

What You Need to Know About President Biden's Prescription Drug Agenda

Doug Badger, Adam Mossoff, Peter Pitts, and Marie Fishpaw

KEY TAKEAWAYS

Congress and the Administration are fighting a two-front war against medical innovation—for drug price controls and for waiving COVID-19 vaccine patents.

These government penalties on innovation will have negative consequences for American patients by limiting access to new drugs and discouraging their development.

Lawmakers should remove government barriers to research and production and allow more competition in the market to reduce prices.

On May 27, 2021, The Heritage Foundation held a virtual panel discussion on President Biden's prescription drug agenda. Heritage's Doug Badger and Adam Mossoff, as well as Peter Pitts, a former U.S. Food and Drug Administration Associate Commissioner, discussed policies that protect access to today's treatments without sacrificing tomorrow's cures. The three experts weighed in on waiving patent rights and government price negotiations—and how these affect access to drugs around the world, as well as innovation for creating future medicines. The transcript of this discussion has been edited for clarity and readability.

Marie Fishpaw: Thank you for joining us today at our event: What You Need to Know About President Biden's Prescription Drug Agenda. Our panelists are Doug Badger, senior fellow at The Heritage

This paper, in its entirety, can be found at <http://report.heritage.org/hl1324>

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Foundation; Adam Mossoff, visiting intellectual property fellow at Heritage and a professor at George Mason University's Antonin Scalia Law School; and Peter Pitts, president of the Center for Medicine in the Public Interest, and a former Associate Food and Drug Administration (FDA) Commissioner.

Doug Badger, lay the landscape for us. What is going on with the Biden Administration's proposals on prescription drugs, and what's going on in Congress? How should we think about it?

Doug Badger: There are two major proposals. The first is legislative—H.R. 3,¹ a bill that has been introduced in the Congress. The second is an effort by the Biden Administration to waive intellectual property (IP) rights for COVID-19 vaccines, which would be an international effort through the World Trade Organization (WTO). Let me break those two down for you.

Let's start with H.R. 3. The bill proposes that the Secretary of Health and Human Services negotiate the price of certain drugs in the United States. The Secretary would identify those drugs by compiling two lists: a list of 125 drugs that have the highest net spending in the Medicare Part D program, and another list of 125 drugs that have the highest net spending in the economy at large. Obviously, there might be some overlap between those two lists. On April 15, 2022, on tax day, the Secretary will select at least 25 drugs from those lists for price negotiation. In addition, any insulin product would be subject to government negotiation, as well as certain new market entrants.

How does the negotiation work? The Secretary looks at the average international market price, as the legislation puts it. The Secretary looks at six countries—Australia, Canada, France, Germany, Japan, and the United Kingdom—and asks: "What's the average price of that product in those six countries?" And then, based on that price, the Secretary sets two goalposts for negotiation. One is the so-called target price, which would be the lowest price in those six countries. The other would be 120 percent of the average price. The Secretary would then enter into a negotiation over each of these products with the manufacturer to establish the maximum fair price. Now that fair price does not only apply to government programs. It applies to every single private health insurance plan in the country, both in the individual and the group market. These plans are automatically deemed part of those negotiations.

Why would a manufacturer even get into that negotiation game? The answer is pretty simple: There are penalties. If a manufacturer does not accept the last best offer by the Secretary by a time certain, the government

then imposes an excise tax on the manufacturer—which rises every day that the manufacturer doesn’t agree to the price. Ultimately, the excise tax can rise to 95 percent of the manufacturer’s revenue from that product in the preceding year. That’s in addition to the corporate tax, and is not deductible. Basically, the government says, “If you will not accept our final offer, we will take the revenue from your product in the form of an excise tax.” So, it is a negotiation, but it’s not a negotiation in the ordinary sense of the term.

Now on to the second front. The Biden Administration announced on May 5 that U.S. Trade Representative Katherine Tai will be part of the WTO process in which the U.S. will join Russia and China in advocating a waiver of intellectual property rights for COVID-19 vaccine manufacturers like Pfizer, Moderna, and BioNTech. The Administration is committed to negotiating in favor of this waiver of IP rights and getting the WTO to adopt it. The WTO has a consensus process. All 124 members must sign onto whatever this text-based agreement is, in order for it to take effect. So far, Germany, Japan, and other countries are not supportive of the proposal to waive IP rights to COVID vaccines. The U.S., China, Russia, and other countries are supportive of the waiver. The expectation is that this issue will not be resolved until a ministerial meeting scheduled for November this year.

So, the two major assaults on medical innovation are (1) price-control legislation, which the President supports; and (2) the WTO process that the Biden Administration is pursuing.

Marie Fishpaw: Adam, take a deeper dive for us into what the Biden Administration is proposing to do with intellectual property patents. How should we think about that?

