



# Preserving U.S. Leadership in Biopharmaceutical Innovation

## EXPERT BRIEFING EVENT

U.S. leadership in advanced technology industries is never guaranteed. It takes ongoing stewardship from policymakers to ensure America provides the most globally competitive environment to support cutting-edge innovation. Unfortunately, policy lapses in recent decades have contributed to America losing its global competitiveness, market share, and high-skilled, high-value-added employment across a wide range of advanced technology industries, including semiconductors, telecommunications equipment, televisions, solar panels, and chemicals. Now we are at risk of compromising U.S. biopharmaceutical leadership, which has become increasingly imperiled by policies imposing price controls and weakening intellectual property rights (IPR), with measures such as COVID-19 waivers and proposals to expand Bayh-Dole march-in rights.

The Information Technology and Innovation Foundation (ITIF) hosted an expert panel at the U.S. Capitol Visitor Center on March 5, 2024, to discuss a new ITIF report examining why the United States lost its lead in other advanced technology industries, and how policymakers can avoid repeating the same mistakes in the biopharmaceutical sector.

### Speakers:

- **Sandra Barbosu**, Senior Policy Manager, ITIF
- **Stephen Ezell**, Vice President, Global Innovation Policy, and Director, Center for Life Sciences Innovation, ITIF (Moderator)
- **David Kappos**, Partner, Cravath, Swaine & Moore LLP
- **Frank R. Lichtenberg**, Cain Brothers & Company Professor of Healthcare Management in the Faculty of Business, Columbia University Graduate School of Business
- **Hon. Paul R. Michel**, Chief Judge (ret.), U.S. Court of Appeals for the Federal Circuit
- **Richard Tillyer**, Ph.D., Global Head, Discovery, Product Development & Supply, Johnson & Johnson

## AUTO-TRANSCRIPT

### Stephen Ezell:

Well good afternoon, and thank you for joining us. I'm Stephen Ezell, the Vice President for Global Innovation Policy at ITIF, and the director of our Center for Life Sciences Innovation. And we welcome you to today's event as we release a new report entitled, "[Not Again: Why the United States Can't Afford to Lose Its Biopharma Industry.](#)"

The report makes the case that America's leadership in advanced technology industries can never be taken for granted. It contains histories of how the U.S. created and held, but then squandered leadership across a number of advanced technology industries, including telecommunications equipment, semiconductors, televisions, solar panels, and chemicals. And it shows how this holds lessons for the policy environment that attains to America's Life Sciences industry today.

That's particularly the case because policies such as government-imposed drug price controls weaken intellectual property protections such as proposals for the government to be able to use Bayh-Dole march-in rights to control the price of products that have been developed, in part through federally funded research, calls for compulsory licensing of Life Sciences IP, limitations on patent subject eligibility rights, giving away U.S. intellectual property in global form like the WTO, have inspired to imperil U.S. Life Sciences innovation leadership.

At ITIF, we also recognize that advancing public health depends on robust IP rights. And further, that while access to medicines is certainly a vitally important issue, it presupposes the existence of medicines. You can't have access exist, and we believe that intellectual property rights fundamentally enabled biomedical innovation. My colleague, Sandra Barbosu, the report's author and our panelists will further elaborate on these issues. So, I'll turn the conversation over to them and introduce them for their remarks.

I want to note that we will take questions at the end. And for those who are watching online, you can submit your questions through the Slido application found at the bottom of the event page. Okay. Sandra Barbosu, lead author of the report is Senior Policy Manager for Economics of Biopharmaceutical Innovation at ITIF. She's also an adjunct professor in the Technology Management and Innovation Department at New York's Tandon School of Engineering. Prior to joining ITIF, Sandra served as Program Officer and Economics at the Alfred P. Sloan Foundation in New York. She has a PhD in Strategic Management from the Rotman School of Management at U Toronto, as well as a master's in Precision Cancer Medicine from the University of Oxford.

Next, we'll hear from Dr. Richard or Rich Tillyer. He's the global head of the Johnson & Johnson Discovery Product Development and Supply Organization, DPDS, within the company's Innovative Medicines Research and Development Group. Richard is also a member of the Innovative Medicines R&D Leadership Team, the Johnson & Johnson Group Operating Committee, and serves as the R&D executive sponsor for the Scientist Mentoring and Diversity Program within Johnson & Johnson's Innovative Medicines. As the head of DPDS, Richard leads a global team of multidisciplinary scientists, drug hunters, drug developers and supply experts, co-working to develop innovative, transformational therapeutics and optimize J&J manufacturing processes. Richard joined J&J from Merck in 2018 and holds a PhD in chemistry from the University of British Columbia.

Next, David Kappos is widely recognized as one of the world's foremost leaders in the field of Intellectual Property. Now a partner at Cravath, Swaine & Moore LLP, from August 2009 to January 2013, Mr. Kappos served as Under Secretary of Commerce and director of the U.S. Patent and Trademark Office, the U.S. PTO, David was instrumental in passage of the Leahy-Smith America Invents Act signed into law by President Obama in 2011. David holds a JD in law from the University of California Berkeley. Next, delighted to have with us the honorable Judge Paul Redmond-Michel. He was appointed to the U.S. Court of Appeals for the Federal Circuit in March of 1988 by President Ronald Reagan. We have a bipartisan panel today. On December 25th, 2004, he assumed the duties of chief judge and served as one of 27 judges on the Judicial Conference of the U.S., the governing body of the judicial branch. In 2005, he was appointed by Chief Justice William Rehnquist to also serve on the Judicial Conference's seven Judge Executive Committee.

Judge Michel has issued over 800 opinions while on the bench, approximately one third of which were in patent cases. He testified before Congress on patent reform legislation and served as special advisor to the Patent Reform task force. He holds JD from University of Virginia. Last but not least, delighted have with us Mr. Frank Lichtenberg. He is the Cain Brothers & Company Professor of Healthcare Management in the Faculty of Business economics at Columbia University Graduate School of Business, where he also teaches, he's also a research associate with the National Bureau of Economic Research. Rick Frank is one of the country's leading healthcare economists, and his papers have received numerous distinctions, including one, the 1998 Schumpeter Prize for his paper Pharmaceutical Innovation as a Process of Creative Destruction. Frank holds a master's and a Ph.D. in economics from the University of Pennsylvania. Okay, with that, I'm going to turn the floor over to my colleague, Sandra Barbosu, who will present the report.

**Sandra Barbosu:**

Okay, thank you Stephen, and thank you everybody for joining us today. So I'm happy to share with you highlights from my new report, "[Not Again: Why the United States Can't Afford to Lose Its Biopharma Industry](#)." So I want to start off by discussing the state of U.S. biopharma leadership, the factors that have contributed to this success, as well as China's rapid rise. Then I'll describe several events, industries in which the U.S. lost its lead and the lessons that can be learned and applied to the U.S. biopharma industry today. And then I'll conclude with some recommendations for policymakers such as yourselves on ways to create a supportive policy environment that will enable the U.S. to maintain its lead in this very important sector.

So today, the U.S. biopharma industry leads the world on most measures. It has a very large domestic market that accounts for 42 percent of all global drug sales. It ranks first in pharma production with 28 percent of the share of global output in 2020, followed by China with 17 percent. It launches substantially more new drugs than any other country in the world, twice as many as Europe and four times as many as Japan. And most of those novel drugs are available in the U.S. first before they're available in any other country. So why does all this matter? Well, biopharma is a key advanced industry for the U.S. It's important for the country's global competitiveness, national security, and domestic economic growth. It offers well-paying jobs, opportunities for skilled workers, and the sector employs more than one quarter of America's total R&D workforce. The industry is of course also critical for American's health. So for example,

in the past two decades, biopharma innovation has reduced the cancer death rate by more than 30 percent.

