EAGLE FORUM
EDUCATION & LEGAL DEFENSE FUND

Benefiting from Federal Research Funding

Technology Transfer, the Bayh-Dole Act, Patent Rights, and Society

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"One of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property."

Congressional Research Service

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Eagle Forum Education & Legal Defense Fund hosted an October 18, 2018, briefing, where a packed room of congressional staff, industry representatives, and policy experts heard experts discuss the transfer of discoveries from federal research funding and the benefits to society. Panelists explained how the Bayh-Dole Act fosters commercialization of inventions from federal funding of basic research by letting universities own the patents to their inventions.

Eagle Forum Education President Ed Martin welcomed attendees, Patent Policy Advisor **James Edwards** moderated the panel discussion, and panelists **Joseph Allen**, former Senate Judiciary Committee aide to Sen. Bayh and Reagan administration Commerce Department official; **Stephen Susalka**, chief executive officer of **AUTM**; **Hans Sauer**, deputy general counsel and vice president of the **Biotechnology Innovation Organization**; and **Stephen Ezell**, vice president for global innovation policy at the **Information Technology & Innovation Foundation**, each spoke. Summaries of panelists' remarks follow in the order of speaking.

Takeaways included that patents and exclusive licensing deals justify private investors' backing the long, expensive, uncertain path of applied research and development. Secure, exclusive patent rights under Bayh-Dole translate into $5-$10 in private investment to commercialize an invention for every dollar of federal basic research funding. Most of the patents get licensed to small businesses and startups for commercializing. The success of university tech transfer contrasts with that of federal labs, far outpacing federal agency performance.

James Edwards, Moderator

Patent Policy Advisor, Eagle Forum Education & Legal Defense Fund

Our briefing today centers on this question: How can we get society the greatest benefit from the discoveries made from the hundreds of billions of federal research dollars that go to universities and federal facilities?

That's what the National Institute of Standards and Technology seeks to answer through its Return on Investment Initiative. This past spring, NIST put out a Request for Information and has convened listening sessions. Eagle Forum Education and most of the groups on our panel responded to NIST's RFI.

First, a little context. Federal funding supports basic research — discovering fundamental scientific knowledge. To get practical use from that new knowledge, there's a whole different, lengthy, expensive process. It involves applied research, development and commercialization. Private investment supports this stage. To move a discovery from basic research to commercialization, the new technology must be handed off to a company or entrepreneur willing to attempt its commercialization. That's technology transfer.

To restate the basic question: How can society get the most benefit from federally funded research?

Fortunately, this question's been asked and answered over the past 40 years. The bipartisan Bayh-Dole Act intentionally employs secure, exclusive intellectual property rights as the vehicle for commercializing federally funded discoveries. Bayh-Dole is a game-changer. Before Bayh-Dole, the government owned 28,000 patents with fewer than 5% commercialized. Bayh-Dole opened the floodgates.

As the Congressional Research Service put it, "One of the major factors in the reported success of the Bayh-Dole Act is the certainty it conveys concerning ownership of intellectual property." Bayh-Dole teaches that secure patent rights are the lynchpin to society getting the greatest benefit from federal research dollars.

And NIST Director Walter Copan is right to examine how federal research facilities could improve their tech transfer record. Commerce Secretary Wilbur Ross points out how federal agencies trail universities in this area. Secretary Ross says "federally funded university

research is about five times more likely to result in a licensed patent technology and about seven times more likely to result in an active patent license" than federal agencies.

The solution is straightforward. As Eagle Forum Education put it in our RFI comments: "The best, most cost-effective and efficient means of improving the return on investment of federal labs' discoveries is to adopt the attributes of the highly successful U.S. private-sector patent licensing and commercialization as well as the Bayh-Dole regime."

