from the Ivy schools and others, they will laugh at this. But Duke is celebrating its 100th anniversary. Yes, we are still a baby, but as part of our celebration, we've done 100 years of innovation and all this kind of stuff. Interestingly, before 1980, we can identify a whopping somewhere around 20 patents that were owned by Duke because back then before 1980, there was no office. If anybody filed a patent, it was usually owned by the inventor or whatever. Since 1980, we have well over 8,200 patents and six, seven drugs on the market, multiple companies that have gone public, blah, blah, blah in our baby 100 years. But when we talk about all the other institutions that are much older than us, they will have very similar numbers, I suspect, of pre-1980 and post that. Now obviously, federal funding increased and research increased, but I think it really goes to show how much change has happened post Bayh-Dole.

Brooke Beier (00:58:27):

I think one of the things that maybe we didn't talk about is just the volume of things. At Purdue, we get 400 new invention disclosures a year coming from our faculty and grad students. And the amount of resources, I know the office at Purdue pre-1980 maybe had a couple of people in it. Now if you look at how our office is structured at Purdue Innovates, we've got close to 40, whether they're de-risking the technology and actively trying to do that, whether it's patent attorneys, business development managers, licensing. It's a huge operation in time and investment. And so 400 inventions and trying to find that blockbuster or that one product or a couple products that can make it to market every year is a real focus, and it's a passion.

Joe Allen (00:59:15):

Well, it's only because of Brooke's predecessor, Ralph Davis, who actually had an appointment to come into Birch Bayh's office, and Senator Bayh was a graduate of Purdue. So whenever Purdue called, we met with him whether we knew what they were going to talk about or not. And he brought with him Howard Bremer from WARF and that changed my life. This is where all this came from. It was a happenstance meeting one afternoon. We had no idea what Purdue's problem was, but they really talked about us, about the ineffectiveness of billions of dollars of being wasted because they were not being commercialized. And it was really, again, because of that chance meeting that this whole thing changed. But again, even with that meeting, without what you three are doing and your colleagues, this would still be potential. This is not a cookie cutter job. It can't just be done from afar.

Thank you very much on everything you've done. Thank you for joining us today. I think this has been a great conversation. Again, thank you to all of the folks in the audience for participating. We'll be doing another webinar on some other topic down the line. In fact, before we started, our three panelists said that they can always tell if there's three guys on a panel, which one will be talking first. We may just do a webinar on that. And they didn't mention me, by the way, but I appreciate that. But that's probably the benefit of being the host. Again, thank you very much. The Bayh-Dole Coalition appreciates your attention. We'll also be posting this on our website fairly soon. We'll let you know when that is, and I'm sure we're not going to run out of issues to talk about. But this has been a great discussion. Again, Jennifer, Robin and Brooke, thank you for your time. We really appreciate it.

Robin Rasor (01:00:47):

Thank you, Joe.

Brooke Beier (01:00:48):

Thanks, Joe.