Several factors have contributed to U.S. leadership in biopharma. One is a robust IP protection regime, which stimulates private R&D investments and results in more novel drugs. Another is historically limited government-imposed drug price controls. Rather than being centrally set, drug prices are determined by market forces, competition and negotiations between drug developers and various buyers. And these two factors are very important because there's an inherent link between the ability to earn profits and the ability to invest in future drug R&D. In an industry where drug development is long, costly and risky, it takes on average \$2.6 billion and more than 10 years to bring a new drug to market. The assurance of recouping R&D investments and earning profits for future R&D is critical for innovation. And biopharma is the country's most R&D-intensive industry of any kind. With more than 25 percent of revenues spent on R&D compared to an average of two to 3 percent across all industries, and about 18 percent, for example, in semiconductors.

A third factor that contributes to biopharma leadership is supportive science policies, such as the Orphan Drug Act and the Prescription Drug User Fee Act, which have incentivized drug development for a range of rare diseases and also accelerated drug review processes. And a fourth factor is the existence of strong institutions including top research universities and institutions like the NIH and more ARPA-H that support hundreds of thousands of scientists. And so the key question is, especially as the first two factors are being targeted by new and proposed policies, is whether this leadership position will continue.

So now let's turn to China. So in recent years, China's biopharma industry has grown rapidly backed by government R&D subsidies, faster drug review processes, strengthened IP protections and enforcement mechanisms, and partnerships with foreign firms aimed at acquiring science and technology know-how. And at the same time, the U.S. has been losing domestic biopharma manufacturing, particularly for APIs, the active ingredients in drugs, as production subsidies and cheaper labor are attracting API manufacturers to build plants overseas. And so today, only 28 percent of API manufacturers for U.S. pharma firms are based in the U.S. Over the last two decades, Chinese biopharma output has grown almost 11 times from 14 billion in 2002 to 158 billion in 2020, so China is closing the gap. And in light of this competition, the next couple of decades will be critical to upholding global U.S. biopharma competitiveness.

And we've seen this movie play out before with the U.S. initially leading the world in a number of advanced industries only to lose that lead to countries with more effective domestic policies. The report discusses five such industry case studies, but I will highlight two of them here, semiconductors and solar panels. So semiconductors are critical, of course, for the operation of most electronic devices. And in 1946, Bell Labs invented the transistor and then received a military contract to support semiconductor research. And in the following two decades, U.S. government support continued to play an important role in the form of procurement contracts and research funding. And with all this, by the early 1970s, the U.S. was leading the world in semiconductors. But in the 1980s, Japan's industry grew thanks to government subsidies and protectionist trade policies that were restricting foreign competition at a time that U.S. firms attracted by subsidies and cheap labor abroad were opening plants overseas.

And so within a decade, Japan had overtaken America's global lead in semiconductors. In the past two decades, China has also invested heavily in its domestic sector. And so today, while the U.S. still leads in terms of global market share, so it accounts for 48 percent of global industry sales. The story is very different when it comes to manufacturing. The graph here shows that in the past two decades, the U.S. share of global semiconductor manufacturing fell from 37 percent to 12 percent, while China's grew from less than 1 percent to 15 percent over the same time period. And so while other countries have been willing to subsidize the building of semiconductor plants, the U.S. largely has not, and this accounts for a large part of this manufacturing decline. And this decline in light of geopolitical tensions and the COVID-nineteen pandemic that had led to a chip shortage and also exposed supply chain vulnerabilities was a critical motivating factor behind the Chips Act to restore domestic manufacturing. But this experience of the semiconductor industry carries an important lesson, which is that once the U.S. loses advanced industry share globally, it becomes very difficult and expensive to get it back.

Another industry where the U.S. lost leadership is solar panels. So in 1954, Bell Labs developed the first practical solar cell using the same silicon material it had used to invent the transistor seven years earlier. But solar cells at the time were very expensive, so pretty much the only market was aerospace. The U.S. government was really critical in jumpstarting the solar space industry through federal procurement contracts. And then in the 1970s, demand for solar cells increased a lot during the 1970s oil crisis. And so the U.S. provided hundreds of millions of dollars to adapt solar cells to terrestrial applications. By the late 1980s, the U.S. was a global leader and it boasted the world's top suppliers of solar technology. But then U.S. interest in solar energy waned in the 1990s because fossil fuel prices fell and this led to an end in government support as well.

At the same time, countries that had higher energy prices, greater environmental awareness, or more proactive industrial policies, and notably Japan and Germany, grew their domestic industries. And so by the late 1990s, the global industry was roughly evenly divided between the U.S., Japan and Europe. Since 2000, China has also surged in its domestic industries to meet a rising global demand backed by government subsidies, and this has driven many foreign firms out of business. So today, China controls 80 percent of the global solar panel supply chain, has the world's top 10 solar cell suppliers, and has added the most solar capacity in 2022, 5 times more than the U.S. And the Inflation Reduction Act could serve as a catalyst for the U.S. solar panel industry as it contains incentives for solar panel installations and tax credits for domestic manufacturing. But similar to the Chips Act, once leadership is lost, it's very expensive to get it back.

So as these examples of the semiconductor and solar panel industries show us, leadership has eroded in several important advanced industries since the 1960s. Among the reasons for these losses, a common threat is that the U.S. took an overly laissez-faire approach leaving the industries to the free market alone without providing adequate policy support, such as protecting them from foreign predatory trade practices, recognizing that they require scale to compete in global markets, or supporting their innovation potential with R&D funding. And once leadership is lost, as I mentioned, it becomes much more challenging to get it back. And so it's critical for the U.S. not to repeat similar mistakes today in the still strong biopharma industry. So while China is committed to growing its own industry, the U.S. is neglecting its position and

hamstringing the industry with government imposed price controls and policies that weaken IP protections.

Studies show that the impact of price controls proposed by the IRA would result in a 45 percent decrease in pharma R&D over the next two decades. 254 fewer new drugs, a 50 percent reduction in early phase research and a loss of life in the next decade. That is 20 times larger than that from COVID-19 in the first year and a half of the pandemic in the U.S. Another proposed way to control drug prices is through the misuse of the Buy Dole Marching rights. So the 1980 Buy Dole Act enabled universities and small businesses to patent and license inventions developed with federal funding, and was hugely successful in spurring university innovation and public-private partnerships. Under the act, march-in rights allow the government to intervene and license the patent to others if the patent holder does not make reasonable efforts to commercialize and innovation. But march-in rights were never intended to control prices.

However, back in December, the Biden administration proposed using such march-in rights to control drug prices if they're deemed to be too high. But such a move would also weaken IP protections. The ACT was critical in spurring innovation and using march-in rights basically to tie price to technology would disrupt this important function, reduce innovation incentives, and discourage public-private collaborations. Also, in 2022, the WTO waived IP protections for COVID-19 vaccines, which meant that any WTO member could freely use patented knowledge related to vaccine production. One such has several takeaways and recommendations on ways to uphold biopharma leadership at this critical time. First of all, as the experiences of other industries show U.S. leadership in biopharma is never guaranteed and must be constantly nurtured through a supportive policy environment, especially amidst this robust foreign competition is targeting the industry are harming innovation, and instead to maintain biopharma leadership, the U.S. should continue to invest in robust federal R&D investments as well as efforts to strengthen domestic supply chains for essential medical ingredients, as announced recently by the Biden administration. It should also avoid government price controls and restore a strong IP environment to support innovation and maintain America's leadership in this important sector. Thank you very much.