Our briefing explores technology transfer and secure property rights as the keys for society to benefit from our taxpayer dollars at work in research. Our panel will discuss the Bayh-Dole Act and its record of commercialization success, along with threats to its continued success. We'll talk about improving federal tech transfer. We'll also see how patents and IP turn basic research into new medicines, new advanced materials, new energy and agriculture, and new manufacturing and other technologies. We have distinguished panelists for this timely discussion.

"The Bayh-Dole Act's running like a finely tuned machine and doesn't need any legislative tinkering. However, it must be maintained. The Department of Commerce is charged with overseeing the law so that it's properly implemented. Unfortunately, the Department's been missing in action. . . .

"Commercialization remains a neglected step child in many agencies. Government technology managers are often hamstrung from effectively making deals by bureaucratic procedures and second guessing from agency lawyers. Many lab directors and middle managers see tech transfer as an unfunded mandate, taking time and resources away from their mission. What's needed is a signal that business as usual is over."

Joseph P. Allen, comments filed with the National Institute of Standards and Technology to its Request for Information Regarding Federal Technology Transfer Authorities and Processes

Joseph P. Allen

President, Joseph Allen & Associates; former Senate Judiciary aide

It's always fun talking about the importance of federally funded R&D because something new is always coming out. Just a couple of days ago, the headline article in the *Wall Street Journal*'s Review section was "The Great American Growth Machine" by former Federal Reserve Chairman Alan Greenspan and Adrian Wooldridge with *The Economist*. Here's what they said:

“Today, the United States has the most powerful economy in the world: with less than 5% of the world's population, it still accounts for almost a quarter of global GDP. America has the world's highest standard of living apart from a handful of countries with small populations ... It also dominates the industries that are inventing the future — intelligent robots, driverless cars, life-extending drugs. The fact that 15 of the world's top 20 universities are based in the U.S. ... suggests that it is well-placed to dominate the ideas economy.”

That last sentence would not have been written 40 years ago because at that time the government took inventions away from our universities and made them freely available to any and all. The result was that few were developed here. The Bayh-Dole Act stopped the giveaway of inventions made with billions of dollars of taxpayer-supported R&D. It injected the incentives of patent ownership into the system, decentralized technology management from Washington to the creators of inventions made with government support, gave preferences to licensing small companies and those who would manufacture resulting products here while allowing the government to use discoveries it had helped fund. This change in policy, combined with a strengthening of our patent laws, ignited one of the greatest industrial Renaissances in history.

It's hard to remember now, but in the 1970s it looked like America had permanently lost its lead in critical fields of technology. Japan and Germany had taken away our lead in fields like electronics, automobiles, and steel, and it looked like just a question of time before others were lost as well. But that didn't happen because Bayh-Dole helped unleash the American entrepreneurial spirit.

President Lincoln said the patent system "adds the fuel of interest to the fire of genius.” Lincoln was our only president who owned a patent, so he knew what he was talking about.

The government funds research for two reasons: to meet its mission needs and to further the frontiers of science. Neither is geared towards developing new products, so resulting discoveries are very early stage, more like ideas than anything that can be sold in stores. Thus, partnerships with industry are critical if the public is to receive the full benefits from $150 billion spent every year in government-supported research. These companies typically invest many times what the government spent in the initial research, with no guarantee of success. They simply can't take that risk without strong intellectual property rights to protect the risk and expense of commercialization.

The numbers tell the story. Before the Bayh-Dole Act, the government accumulated 28,000 inventions and less than 5% were licensed. Not a single new drug was developed when the government took inventions away from the creating institution. Congress saw that keeping these discoveries on the shelf was a waste we could no longer afford.

Bayh-Dole triggered an explosion of creativity. The U.S. biotechnology industry is founded on university-industry research partnerships founded on the law. More than two new companies and two new products are developed every day from university inventions. Academic patent licensing contributed $1.13 trillion to our economy while supporting more than 4 million new jobs over a 15-year period. No other country comes close to matching these numbers. Indeed, Bayh-Dole has become the gold standard of technology management and is widely copied around the world.