Adam Mossoff: As Doug described, the intellectual property waiver at the WTO that the Biden Administration is supporting is an unprecedented move. The United States has never supported a waiver from our international treaty obligations to enforce and protect the rights of creators and innovators in our country and in other countries. This will ultimately have to be implemented through legislation in this country, and it will eventually involve not just a waiver of patent rights, but a waiver of intellectual property rights in trade secrets, copyrights, and any other types of protected knowledge and know-how. That really is of great concern, because patents are publicly disclosed, but trade secrets are secret. Once you disclose them, the cat is out of the bag, and you can’t get it back in.

We’re talking about really significant, valuable trade-secret information, for instance, how you develop messenger RNA (mRNA) vaccines and drugs. mRNA is a platform technology. Once that’s released to the world through a coerced transfer or through other types of “incentives” that Doug described,

such as excise taxes or other types of punishments, then anyone can use it for any purposes beyond just the COVID pandemic. The value in the intellectual property is completely wiped out. This is very significant because it strikes at the core of what has been the driver of the U.S. innovation economy—reliable and effective intellectual property rights.

The driver of the biotech revolution of the past several decades has been the patent system and the American intellectual property system more broadly. Reliable and effective property rights made possible billions of private research and development (R&D) investments in supporting millions of labor hours to create technologies like the mRNA platform. Once that's released to the world, people can use it for ongoing development of other drugs—and we're talking about any country, including Russia and China—as well as the countries that originally were pushing for the waiver, such as India and South Africa.

This is of concern, because not only will China and Russia continue to ignore our intellectual property rights, they could also potentially use it to manufacture biological weapons or other types of threats to our national security. So, this move by the Biden Administration to support the IP waiver at the WTO is really significant. It's a tremendous threat to our innovators and our creators, and it really undermines everything that our intellectual property system has made possible, not just for people in our country, but for the entire world. We produce almost two-thirds of all new medical innovations in part because of the legal protections and commercial incentives provided by reliable and effective patent rights.

Marie Fishpaw: Both of you put a lot on the table. Some of these changes sound sweeping, and some of the rationale for these changes is tied specifically to the COVID-19 vaccine. We saw these vaccines come to market in unprecedented time far ahead of the normal schedule. There's a big debate about the role that government played. Those on the left argue: "The government made this possible, with taxpayer money." So that's one reason that the drug companies should not profit from these particular vaccines, nor should they keep their patents.

How we should think about this? Peter, you were at the FDA overseeing the process that brought these vaccines to market so quickly. What do you think about the Left's argument? What do you think are the true successes, and the lessons we should be learning, from bringing the COVID-19 vaccine to market as quickly as it was?

Peter Pitts: Not to put too fine a point on it, but whether it's H.R. 3 or the temporary waivers of vaccine patents, this is a war against innovation and will have a lot of negative consequences. And they're not unintended consequences.

What the hard Left really wants is government-run health care from top to bottom. Let's face it. Price controls equal choice controls and a lack of respect and understanding of where innovation comes from. Innovation comes from countries that have a robust free-market system, and patent and intellectual property protection, and that's not an accident. Relative to who invents therapeutics and diagnostics and vaccines, the answer is, it's complicated. The simplistic answer from people like Senator Bernie Sanders (I-VT) and Senator Elizabeth Warren (D-MA) and others, is that the government does all the work and all pharmaceutical companies do is market somebody else's discoveries and make all the profits. Nothing could be further from the truth.

Let's start with therapeutics like remdesivir. Remdesivir was the first therapeutic for which the FDA granted an emergency-use authorization. And it worked. It kept people who suffer from serious manifestations of COVID-19 (the elderly with respiratory conditions and other serious health care conditions) from dying. Gilead Science, the company that developed the drug, gave the patent away for free to about 125 low-income and developing countries. When people say the pharmaceutical industry is "just in it for the money," quite frankly I don't know what they're talking about. And I think it's offensive.

Many Members of Congress called the White House and said, "We want you to invoke Bayh-Dole march-in rights. This drug, remdesivir, was developed by the government, we shouldn't have to pay money for it, we want the patent to be revoked."² So, the Government Accountability Office did a comprehensive study.³ But rather than finding in favor of the progressives, the study found that, in actuality, the government did very little relative to this innovation and there aren't going to be any march-in rights. The patent remains with the innovator—as it should. And the people who were baying and howling for marching in, all of a sudden had nothing to say.

The federal government plays a very important role in early research. No doubt about it. But, overwhelmingly, innovation comes from the private sector, and most of the spending on research and development comes from the private sector. John Adams said that "facts are pesky things," and we can't allow the facts not to be part of this conversation. If science is back, then that has to be back for everybody.