**Richard Tillyer:**

Can you hear me? Yes. Very good. Okay, so Sandra, great job. Thank you. Excellent, excellent. I, first of all, want to say thank you to everyone here for joining today and really appreciate the opportunity to be on this panel and to share my perspectives. As a thirty-year scientist in pharma, I've witnessed amazing progress in the invention of therapeutics against some really awful diseases, but there's just so much more to do. Today I'm going to talk a little bit about what it takes to actually bring a therapeutic forward. The invention of a therapeutic is incredibly complicated, it's time-consuming, it's expensive, and it's high risk. Why is that? It's because human biology is infinitely complex. We're trying to fix the machine and we don't really know how the machine works. So pharmaceutical innovation takes decades of research by thousands of scientists. First of all, we need to identify the biological basis of that disease.

And then largely pharmaceutical companies are taking on the task of inventing a therapeutic and intervention that works safely and with a high degree of efficacy. This innovation is highly collaborative, it requires the entire ecosystem to pull off something like this. So let's talk about

disease just a little bit. I'm a chemist, so I'm going to talk in reasonably simple terms about this. Normal biological function is driven by hundreds of thousands of individual proteins that are expressed in each one of our cells by about 20,000 different genes. These proteins, they exist in different amounts in different cells to support their function, and they interact dynamically with each other. And they do this to regulate the activity, the processes in the cell, the tissue, the organ, and ultimately the body. And what is disease, disease really occurs when one or more of those proteins doesn't function properly, or it's not there at all. It's just not present.

And so therapeutic interventions then generally are designed to restore that normal protein function in the cell. Some interventions are actually aimed at killing disease cells, for example, in cancer that's generally what we do. So how do you do that? The first step in tackling disease is figure out which proteins not working properly. And then the next thing is to invent a therapeutic. That first step is a really, really big part of this big research ecosystem and knowledge in the biological basis of disease, been driven by decades of research, leveraging large cellular models of disease, animal models of disease, and more recently, large population-based studies of human disease associated with human genetics. Now, this has been a profound effort for many, many years now, but even today [inaudible 00:20:46] powerful understanding with the protein function at leads to disease. And as a result, most of the hypotheses that we test in a human clinical trial don't work as expected.

So once we've identified a target, the protein that we actually want to go after, the next step is we need to invent a therapeutic. We selectively resource the normal function of that protein in the cell. We want to do that without introducing a wanted biological activity or toxicities, the product has to be safe. And a key choice that we make very early on in a discovery program is what type of therapeutic or modality do we actually want to deploy to correct that disease biology. Now, there are several classes that you've all heard of, small molecules, proteins, RNA, gene and cell therapy, and they all work in slightly different ways to restore normal function to cells or to the body. Very often, we need to test more than one. We don't know which one's going to work first. We try our best hypothesis in the clinic and we find out we need to do it in a different way, so this can add to the time cycle of discovery and development.

Now, the invention of an individual therapeutic, regardless of what it is, the molecule proteins developing, regardless of what it's requires, the parallel and simultaneous optimization are hundreds of factors, hundreds of properties in each molecule to optimize the actual biological activity. And so that process itself is incredibly complicated and time-consuming, and it really is done uniquely well in large pharma, benefiting from broad expertise as well as our ability to industrialize that process. It benefits from very high throughput industrialization techniques. Okay, so let's talk about the start of this. The start generally is searching for a lead molecule that's active, has the right biological activity, and that generally is carried out through a screening process where we screen millions or billions of individual molecules looking for one that has desired biological activity as a starting point for our program.

PART 1 OF 4 ENDS [00:23:04]

**Richard Tillyer:**

... desired biological activity is a starting point for our program. I like to think of this as being like looking for a needle in a haystack. Well, I'm not really sure which haystack to go look in. It's

a very, very complicated and somewhat frustrating process to get that [inaudible 00:23:21]. The best leads then are taken and then we optimize those through rounds and rounds, and many, many scientists do this, through rounds and rounds of iterative bespoke we call it design, make test. Our scientists are actually designing these molecules and then testing their biological activity. And this takes years, takes about three years to go from a hair on a screen to a candidate that we can take into the clinic. After extensive preclinical safety testing, we then go into phase one, phase two, and phase three clinical trials. And all throughout that process we're learning what's working in a human and what isn't. We take that information back to our design process and then try to make a better candidate.

So how long does it take? Approximately 15 years from that initial screen for a product that makes it to market. 10 percent of our programs actually make it there. So 90 percent of what we actually take into the human clinical study doesn't make it to market. And to add to this, in that 15 years, we can be halfway through this and find out that, hey, there's a better way to actually intervene in this biology, and then we have to stop and start all over again. Happens all the time.

Once we get a therapeutic, all those made it to continue to improve next generation therapeutic for that disease. This often requires inventing a completely new molecule. It could be in the same modality, it could be in a different modality. We're looking for some of them has significant advantage over the first generation therapeutic, and we look for combination therapies where we have multiple biological pathways that we intervene in, and we combine those therapeutics in a human trial to see if we can have a better outcome.

Our goal then is to continue innovation until we achieve the safest, most effective solution. Sometimes that can include cure. I'm going to give you two examples of this now. When I started in industry back in 1993, we were right at the front end of the HIV epidemic. It was considered at that time a death sentence if you were HIV positive long to live. Here we are 30 years later, and this disease is now, for most patients, a chronic condition. It's very good life expectancy, good quality of life if you're HIV positive on therapies designed and inventive, and these are small molecule antiviral therapeutics.

Now, the initial results we got from those first protease inhibitors in HIV showed very quickly the combination therapy was going to be needed. Just shutting down one of those viral proteins was not going to be enough to stop the disease. And so the pharma companies across the world started to invent therapeutics across multiple pathways and then in humans, combinations of these. Here we are today with combination therapy being the basis of care with minimal pill burden, convenient regimens where patients have their disease under control and are leading normal lives.

One more example now in cancer, something that's near and dear to me. Multiple myeloma is an incurable blood cancer. J&J has been committed to R&D in this space for over 20 years. Now, back in 2003, long before I joined the company, they introduced small molecule therapeutics that was [inaudible 00:27:06], it was essential for survival and proliferation of these cancer cells. Now, this agent, when it was taken into humans, was shown to be highly effective, it actually slowed down the progression of cancer, but it was found out pretty quickly even with this breakthrough that next generation therapeutics were needed to get more durable responses and put more patients into remission.



Since then, our company has invented numerous novel therapeutics targeting myeloma cells. Now we're using powerful therapeutic modalities that engage the patient immune system. These are monoclonal antibodies and we introduced a T-cell engager, which has a profound efficacy in multiple myeloma. Now it doubles the life expectancy of patients that are diagnosed with this disease, but it's not cure. So we continue to innovate. We focus with the power of the human immune system on a new modality that we take. This is the type of cell therapy that involves engineering the individual patient's T cells, immune system to fight the disease. This is delivering absolutely incredible results, and it's actually proven to be curative in some patients, and we hope to cure many patients in this way.

So I'm going to summarize. As you can see, therapeutic innovation, it's horrendously complicated, but we have a multidimensional multi-generational approach that we've nurtured over many years and it's working. We're seeing transformational products like CAR T, solutions that we can only imagine a decade ago. There's currently a robust pipeline of 8,000 medicines in the clinic. They're testing different [inaudible 00:29:01] in different diseases and using many therapeutic modalities. Our company J&J alone has invested \$60 billion in R&D over the last five years.

But even with the scale of investment, the unmet needs exist, there are profound needs for patients, and there are many, many hypotheses to test. But as I've said today, a hypothesis is a long way from a product that can impact a patient. Getting there requires deep expertise in the disease biology. It requires industrialization of molecular invention. It requires well-designed human clinical trials and the ability to manufacture highly complex agents at scale. Companies like J&J are able to uniquely bring this kind of expertise to this problem and to solve them and deliver the next wave of innovation. Thanks very much for listening.