Yet for all of its accomplishments, a small band of critics is determined to roll back the clock. They urge a return to government micromanagement while disparaging our patent system, which is in disrepair. We can't afford to go backwards for many reasons.

While we rightly tout the economic impact of Bayh-Dole, there's another story we shouldn't forget. Several years ago, we celebrated the 30th anniversary of Bayh-Dole. There were many impressive speakers, including Sen. Birch Bayh, dignitaries from the Patent and Trademark Office, and industry. But of all that was said that day, I can only remember one thing. The very last speaker on the program was a cancer survivor, Betsy de Parry. As she approached the microphone, she suddenly turned around, walked up to Sen. Bayh, and wrapped him in her arms, saying, "If not for your law, I would not be alive today." If there was a dry eye in the house, it wasn't mine.

Stories like that are our real success. We owe it to people like Betsy to make sure our laws incentivize commercialization so the benefits of federally funded research get out of the labs and into the marketplace where they help make the world a better place.

Stephen Susalka

Chief Executive Officer, AUTM

AUTM is a nonprofit association focused on empowering, promoting, and connecting our 3,100-plus technology transfer professionals who make the world a better place through the commercialization of academic and other nonprofit innovations.

While you might not be familiar with technology transfer, you've undoubtedly used many of the products and services originating from universities, hospitals, and research labs. Among the tens of thousands are:

- Allegra for severe allergy sufferers, thanks to Georgetown University
- Robotic exoskeletons to help those with paralysis from the University of California, Berkeley
- FluMist for kids who hate shots, out of the University of Michigan and St. Louis University
- The nicotine patch for people who want to quit smoking, which UCLA created
- Rotavirus vaccine came from Cincinnati's Children's Hospital
- Even Honeycrisp apples! They're from the University of Minnesota.

All these inventions were originally developed at universities and commercialized because of tech transfer. But we didn't always have such a robust innovation ecosystem, and it quickly accelerated with the passage of the Bayh-Dole Act in 1980.

It is the Bayh-Dole Act that has played a pivotal role in the unleashing of American innovation and is now the gold standard that countries are adopting around the world. In order to maximize the impact of our predominantly taxpayer research, we must keep investment strong, strengthen our patent rights, and protect the core of what turned us into the most innovative economy globally: the Bayh-Dole Act.

So, what is tech transfer?
Tech transfer involves moving inventions and discoveries made in university labs to those who can develop them for commercial use. Professionals in the field help make that happen. The process involves evaluation, protection, and commercialization.

The critical accelerant to this process is research funding. There's a linear relationship of

research funding to inventions. On average, $2.7 million in research funding is behind each invention. Researchers discover something in the lab that potentially could be translated into practical application. That's where technology transfer professionals come in.

First, evaluation. This is where professionals look at two major aspects: if the invention is commercializable and protectable. Commercializable means the research finding could be turned into a product or process that's commercially useful.

Second, protection. Protectable generally means it's patentable. Is the discovery new, practically useful, and not obvious? Protecting the institution's ownership rights in an invention is critical. At this point, the intellectual property is really all the university has. Strong, consistent patent rights are essential; otherwise the inventions will die on the vine.

Third, commercialization. Universities don't sell inventions. Instead, they license those inventions to companies to further develop and sell the resulting products. Licenses come in two flavors – licenses to existing companies and licenses to new start-up companies. Royalty revenue goes back to the university and individual inventors to fund the next generation of inventions.

By the numbers

Since 1991, AUTM has been collecting licensing survey data in the U.S. The data show that university tech transfer, which Bayh-Dole enables, has been a tremendous success.

Going around the lifecycle, in 2017, a record $68.2 billion in research expenditures is reported – a new high and up 2 percent from the previous year. That research funding led to almost 25,000 invention disclosures. However, that was the first decline (albeit very modest) we've seen in 27 years of data. This could be the proverbial canary in the coal mine regarding the negative impact of the weakening of the patent process – the fear is that ideas will not be disclosed, and potential innovations will never make it to market.