What the government did with the COVID-19 vaccines was to underwrite manufacturing at risk. That's huge. What it shows isn't that one partner is superior to another, but that when you bring the power of the ecosystem to bear against a public health threat, we can accomplish amazing things. I'm

very proud to say that the FDA played a very important nonpolitical role in making that happen by following the science and leading us towards victory against the pandemic.

Marie Fishpaw: Let's dig in a bit more on this. A *New York Times* article⁴ recently—and I'm going to paraphrase the headline a bit—basically suggested that the U.S. government is the reason, which you've just rebutted, for the success of the vaccine, because it got in business with the pharmaceutical industry, and the European Union tried to rely on the private market. What's your reaction to that claim?

Peter Pitts: I read *The New York Times* every day, it's my hometown paper. And let me say something positive: I love the crossword puzzles.

When you think about what they're writing relative to where drugs come from, where vaccines come from, what Operation Warp Speed meant, who played which role, they're dancing in the dark and telling half-truths and mistruths. And a half-truth is a whole lie. That's highly unfortunate, because people go to our nation's newspaper of record for the truth, not distorted facts twisted for political convenience.

The fact of the matter is that certainly with the Pfizer-BioNTech vaccine, the government invested no development money. But what it did do was to underwrite the risk of manufacturing. There aren't good guys and bad guys in this scenario. We're all good guys. We made it happen together. Again, this goes back to the Hard Left playbook, to the scenario that government does everything well and private industry is a leech sucking money from the pockets of Americans. That simply is not true. Unless we focus on the value of these medications and these vaccines and these diagnostics and where they came from, the hard work of hundreds of private-sector and government individuals, we're doing ourselves a tremendous disservice. It was a team effort and it needs to be a team effort going forward. Looking for good guys and bad guys is politics, and that should have no role whatsoever in this conversation. Maybe that's being naïve, but that's the way I feel.

Marie Fishpaw: Thank you. Doug, is there anything you want to add on the EU's approach?

Doug Badger: As Peter said, the Trump Administration aggressively pursued manufacturing agreements. It was criticized for this. By pre-committing to buying hundreds of millions of doses from multiple vaccine manufacturers, it bet on every horse. Not every horse crossed the finish line. So far, only three of the six companies with whom the Trump Administration made agreements have gotten emergency-use authorizations from the FDA.

The EU took the approach typical of government-run health care. The EU sought one supplier, the one that would deliver the lowest price. That turned out to be AstraZeneca. And the experience they've had over there has been a little less happy than what we've seen here. Since then, the EU members are also getting vaccines from Pfizer and other companies. They are beginning to catch up with the U.S. The approach taken by the Trump Administration was the better one. It said: "You guys go out and compete. If the FDA gives you a green light to bring your product to market, we'll buy it." The results have been exceptionally good.

Marie Fishpaw: Let's talk about one of the results, and the role of intellectual property in laying the groundwork for it. According to an analysis by a group called the People's Vaccine Alliance,⁵ at least nine new billionaires have been created because the COVID-19 vaccines earned so much money, including through these pre-purchases from government. One of those nine billionaires is the CEO of Moderna, which makes a very widely used vaccine in United States. Some on the left are arguing that these profits, which stem from patent rights, have created inequalities. These inequalities are leaving people behind in some of the less developed parts of the world. The solution the Left proposes is to strip these companies of their patent rights.

What is the role, in your view, of patents advancing vaccine development? Is it better for the world, particularly for those living in the most impoverished countries, if the WTO proceeds with this petition by the Biden Administration to strip these companies of their patent rights?

Adam Mossoff: This is an area, as Peter emphasized, where there is a massive amount of rhetoric and very little facts and data in the claims made by leftist activists and others.

Let me start with the point that you ended on in your question about the developing world and patents as a driver of medical innovation. I would like to explicitly state an undeniable fact for our audience: There is zero evidence that patents have stymied, held up, or otherwise prevented the development, the manufacture, or the distribution of any drugs or vaccines to treat COVID-19. In fact, the evidence is all the opposite: Patents have been a facilitator of the mRNA platform developed by Moderna and BioNTech, and patents facilitated BioNTech's agreement with Pfizer. The mRNA technology was developed over two decades, as Katalin Karikó, who is now a senior vice president at BioNTech, began researching a key part of this technology in the mid-1990s. She couldn't get grants for it, because it was such a radical technology. People thought she was crazy.⁶

This goes to Peter's point that this was almost entirely privately funded. These investments were made on the basis of the promise of reliable and effective property rights in the fruits of their labors, which is why they engaged in these significant efforts over several decades to create this incredible technology that has facilitated a historically unprecedented response to a worldwide pandemic. The COVID-19 pandemic won't even come close to the 1918 Spanish Flu pandemic, which killed an estimated 15 million⁷ people worldwide at a time when the world population was 15 percent of what it is today.