**David Kappos:**

All right, well, good afternoon. Great to be here in Washington DC here at the Capitol and talking about such an interesting and helpful report. I'll start by thanking ITIF and Steve and Sandra for bringing this report to our attention and investing in bringing facts and data to the topic of U.S. leadership in the biopharma industry. I say it that way because it's so natural and important, but we so rarely actually do that. So thank you to ITIF and Sandra in particular.

Let me also come back to a comment that Steve made in his introduction, which I thought put the entire conversation this afternoon. And the comments that Richard just made in perspective, which is that the single-minded focus on reducing patient cost for medicines, which by the way I will stipulate, is super important, and I personally think it is essential that all humans get access to the medicines they need. I don't speak for J&J, but Richard's nodding his head, I think everybody agrees on that. That is definitely not the issue here. The issue is the one that Steve raised, which is you don't have the product at any price if you don't have appropriate incentives to invest in the R&D that Richard just explained to us.

As Richard said, the whole notion of reducing patient costs presupposes the existence of medicines. That's a great framing, Steve. The way I frequently put it is the cost of the medicine that doesn't exist, infinite. No matter how much money you have, you can't afford it. And we should all ask ourselves a simple question or play out a simple metaphor for ourselves when we get into this topic, which is picture yourself standing at the bedside of a sick loved one who is

permanently ill and having to confront with them that that person's going to have to die so that others could get today's medicines more cheaply. Not a narrative any one of us wants to face, and there's got to be a better way.

So I'll go from there and try and bring us into a focus on the one thing. I know anything about intellectual property and Rich, I thought your data points were so poignant and critical about how the technology actually works. I'll try and tie into them a bit also in the next few minutes. What in my mind we all need to recognize is again, just call it reality therapy. New products like the ones that Richard was talking about that are so magical and transformative and save the lives of so many people, they simply don't happen without substantial private sector investment.

We love our government and we love what NIH invests in, what I call upstream or basic R&D, but it's a very small fraction of what's required to bring products and billions of dollars that Richard is talking about is after the government invests a few million dollars at the top end in a particular area of science. So there's an ecosystem. The ecosystem in the U.S., the biotech industry as Sandra's report reveals, works extraordinarily well. We are the envy of the world. Our system works really, really well. It is a symbiosis between a little bit of government investment at the top and in an enormous amount, billions of dollars of very loss-y risky private sector investment that results in products coming to the marketplace. You take away the incentives for the private sector investment, you take away the ecosystem and the government investment gets stranded. That is simply the way it works.

So the private sector investment is essential. Next point, it doesn't happen unless there are exclusivity incentives. Great companies like Richard's and others that I think are probably represented in this room and hopefully watching online believe deeply in supporting patient outcomes and healing people, but they've also got to run a business. Picture yourself in the boardroom of any company trying to explain, well, we're just going to pour billions of dollars into something and we're going to lose money on it. That's a going out of business strategy.

Nobody actually has that discussion in a boardroom. The discussion is a balanced one that talks about going after important patient conditions in a way that can return economics to be [inaudible 00:35:47] patient condition, but we've got to be very clear-eyed and recognize that without exclusivity incentives, either the government granting an incentive or a patent incentive or regulatory exclusivity, some form of incentive. In this field, given that once the discovery has been made the cost to manufacture and copy is so low, there's nobody who will be able to invest, and that doesn't help the generics industry, which depends on investments by companies like Richards. It doesn't patient outcomes, it doesn't help our country. It doesn't help anybody.

So next point after that, the U.S. IP system, we just have to be clear-eyed about this. The U.S. IP system generally and in particular with respect to the biotech area, is under siege. Okay? There's really just no way to put it and be honest about it. Why do I say that? Subject matter eligibility is a mess. Many of us in this room have been working on it for a long time. That means, and this is particularly in the pharma industry, including diagnostics, including cell related therapy, including gene related therapy, simply aren't available no matter how great the discovery is. We have crafted for our country an eligibility requirement to get into the patent system that simply excludes entire areas of science. As crazy as it sounds, we've done that. Have other countries followed us? Absolutely not. Chinese are much smarter. Japan, much smarter. Europe, much smarter. None of them have these eligibility constraints that we self-imposed in the U.S.

Second part of the siege, exclusivity associated with the patent right, or I should say lack thereof. It's no longer viable to expect in the U.S., even if you have a valid, enforceable and infringed patent clear as the driven snow, you are not likely to get injunctive relief. You are not likely to actually have an exclusive right resulting from what the Constitution itself said was supposed to be an exclusive right. So under siege, then you get to the trips waiver that we're dealing with, not just one, but multiple. Our global treatment system or trade is declaring multiple times that vaccines, diagnostics, and other treatments for important diseases, the intellectual property has to be waived. So companies that have invested billions actually have to give their IP away on the basis, and I'll come back to this in my closing comments here in just a moment, on the basis of what we now know are some plainly false narratives. The false narrative that intellectual property is standing in the way of making important therapeutics, vaccines, and tests available to people in developing parts of the world.

Now, coming back to the point I mentioned before, it's super important that people in developing parts of the world get access to treatments. Going back to the pandemic, the COVID vaccine, COVID tests, COVID diagnostics. And there was an effort through these trips waivers to pin the blame for the slowness of getting vaccines, treatments, diagnostics, et cetera, to developing countries to blame that on the IP system. False narrative. We now know clearly that the IP system never had anything to do with developing countries not getting access to the treatments that they desperately needed quickly. What did cause it? Of course, lack of infrastructure, refrigeration, power, roads. How about corruption? How about lack of confidence in the government by people in developing countries? That's what caused the vaccines not to get distributed.

In fact, the opposite of the narrative was true of the companies like Richard's that had so much to do with saving the world. They formed hundreds of voluntary agreements. They worked around the world. They created actually a glut of the vaccines, diagnostics, and other treatments, and they did it to save the world, and they succeeded. It's incredible that we blame them for that rather than championing the cause for that. Okay, that's trips.

Last point on the why I feel our IP system is under siege. Steve mentioned this in his opening comments. I think Sandra may have mentioned it also, turning the Bayh-Dole Act on its head. This is a law that's been heralded as possibly the most successful piece of commercial legislation of the entire 20th century. If you believe in an effective federal government, like I certainly do, and probably most everyone in this room, you would say the Bayh-Dole Act marks a high watermark of congressional achievement from the 20th century. So why in the world would we tear it apart, turn it on its head given how successful it's been? That's what we're doing right now, and the White House just doubled down on that as recently as yesterday. So I think there's no debate that our IP system is under siege.

Last thing I want to mention and then I'll turn over to Judge Michel is, well, does it make sense? Is there a policy basis? Is there a good reason why we should be across the board voluntarily weakening our IP system, if you will, disarming in the fight against disease? Is there a good reason for it? I would tell you no. There is a false narrative or a series of false narratives. There's this false narrative about so-called patent thickets, ostensibly drug companies getting thick of a thicket, hundreds, thousands, millions of patents that cover a single drug so that nobody can penetrate the thicket. That is a false narrative.

In fact, the numbers of patents that drug companies get are low, and you can research this yourself. Go to the FDA's orange book. It lists the patents that cover the drugs, and they're numbers that almost invariably you can fit on one hand and you don't even need all your fingers to count them up. So we can get into the facts if people want to in more detail, but I believe that is a demonstrably clearly false narrative. Then there's the false narrative of so-called evergreening. Oh my God, the drug companies are getting one patent after another so that they can get, and then just make up a number 40, 50, 60 years of exclusivity. Garbage. That is a totally false narrative. The data shows clearly that the actual exclusivity from patents in this industry has been between 12 and 13 years for generations, for a long time, and you can easily count this. So false narrative.