While we hit a record of patents issuing — 7,459 — keep in mind they take 3-7 years on average, so they've been in the pipeline for a long time. However, new patent applications, 15,335 in 2017, have declined by almost 10 percent in the last five years – a troubling trend, again likely driven by the weakening of the patent system.

We saw 7,849 licenses and options reported. Each of those could be for the next life-changing invention like the ones we have seen; and 755 new products were created in 2017 alone. Another bright spot was the growth in start-up companies, which grew to a record 1,080 in 2017 – a 5.5 percent increase. Importantly, more than 72 percent of those start-ups are headquartered in the home state of the institution, which leads to local and regional economic development.

Taken together, these results show that the research engine continues to be strong, but the uncertainty in the value of patents more recently has begun to affect the number of inventions and patent applications – the raw materials that blossom into products, companies, and jobs.

A separate report detailed the economic impact of tech transfer activity. A joint AUTM-BIO report found, over a 20-year period, up to $591 billion added to the GDP and up to 4.3 million jobs supported.

AUTM and BIO are anticipating the release of a joint follow-up report in 2019.

About AUTM

AUTM is the nonprofit leader in efforts to educate, promote and inspire professionals to support the development of academic research that changes the world and drives innovation forward. Our community is comprised of more than 3,100 members who work in more than 800 universities, research centers, hospitals, businesses and government organizations around the globe.

AUTM's members work closely with commercial partners to transform ideas into opportunities, resulting in the creation each year of thousands of products, services and start-ups, and millions of dollars in economic development. First and foremost, their work means improved lives, every day, everywhere.

AUTM advocates and supports the full spectrum of its members' work – from corporate engagement to intellectual property protection — empowering dynamic, forward-leading professional practices and advancing current and future generations of leaders in the field of technology transfer.

"Universities seem to be doing far better than the federal labs and can teach us a thing or two. . . . Recent studies have shown that federally funded university research is about five times more likely to result in a licensed patent technology and about seven times more likely to result in an active patent license. Universities received $1.78 billion in licensing revenue from their innovations in 2014. In comparison, the total amount of royalties received from licensing government inventions was only $194 million in 2014, the latest year for which data are available. In that year, universities received $66½ billion for R&D while federal labs received $42 billion.

"Now if you do the math, universities received just over 50% of the R&D funding, but licensed nearly 10 times the value of technology. One would imagine that the gap has widened even further, as university activity has exploded, generating $2.96 billion in licensing income from their inventions in 2016.

"Now obviously, R&D in a given year is not what has resulted in royalty income in that year because of leads and lags. But the pattern has persisted long enough, and the math is so lopsided that it seems to me that there is a message in it."

Secretary of Commerce Wilbur Ross

Hans Sauer

Deputy General Counsel and Vice President, Biotechnology Innovation Organization

The Biotechnology Innovation Organization is the world's largest trade association representing biotechnology companies, academic institutions, state biotechnology centers, and related organizations across the United States and in more than 30 other nations. BIO members are involved in the research and development of innovative healthcare, agricultural, industrial and environmental biotech products.

BIO's membership includes many small biotech companies. Small companies hold 70% of the drug development pipeline. The United States originates more new drugs than the rest of the world combined: 57% of new drugs come from this country.

The U.S. government generously funds biomedical R&D. The National Institutes of Health budget is over $30 billion. But the biggest contributor is industry; industry spends over $100 billion annually on R&D.

As you've heard, the roles of industry and publicly funded research institutions are different, and that's true in the biomedical field as well. So the relative monetary contributions, public and private, pay for different, but related things. Public funds are for basic research; industry funds are for applied research and development.

Not all publicly funded biomedical research ends up being commercially relevant, but a large proportion does. Estimates are that around 20-30% of NIH grants result in research that later becomes relevant to new drugs. This is what people mean when they say that the federal government funded the creation of new drugs.

Federal funding generally doesn't pay for the cost of developing a new drug, but it paid for much of the scientific foundation. Once the cause of disease is understood, that provides opportunities then to devise new treatments or better diagnostics, whose development must also be funded. You can think of it as a kind of infrastructure investment. "When the railroad comes," businesses start popping up, commerce grows around it. We have many historic examples of this — early federal post and military roads and canals fueled expansion to the Ohio River. Railroads drove expansion further west. Electrification, the Interstate Highway

System, all these are examples of public investments that, amongst other things, provided the foundation and opportunities for private enterprise, and raised overall prosperity.

Even today, economists fix the return on investment for federal transportation infrastructure grants at around 2, meaning every federal dollar spent on improving roads or rail results in a $2 increase in the state's economic output. I want to propose to you that federal funding of basic biomedical research is likewise a good form of investment, a foundation that mobilizes and pulls along large amounts of private investment.

We know that, on average, for every new drug, companies and their investors spend out-of-pocket private funds approaching $1.3 billion per drug, over an almost 10-year R&D period. What's more, almost 9 out of 10 new experimental drugs that enter clinical development fail at some point and are never approved for human use.

When you put this together, this means that, through the Bayh-Dole Act, the public investment in biomedical R&D becomes very highly leveraged – every public research dollar recruits 5-10 or more private dollars for subsequent, applied R&D. This is money the government would otherwise have to spend. And remember the 90% failure rate in drug development.

The Bayh-Dole Act provides the incentive for the private sector to step up and assume that risk of failure, which otherwise would have to be borne by the government. We normally don't want large amounts of taxpayer dollars to go to projects that have 90% failure rates, so recruiting the private sector through the Bayh-Dole Act seems like pretty smart policy that saves the taxpayer money and risk.

- *Promote strong IP rights for private-sector commercialization.*
- *Establish high-level technology transfer oversight and accountability.*
- *Align incentives for improving agency technology transfer.*
- *Enable federal inventor and tech transfer officer entrepreneurial opportunities.*

Andrew Schlafly, recommendations filed on behalf of Eagle Forum Education with the National Institute of Standards and Technology to its Request for Information Regarding Federal Technology Transfer Authorities and Processes

Stephen Ezell

Vice President for Global Innovation Policy, Information Technology & Innovation Foundation

As my fellow panelists have elegantly articulated, the Bayh-Dole Act truly has been an unparalleled success. As *The Economist* has written, Bayh-Dole was "[p]ossibly the most inspired piece of legislation to be enacted in America over the past half-century …. It unlocked all the inventions and discoveries that had been made in American laboratories throughout the United States with the help of taxpayers' money" and helped bring them to market.

Enterprises need to be able to license intellectual property or technology with the knowledge those IP rights will be secure, giving them confidence to engage in the difficult, risky, uncertain, and expensive process of investing in new-to-the-world products, especially in the life-sciences, where bringing a new prescription medicine to market can take 12-14 years and cost as much as $2.6 billion. Moreover, the life-sciences industry is the world's most R&D-intensive, investing 21% of its sales in R&D, and — like all innovative industries — it fundamentally depends on the profits earned from one generation of biomedical innovation to finance investment in the next.

Yet, despite Bayh-Dole's well-documented success, some have advocated for policies that would significantly compromise it. In particular, I'm referring to calls to employ Bayh-Dole "march-in rights" to control drug prices. "March-in rights" refer to a provision within the act permitting the federal government — in extremely specified and limited circumstances — to "march-in" and require holders of patents derived from publicly funded R&D to issue a license for the intellectual property to others. The Bayh-Dole Act proscribes only three principle instances in which the government would be permitted to exercise march-in rights:

- If the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention;
- If action is necessary to alleviate health or safety needs which are not reasonably satisfied by the patent holder or its licensees;
- If action is necessary, in exigent cases, because the patented product can't be manufactured substantially in the United States.