The last one I want to mention is the other false narrative of product hopping. The idea there being these bad drug companies, once a patent is expiring on the basic drug, they will make an insubstantial trivial treat. Now, the metaphor that's usually used is they'll change the color of the pill or the shape of the pill. Garbage. That's not what it's about at all. What's really happening is companies like Richard's are investing more, hundreds of millions of dollars or billions of dollars to come up with really important improvements. So these are drugs that maybe people in families here today have to take intravenously. So you got to go to a hospital or a clinic once or twice a week and spend half a day getting an IV in order to ingest this drug, and then these great companies will come up with a way to just take a single pill once a week or something of the sort.

That's a huge improvement. I want that improvement. I want to permit patents on that improvement. That's not product hopping, that's treating patients in ways that cure people. And as a result, I would tell you, I believe the product hopping narrative also demonstrably false. So I could go on forever, but I will stop there and turn it over to Judge Michel. Let me turn this off.

**Paul Michel:**

I'd like to focus on how we got here and suggest to you that the way we got into the current mess, the siege, is by institutions getting out of their proper role and engaging in things they're not competent to do. I particularly have to call out the courts because most of the eligibility problems came from Supreme Court decisions, particularly four decisions about a decade ago. The lack of injunctions that Director Kappos mentioned again was a result of a Supreme Court decision, and there are a number of other areas where Supreme Court interventions crimped the ability of the patent system to provide the necessary incentives for the huge investments that need to be made in order to advance human health. And the same thing happened to a lesser degree, fortunately, with the Congress. That the Congress was besieged and is still besieged with aggressive narratives, mostly exaggerated, sometimes flat out false, in order to try to get the Congress to upend the Bayh-Dole system that has been such a signal success for over four decades. So we have a problem of ...

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**Paul Michel:**

... for four decades. So we have a problem of institutional competence. If you step back and think about the patent law that creates the structure of the patent system that leads to these necessary investment incentives, necessary both for corporations and for startups and for venture

capitalists and all the other players in this huge, complicated ecosystem, we have a problem against narrative, devoid effects, devoid of reliable statistics have confused people so badly that they've tried to address nonexistent problems and done so with extremely harmful solutions.

So the Bayh-Dole framework proposed by the President Administration is the perfect example. First of all, right off the bat, it's flatly illegal. The Bayh-Dole Act that does not provide authority to try to control prices by rescinding licenses to patents. In fact, it's directly against the whole purpose of the Bayh-Dole Act, which was to generate this fabulous system, public-private partnership mainly with research universities and national labs, doing the great upstream scientific work as Dave Kappos mentioned, and then industry taking over and spending tens, hundreds, thousands of times more money than the government research money upfront in order to get the cure into the hands of patients.

So we created this system. It's been a huge success. We went from having a very weak biopharma industry in the 70s to having the world gold standard biopharma industry in recent decades. But now its power is being sapped by ill-advised interventions, this time, not by the courts, but by the executive branch of government. I complained earlier about the courts being out of their zone of competence. Now the executive is getting out of its zone of competence. First of all, neither set of policy actors has a good grasp on business realities, how companies make decisions, how venture capitalists make decisions, what incentives are needed to make the decision be, "Yes, we are going to invest the \$20 billion in the such-and-such therapeutic." That's the answer that we need and we're not going to get it now because already there's a threat over every patent that industry has licensed from one of our great research universities because it may end up evaporating because some bureaucrat will say, "Well, I think the price is higher than I think it should be. And therefore, your patent is gone."

Now anybody can make the invention that you patented. So you went from being the exclusive right holder to a non-right holder overnight because, I, the bureaucrat don't like the price. So this is a recipe for no new cures basically. Now it's true that there are problems that deserve solution in terms of affordability of critical drugs for patients who are now economically struggling or even unable to finance them. But the answer to that is to make modest adjustments in the healthcare insurance system so that the out-of-pocket expense, the so-called co-pay that the customer actually has to fork over is reduced to take care of those limited number of people who really have an affordability problem. But in general, we don't have an affordability problem in this country. 93 percent of all prescriptions are to generics. They aren't even covered by patents. And even some therapeutic or other medical interventions that are covered by a patent aren't the only way to attack that disease.

There are other interventions that attack the same disease. So the idea that cures are being blocked by patents is close to a flat falsehood. And in any event, the whole thing is a total distortion of law. Step back and think of the patent law. The patent law is a statute passed by Congress, amended by Congress from time to time. Congress and our democracy is the only proper institution to be making broad public policy decisions about innovation policy because the courts and the executive are not competent to do it. They don't have the expertise, they don't have the experience. They're not set up to collect the kind of data that you need. Congress is much better situated to do that, and we've seen that proven over and over. So what we have is

Congress has been basically countermanded by the Supreme Court and to an extent by lower courts.

And now with the Bayh-Dole march-in framework proposal, the executive is trying to undo the Patent Act, the way the people's elected representatives shaped it. This is a total distortion of how our country's supposed to work. Congress is in the driver's seat on broad innovation policy and the other two branches are not, and they've frankly made a mess out of it, by interventions that over respond overreact to hugely exaggerated, and as I said, sometimes flat out false narratives. Well, one of the things we have to do is better equip courts and executives to be able to spot the falsity in the exaggeration because right now their ability to detect nonsense from truth is way too limited and even the Congress could use some help. That's part of the reason why we're all here and working so hard to try to help policymakers and their advisors and staff better understand how all this works in real life, not in a narrative by some narrow cause group that's flogging its own particular narrow interest.

We have to take the whole picture into consideration and come up with balanced, sensible approaches that we know from experience will work. It's not that hard to do. We've done it before. We can do it again, but we have to conquer the false narrative problem. It's really a PR war between special cause groups and everybody else. And the judges, or congressional staffers and members, people in the White House and so on, in my opinion, they need help. It's our duty, really, our responsibility as citizens to make sure they get the technical advice and help that they need. So it's not an unsolvable problem, but it's not going to be solved unless we get better at exposing nonsense and false narratives, so that true narrative and real data like Sandra's report summarized can control things instead of propaganda, which is more or less what we have now.

So I implore all of you in the room and those watching remotely now or later to get into the act of helping our leaders sort out truth from nonsense so they can make decisions that will be in the best interest of all patients and also the economy of our country. It's not only a question of leadership compared to some foreign rival, and we have many all over Europe and in many Asian countries including China. But it's also a question of just flat out need. Human health needs are acute. There are all sorts of diseases that have no cure, that don't even have a beginning of a cure. So we need to have more incentive, faster work, not less. So we need to reverse course. It's really that simple and everyone should help. Thank you.

**Frank Lichtenberg:**

[inaudible 00:54:36] Thank you. Well, I will show the fact that I'm a professor by, I have to stand up and I have to have a PowerPoint, otherwise I'm not comfortable. So we've heard about the value of pharmaceutical innovation. But we have to be careful. We don't want to be cherry-picking. We don't want to just pick some really good examples like HIV. So there's a question of, what's true in general? What has the value of pharmaceutical innovation been for the United States and globally? And that's something that I've been studying and trying to analyze for many years. And hopefully, I will not deliver a false narrative. In fact, I'm only going to tell you about peer-reviewed research that's gotten a lot of scrutiny. And also, there're certainly critics of the industry that argue, "Gee, a lot of innovation is me too. Most drugs are me-too drugs. They don't really add any value."

So how true is that? So what I'd like to discuss, and I really want to make two major points about biopharmaceutical innovation. And the first one is, and I'll try to convince you, that has been extremely valuable in the U.S. and globally in that, it has increased longevity, it has reduced disability, and in fact, that it's reduced the average cost of healthcare episodes. And then at the end, I will make a point that financial incentives influenced the amount of biopharmaceutical innovation, as some of my colleagues here have already emphasized. So let me talk first about longevity. Longevity is certainly a very important health outcome and it's certainly the best measured because we have death certificates. We know how old people are when they die. We know what their cause of death is. So we can measure mortality quite well. And I've exploited that in some of my research.

So I published a paper two years ago, the effect of pharmaceutical innovation on longevity, both in the United States and globally. And in a nutshell, what I find is that I estimated that the increase, that pharmaceutical innovation, basically was responsible for the entire increase in longevity in the United States over the period 2006-2018. The way I measure innovation is we look at what drugs people are taking. We look at when those drugs were approved by the FDA. And the hypothesis is that newer drugs are better than older drugs. Yes, there are some good old drugs. But in general, newer drugs are better. Just like newer airplanes are better than older airplanes, newer computers are better. This applies to drugs as well. So what I measure is the mean vintage of drugs. Like when we look at the population and say, "When were the drugs taken by the population first approved?"

And based on that, I estimate that, in fact, the entire increase in longevity in the U.S. over this period was due to pharmaceutical innovation. Now, there are some other factors that might contribute to increased longevity like declining smoking, increased education. On the other hand, there are some factors that would reduce longevity like increased obesity. Obesity and severe obesity has increased in the United States. That certainly tended to reduce longevity. I also look at not only longevity of all Americans, but of black Americans because we worry about racial disparities. And in fact, I find a larger effect of innovation on the longevity of black Americans than I do for the entire population. So that's one result that I had about U.S. longevity. I also look at longevity internationally, and I find that biopharmaceutical innovation increased the mean age of death in 26 countries by about a year and a half between 2006 and 2016.

Now, that turns out to be only about a third of the overall increase in longevity in these countries, but it's still a very significant contribution. And by the way, my PowerPoint includes links to my papers. And I'd be glad to share any of them with you now. Okay, increasing longevity, that's a good thing. But we also care about quality of life, disability, use of medical care, and so on. So I did another study that was actually sponsored by the Social Security Administration where I tried to evaluate the effect of innovation on disability, on whether people receive social security or not and their use of medical care. And the strategy is to look at different diseases. And I take advantage of the fact that there's been more innovation for some diseases than for others. In fact, there's been no innovation, the number of drug classes that have ever been approved for some diseases has not increased. But the number for other diseases has increased dramatically.

So the question that I ask is, "Do we see greater improvements in health, greater reductions in disability for the diseases where there's been more innovation, controlling for other factors, controlling for the overall trend in disability and so forth?" And I find that the answer is,

definitely yes. That my estimates indicate that the probability of being disabled, of collecting social security and of using medical care is inversely related to the number of drug classes previously approved by the FDA.

Now, a new drug class is more important than just another drug within a class. So that makes sense. Also, that there should be a lag that even if the FDA approves a new drug today, it's not going to be widely used for half a dozen years. So there's a lag, and I document that lag. And as a result, I can actually predict how much disability there's going to be six years from now because we know how many drugs the FDA has approved, what diseases those drugs are used to treat.

So we can predict future disability using this methodology. And in fact, I estimate based on this study... I can estimate how much disability and other variables have been reduced by, say, 20 years of innovation. And what I estimate is that the number of people who are completely unable to work has been reduced by about 4.5 percent because in this government survey, the medical expenditure panel survey, they interview people and they ask them, "What medical conditions do you have and are you unable to work?" And what we observe is that if there's been a lot of innovation for a condition, that the probability of being unable to work has declined. And similarly, the number of people with cognitive limitations has declined. Even though we don't certainly have a magic bullet for Alzheimer's, we know that other medical conditions like heart disease can cause people to have cognitive decline.

So if we have better treatments for heart disease, that can reduce the prevalence of cognitive limitations, etc. So those are some of my findings from that study. And in fact, we can also try to attach dollar values to this. That if we reduce the probability of being unable to work by about 4 percent, that that's worth about \$27 billion, given the average earnings of people who are working. And we can measure other things as well. By far, the largest benefit is the decline in hospitalization. That newer better drugs reduce the probability that people have to be hospitalized. And that accounts for about half of the total cost savings. Now, recently, the Bureau of Economic Analysis has started publishing data on the average cost of treating different diseases. Like how much did it cost to treat breast cancer in 2000 and how much does it cost today? And we do that for several hundred diseases.

And what I examine in this study is how the change in the cost of treating a disease is related to the amount of innovation for that disease. And what I find is that the drugs approved during a 14 year period are estimated to have reduced the average cost of healthcare episodes by about 5 percent. That the conditions where there's been more innovation, we see slower growth in the average cost of treating those conditions. And that implies that those drugs actually reduced total medical expenditure in 2014 by about \$93 billion, once we account for the cost offsets and so on that are included in the BEA data. So finally, okay, pharmaceutical innovation, very valuable in a number of respects. But the last point I want to make is that financial incentives are required to encourage this kind of innovation. I actually... I published a paper about 15 years ago called Importation and Innovation, because at that time there was a lot of discussion is, "Should we just import drugs from Canada?" Which is now I understand started to happen in Florida and the rest of the world that would significantly lower U.S. drug prices.

The question is, what impact would that have on innovation? Well, I think a reasonable way to try to examine the effect of incentives on innovation is, let's look at different diseases. Some



diseases are highly prevalent, the market is huge. And therefore, there's a large incentive to develop a drug for a highly prevalent condition. Whereas if it is a rare disease, then there's a very weak incentive. So what I do in this study is I examine the correlation across diseases between market size, that is the prevalence of the condition and the amount of innovation like the number of drugs.

And I find, gee, not surprisingly, there's a very strong relationship. Fewer drugs are developed for rare diseases than for common diseases. In fact, that was a motivation for the Orphan Drug Act. And from that relationship, we can infer in a sense how sensitive drug development is to financial incentives, to market size. And what I found in that paper was that I estimated that in the long run, a 10 percent decline in drug prices would be likely to cause at least a 5-6 percent decline in pharmaceutical innovation. So indeed, there is evidence that financial incentives matter quite a bit. Thank you very much.

**Stephen Ezell:**

All right, well that was great, Frank and another panelists. I appreciate it. I just want to emphasize one point that David alluded to, and that's fully that this broader debate about drug price controls we're having is not really one about whether society wants lower prices in exchange for lower drug company profits. It's really about whether society wants lower drug prices in exchange for less and slower drug innovation. That is cheaper prices today, but less effective drugs when our children become adults in the future. It's also imperative to note that less than half of every dollar spent on drugs in the United States actually goes to the companies that are innovating and manufacturing those drugs. In fact, the share of revenues for each dollar sold in drugs in the U.S. that goes to manufacturers has declined by 13 percent over the past seven years. And it's just 49.5 percent today.

So one very important avenue Congress needs to consider in the drug price control debate is all the middlemen and intermediaries who are taking [inaudible 01:07:23] greater share of every dollar spent on drugs in the U.S. I want to remind our folks watching online that you can submit questions via the Slido application, and I want to encourage questions from our audience here in the room. So get thinking about your questions. But I want to start, if I might, with one question in two parts.

Maybe Richard could take the first part, but it'll lead into a second question that perhaps David or the other panelists could address. So Richard, the significance of partnerships and collaborations really can't be overstated when it comes to today's life sciences sector. Perhaps, you could discuss the role that those relationships play in your work in the discovery of new medicines. The second part of that question, and this is again picking up on something David alluded to, is that some civil society advocates have asserted that today's American, "Pays twice for drugs." They pay once when the government is funding biomedical R&D, and then they pay again when they actually purchase a drug at the pharmacy counter. Maybe David, you could describe why that analysis is misguided, and then talk perhaps a bit more about the respective roles of the public in private sector in the R&D and drug discovery process with the government, funding that basic research into biochemistry and creating knowledge of drug targets that then companies like Richard's takes to the private sector. So go ahead, Richard.