You'll note that none of these cases addresses the price of the patented innovation (whether it be a medicine or another product). That's because, as Senator Birch Bayh himself has explained, Bayh-Dole's march-in rights were never intended to control or ensure "reasonable prices" (in fact, the Bayh-Dole Act contains no definition thereof).

Rather, Bayh-Dole's march-in provisions were designed as a fail-safe for limited instances in which a licensee might not be making a good-faith effort to bring an invention to market or when national emergencies require that more product is needed than a licensee is capable of producing. And that's part of the reason why — even though at least six petitions have been filed requesting that the National Institutes of Health "march in" with respect to a particular pharmaceutical drug — the NIH has denied all six petitions, with the agency noting that the drugs in question were in virtually all cases adequately supplied and NIH explaining that "the extraordinary remedy of march-in is not an appropriate means of controlling prices." Moreover, it's part of the reason why march-in rights have never been exercised during the 38-year history of the Bayh-Dole Act.

Put simply, if the government ever had the ability to go back, after a business had commercialized a product, and mandate the business license the product to someone else, it would destroy Bayh-Dole and any private business incentive to commercialize a product supported by federally funded research.

Some assert that taxpayers are "paying twice" when taxpayer dollars supports basic biomedical scientific research, which may lead to scientific discoveries ultimately leading to therapeutic disease targets or to insight toward chemical or biologic compounds that are commercialized into safe and effective drugs. But this misses that basic scientific research accounts for but a small fraction of the cost of bringing a prescription medicine to market. In fact, one study finds that companies invest $100 in development for every $1 the government invests in research leading to an invention or discovery. And it's why the Tufts Center for the Study of Drug Development finds that, among 35 drugs and drug classes, private-sector research was responsible for central advances in basic science for 7, in applied science for 34, and in the development of drugs yielding improved clinical performance or manufacturing processes for 28. In other words, public and private investment toward biomedical innovation are complements. We need both.

And that's why other proposals — such as "delinkage," which seeks to separate the linkage between patents for pharmaceutical products, and the profits earned from them, to finance investment in future generations of biomedical innovation or the notion that NIH might fully take over drug development — are also wanting. First, they imply that the government would make better allocation decisions than industry, despite the fact that there's little evidence for this. As the report "Wealth, Health and International Trade in the 21st Century" observes, "It's questionable that public sector actors would be more efficient in allocating resources to

research scientists and others working in pharmaceutical R&D than private sector decision-makers for whom efficiency is vital."

A second problem with these proposed alternatives is they have a virtually nil track record of delivering breakthrough prescription medicines to market. In fact, not a single new drug was created from federally funded inventions under the previous to Bayh-Dole policies; whereas a system predicated on genuine innovation supported by the protection of intellectual property rights has resulted in decades of breakthrough biomedical innovation and over 7,000 new-to-the-world drugs under development today.

In conclusion, I'd like to share an observation made by Jack Scannell, a Senior Fellow at Oxford University's Center for the Advancement of Sustainable Medical Innovation (CASMI). As he wrote in a 2015 paper, "I would guess that one can buy today, at rock-bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere in the world, at any price in 1995." He continued, "Nearly all that generic medicine chest was created by firms who invested in R&D to win future profits; short-term financial gain building a long-term common good." We need to be able say, in the year 2040, that patients have access, at rock-bottom generic prices, to a set of pharmaceutical and biological drugs — including breakthrough treatments today such as Avastin or Keytruda for various forms of cancer — that have greater medical utility than the entire set available to anyone, anywhere in the world, at any price in the year 2020.

But that will only happen if we preserve a system of robust intellectual property rights, including the Bayh-Dole Act, that incentivizes innovation and allows enterprise to earn sufficient revenues to reinvest in R&D in a virtuous cycle toward future generations of biomedical innovation.