**Richard Tillyer:**

Okay. Well, thanks for that question. As I said during the talk, the entire ecosystem's needed to solve the kind of problems that we're looking to take on. It just is-

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**Richard Tillyer:**

... solve the problems that we're looking to take on. It just is, and I'll talk about a couple. We have. David, it gets to the point you made about injectables, and going to orals. There's a program that we're working on right now, just as an example, where there are really pretty effective biologicals, injectable biologicals that are used to treat diseases like psoriasis, ulcerative colitis, inflammatory bowel disease. And the thing about the injectables is that while they're effective, what we hear from patients is that there are large, large numbers of patients that are not being served by these. Many reasons why, but there would have vast preference for an oral therapeutic. We started looking at this about 20 years ago, and eventually found a partner that had a really, really interesting idea, a great lead in this space. And our general approach is to be completely agnostic to innovation.

Innovation can occur anywhere, a lot of it in our company, but on most of it outside. And we go and try and find partners that can help us solve a key problem. And we landed on a partner that actually had a really, really good idea, and we went into a partnership with them. And through numerous iterations actually in the clinic, we didn't get it right first time, we together came up with a completely new therapeutic modality that we call a targeted oral peptide. It has exactly the same biological activity as the marketed biological agents, but it actually is orally administered. And we're in a clinic now. It took us 20 years to get there, but we could not have done that without the partner. And one thing I would say is the partner could not have done it without us. This took a massive, massive endeavor of molecular invention, industrialization to pull that off.

That's just one example. Another one, really quickly, I mentioned cell therapy. One of the things you hear about a lot is how difficult it's to manufacture a CAR T product. We have numerous partners that help us with this. We're actually in the middle right now of inventing with our partner a completely robotic solution. Today, this is a very manual, manual process, that involves thousands of people in a manufacturing plant, and we're looking to complete automate this, and invent a robotic solution. And we're doing that with our partner. So every aspect of our business, every aspect of innovation we see, we're completely agnostic to the source of this. We are looking for partners that can add onto our engine, and we're looking for one plus one equals five.

**David Kappos:**

Okay. And just continuing, Steve with your second part of the question, "Is the consumer paying twice for drugs?" As you can imagine, my answer to that question is absolutely not. What's actually going on is the government is funding important upstream basic research, that produces initial candidate innovations, that then require much larger investments to move through first internal trials that Richard explained, and then external clinical phase one, two, and three trials, and sometimes repeating various parts of those to get into the marketplace. So as an example, one study that looked at the year 2000 found that of the 18 FDA approved therapies that came

out that year, the National Institutes for Health funded a total of \$670 million for those same 18 FDA approved therapies from that year. The private sector funding totaled \$44.3 billion. So you're talking around 50 times the investment that the government makes is required on the part of the private sector, in order to turn a great upstream basic research idea into a therapeutic that you can put into patients.

So the patient or the consumer is absolutely not paying twice. What's actually happening is a symbiotic complimentary relationship, the government doing basic research upstream, putting that in the hands of companies that then move the research with huge additional investments into the marketplace.

**Stephen Ezell:**

Great. Thanks. Paul. Yes.

**Paul Michel:**

Let me just add the emphasis that should be due to smaller entities. There's so much discussion about big pharma companies like J&J, and about a dozen others as if they're the entire ecosystem here, but they're not. They're actually the minority of players. Most of the players are much smaller pharma and bio-entities, and those tend to be not only smaller, but newer so-called startups that license patents owned by research universities, and then go through all the trials and tribulations that Richard has described to come up with something of real value. And then they very often get acquired by a larger company, or even by J&J. But that whole system of creating and supporting these smaller startup type companies depends on outside funding. They don't yet have a product on the market. They don't have a revenue stream like J&J does.

So they depend almost totally on outside funders like venture capitalists. And we have ample, ample evidence that venture capitalists are not going to support much of anything without strong patent rights. And it's already starting to dry up. There's more venture capital available now than there was 5 or 10 years ago, but it's not going into real technology like drug development. It's going into entertainment, build casinos, make movies, in large hotels, and things like that, not worthless, but not nearly as valuable as human health improvements. So the ecosystem really is complicated, and you can easily understand. Remember what Richard said about, "It takes a decade or longer. It takes billions of dollars. The vast majority of candidates fail."

All those have to be financed out of the eventual profits of the few drugs that actually become so-called blockbusters, and earn significant revenue. So you can easily see that neither corporate officials nor venture capitalists are going to support this high-risk, slow return, arduous process without strong incentives that come not exclusively, but mainly from patents. So if our country is going to continue to weaken patents, we're going to get less innovation, and worse human health. It's that simple.

**Stephen Ezell:**

Well said. Great. Any questions from our audience? If you would, we have a microphone coming around. If you would just state your name and the organization you're with. Thank you.

**Arthur Daemmrich:**

Thank you. Arthur Daemmrich. I'm at the Arizona State University Consortium for Science Policy and Outcomes. One of the policy innovations that's tossed out a lot on this issue is the idea of using prizes. So I'm curious. I have my own views from historical research, but I'm curious about the panelists' take. Is that a possible solution across the board? Is it possibly helpful in particular targeted areas?

**Stephen Ezell:**

Please? Anyone who would like to take that?

**Paul Michel:**

Well, it's plainly insufficient. It may be helpful in a few narrow areas if it's very well-designed, but consider the reality of our national fiscal mess. Congress is out of money. They've already spent all the taxpayer money available, and then some. So the idea that Congress is going to be able to come up with enough cash to adequately fund prizes for thousands of different diseases is just a total fantasy, and not only for prizes, but also for the idea that we don't need the private sector to be incentivized, because the government can pay for it. No. The government can't pay for it. Already out of money. So I think the idea of prizes is one of these narratives that may sound good superficially if you don't really know the facts, but if you look at the whole factual picture, it's a non-starter of a way to run the system.

**Stephen Ezell:**

Go to it if you want David. Sure.

**David Kappos:**

I'll just add to that briefly, Frank. If this is an area you've done research on, I'm sure we'd love to hear about it. But the question mentioned historical perspective, and that I do know from having looked at the history. Also, the idea of prizes has been tried. This goes back actually to at least the 19th century, if not the 18th century. And what was learned in a great study done by Petra Moser, if I recall, another great academic who researches in this field is that shouldn't be a surprise that when you run prizes, you're injecting government decision-making and oversight into the market, and you're not letting the market work. And the result that you get is researchers spending a lot of time and effort to win prizes, instead of go out, and research, and develop cures for the most important diseases.

**Stephen Ezell:**

For what it's worth, ITIF also has its own report on this topic called Delinkage Debunked, and it explains why prizes in some cases may be legitimate, to use it to provide for the biomedical innovation in America and the world needs it would be wholly insufficient. Go ahead, Frank.

**Frank Lichtenberg:**

Yeah. I think there is one good example of a successful prize, and that was the Navigation Act. There's a wonderful book called Longitude where ships were just crashing, and a clock maker

essentially came up with. So there is an example, but designing the right prize, and doing that on a very large scale does seem formidable.

**Monique Mansoura:**

Good afternoon. Thank you Stephen for all the work you and ITIF do in this domain. Sandra, congratulations on a really valuable insightful report, and to all of you for a really thoughtful panel. I'm Monique Mansoura with the MITRE Corporation. I lead global health security and biotechnology. I've worked previously at Novartis in a multinational pharmaceutical company, and for the government in developing a medical countermeasures program for high consequence events like pandemics. A couple of questions. One is the biotechnology platform as the bioeconomy, as its applications to other sectors beyond pharma, how much do you see that as adding value to the positions you're advocating here? Are they specific to biopharma, especially with regard to competitiveness of the U.S. with other entities? Those other corporate sectors that you've compared are extraordinarily valuable. Most of them I would say have a military application, which really has amplified the need to have a stronger U.S. competitive position.

How much of it all do you think that that national security angle, along with the economics, and the bioeconomy, and medicines is important to the argument you're making? And lastly, one of the policy prescriptions that's going to be at that hearing on Thursday is the proposed BIOSECURE Act, which takes a very different angle at how we would position the U.S. to compete more effectively. And if you have any thoughts on that, I'd appreciate it. Thank you.

**Sandra Barbosu:**

So thank you. Thank you for the questions. So I would say that indeed, I think that the biopharma industry is really important for national security issues, for things like pandemic preparedness, also increasingly for bioweapon attacks. So I think there's all these different applications that it could be very useful for. And I think that's why a lot of this applies more broadly to the U.S. competitiveness, just outside specifically just biopharma as well.

**Stephen Ezell:**

I would just also here highlight the tremendous complementarities that exist across manufacturing, across a number of sectors. Certainly there's tremendous spillover effects when we learn novel biomanufacturing techniques that are applicable with making biologic drugs in large vats, but those also have spillovers to other sectors like chemicals, discrete, and batch, and flow, and process technologies. In fact, this is one area where Congress has been enormously helpful to the U.S. innovation system by setting up a national network for manufacturing innovation I'll call Manufacturing U.S.A, which is 17 institutes of advanced R and D, to create advanced products and process technologies. NIIMBL, the National Institute of Innovation Manufacturing Biologics is a critically important one. Interestingly, that that was the one that was an industry competed manufacturing institute, whereas others were driven by either Department of Engineering, or Department of Defense.

But nevertheless, the point is tremendous I think the synergies and spillover effects in our broader U.S. manufacturing sector. I want to get one question in from our audience online. "Critics assert that biopharmaceutical profits are too high, but studies show that this is not the case when properly adjusting for R and D expenses. How can we correct the record on this

point?” I don’t know if any of y’all have seen Sood or G’s research in this space, but the broad point here is about properly capitalizing the R and D to come up with effective return metrics.

Go ahead, Frank, if you want to comment.

**Frank Lichtenberg:**

Well, I would say that I think that the appropriate metric is not so much the profits of the drug companies, but the value and cost-effectiveness of the drugs, of their products. And that’s certainly what payers care about. They want to look at how much value they’re getting, and whether the drugs are cost-effective, or even cost saving. I think that’s a much more important issue. We certainly know that there is a lot of intense competition in the industry. I’ve written a couple of papers which look at competition between brands, as well as generic versus branded competition. So when new drugs enter a drug class, that tends to put downward pressure on the existing drugs within the class. I think that that’s often overlooked. So I think that there’s quite a lot of competition in the industry.

**Stephen Ezell:**

We actually have a paper called The Economics of Biopharmaceutical Innovation, which delves much deeper onto this point specifically, and looks at some of the academic research. Folks like Sood out at the U.S.C Schaeffer Center have looked at the excess profits across a number of sectors in America’s life sciences industry from pharmacies, and wholesalers, to PBMs. And actually what he finds is that these middlemen, these intermediaries like the PBMs, the wholesalers are actually significantly more profitable than at least America’s biopharmaceutical companies.

And that’s really telling a statement when you consider that companies like the PBMs are not investing one quarter of the revenues back into lifesaving drugs every year, or employing nearly 1/4 of America’s R and D workforce. Maybe time for one final question, and I want to combine a couple of thoughts if I might. Frank, if I have some prior research you had done correctly, and correct me if this is wrong, or out of date, but I believe you had found that from 1977 to 2010, the value of reductions in work loss days in hospital admissions attributable to pharmaceutical innovation was actually three times larger than the cost of new drugs consumed.

There’s other research that’s looked at what’s referred to as follow-on innovations, but really novel secondary or subsequent innovations, and analysis of that literature finds, “Higher adherence rates across conditions with once daily versus multiple doses, but also found lower cost in terms of healthcare resources utilization.” And the point I’m trying to draw here is the enormous secondary effects of novel drug innovation. And that’s important here on Capitol Hill, because the CBO does not consider dynamic scoring, or the downstream effects of innovations when looking at things like the cost of drugs. How can we better help policymakers understand that they have to look the secondary dynamic effects of innovation, and driving not only the U.S. economy, but when they’re making evaluations of the cost of federal expenditures?

**Frank Lichtenberg:**

Well, I think that what we have to do is carefully-

**Event Producer:**

Frank, your microphone please?

**Frank Lichtenberg:**

Oh. We need to carefully investigate, and try to document this, and demonstrate that this is an important phenomenon. And that's a thing that I've been trying to do in my research, trying to identify cost offsets of the kind that you mentioned, like a reduction in work loss, and so on. And hopefully, eventually the message will get through. I have seen some CBO reports where they do acknowledge the existence of these cost offsets, and in fact argue that increased use of drugs by Medicare beneficiaries can actually lower their non-drug costs, and that there's almost a one for one offset. So I think that the CBO does recognize this, at least in some of their studies.

**Stephen Ezell:**

Go ahead Richard.

**Richard Tillyer:**

Yeah. I keep coming back to the patient here. There are many examples we could talk about where the optimization of duration of dosing, and the frequency of dosing actually has a beneficial effect on the outcome. And I think we've got to really make sure we highlight that.

**Stephen Ezell:**

Please do.

**David Kappos:**

Thank you, Steve. And just coming back to your issue about how do we get this narrative out on Capitol Hill, and this came from the previous question as well, what strikes me is, yes. We need great academic papers that explore these topics, but for consumption here on the hill, we need messages that are easily digested in the legislative environment. And that's where if folks get the data to those of us like Judge Michel and I, who work on a voluntary, bipartisan, nonprofit basis to help package messages, and bring them to the attention of members and staff, and ITIF by the way, which does a great job of that as well, including in Sandra's report, I think that goes a long way to turning fact into policy.

**Paul Michel:**

Stephen, I'd like to just raise one thought, because it seems to me there's an assumption abroad in the land that seems to me very foolish. We don't want J&J and like companies to not make money. If they don't make profits, they're not going to continue researching. They might even go out of business. So instead of being upset if a drug company makes profits, Americans should be happy, because that fuels this whole virtuous cycle to get us more and better cures, and therapeutics. So the whole premise that drug companies should only make a tiny bit of money or better yet none is completely wrong, and counterproductive. And that's another perspective that has to be carefully conveyed to policymakers. And Dave is so right. The gateway is the staffer, and he and I spent a lot of time with staffers, and many of you do too. But we all need to do

more of that, because that's the only way we're going to gradually educate the members to see the whole picture, and to be able to sort out truth from fiction.

**Stephen Ezell:**

Now, maybe that's an excellent point for us to end on Judge Michel. What did I tell you? If we work with innovation based industries like semiconductors with the profits from one generation of innovation like the 10 nanometer or the 7 nanometer [inaudible 01:30:48] chip, that gets the profits to invest in that 3 nanometer chip. Likewise in the life sciences industry, it's the profits from a Hepatitis C, or a cholesterol drug that gives the profits, that can then be reinvested to solve here to four intractable problems at the forefront of medical science, whether it's COVID-19, or pancreatic cancer. So it's absolutely imperative that the economics that sustain this life sciences innovation system persist in the future. Okay. With that, I want to first thank the audience for being here today, and then I want to thank our excellent panel. Thank you guys very much for your great presentations. Video of this event, as well as the presentations are up online for you to share with your friends. Thank you for being with us today.

PART 4 OF 4 ENDS [01:31:32]