The response from the biopharmaceutical industry has been incredible by any scientific, commercial, or historical standard. The industry is then attacked for this by people saying, "Oh my gosh, how dare you become successful with your incredible, unprecedented human achievement in creating these new technological marvels!" Remdesivir is itself a byproduct of well over a decade of research and development in which Gilead will spend well over a billion dollars in developing and distributing this drug. And the companies are attacked for this, with Representative Alexandria Ocasio-Cortez (D-NY) and others saying, "Oh, how dare you succeed? How dare you be successful?"

When I hear that these scientists and businesspeople have become billionaires with this cutting-edge, risky medical technology they created, this is confirmation to me that those of us lucky enough to benefit from their innovative work are alive and returning back to our regular lives today because of their achievements. The risk of death, which took over half a million Americans, has been averted because of their productive work, and they should be compensated for this achievement. This is exactly what the United States has stood for. This is what it has represented to the world as the shining city on the hill: "Come to the United States where you are free to work, develop, innovate, create, and you will be protected in the fruits of your productive labors. You will become incredibly successful yourself and other people will benefit and will succeed as well. We will have a growing innovation economy and a thriving, flourishing society."

As Peter made very clear, there was no government support for the development of the mRNA platform. It's not true that pharma companies are profiting from government money. The government purchases, the advance-purchase agreements, and the other things done through operation Warp Speed, were not investments in the creation of the vaccine. These were payments for the final FDA review, manufacture, and production of the vaccine, and then the distribution of it to the world, as all governments decided that they were going to do this. Some companies, like Pfizer, chose not even to accept Warp Speed money.⁸

The government also builds roads and funds public universities, and this is the classic move of the Left. Just take the fact that the government does engage in certain activities in our country and that it funds certain things, and then turn around, just like President Obama said, and say, “You didn’t build that. Therefore, we get to take it away from you, what you did actually build and create, which is the actual innovation.”

Peter Pitts: The progressive hard Left says, “We’ve got a bunch of lies. And if you don’t like this lie, try this one.” This is a war against patents writ large. The World Health Organization has a list of 100 essential drugs. And from aspirin to Zithromax, they’re mostly all off-patent and they’re still in dire shortage in the developing world. If patents are the problem, why is this so? Again, that’s an inconvenient truth. If you stick to the facts, you’ll ultimately get to a good place. If you allow the rhetoric to drive the discussion, patients lose.

Marie Fishpaw: A sobering, and also inspiring, analysis of what can happen when we get the government parameters right to support, not undercut, innovation.

Let’s talk about the consequences of getting it wrong. You have talked about some sweeping changes that could. I think it’s not an overstatement to say, transform the operating environment in which these drug companies bring drugs to market. Doug, tell us a bit about what would happen to patients if we saw these kinds of changes. What happens to their ability to get the treatments that they need?

Doug Badger: I want to go back now to the legislative proposal, H.R. 3. Let me level-set for a minute. The Bureau of Labor Statistics came out with its inflation figures, the increase in consumer price index from April 2020 to April 2021. The overall consumer price index was an unnervingly high 4.2 percent. The index for drug prices was –1.8 percent.⁹ Prescription drug prices have been falling since 2019. And as of April 2021, we’re at a level last seen in the summer of 2017. When we hear the concerns about drug prices, bear in mind that unlike pretty much everything else in our economy right now, they’re going down, not going up. So, let’s understand the facts of the problem we’re trying to address.

Now H.R. 3 says, “Those prices are still too high. We’ve got to get them down.” The bill proposes to do that by basing drug prices in the U.S. on prices set by six foreign governments that “negotiate” prices with manufacturers. This would have two adverse effects, in my view. One has to do with access to newly invented drugs. The second has to do with whether new drugs are ever invented.

Let’s look at the first one. I did an analysis a few years back. The Trump Administration proposed a Medicare demonstration project on Medicare

Part B drug prices. Part B drugs are not the ones you pick up at the pharmacy, but are products that are injected or infused. They are generally physician-administered. Think chemotherapy, think some of the treatments for autoimmune diseases. The Trump Administration proposed to establish an international pricing index for these drugs. It put together a market basket of countries and said, “We’re going to base Part B prices on what they are in these foreign countries.” And what we found was, when we looked at new drugs introduced into the marketplace between 2012 and 2019, Americans had access to an overwhelming majority—around 96 percent—of those new drugs. When you looked at the drugs in countries included in the international pricing index, you found that citizens of those countries had access to only a fraction of new drugs. When the government “negotiates” with a manufacturer, the one thing a manufacturer can do is say, “We’re not going to make this product available in your market.”

More recently, PhRMA has taken a look¹⁰ at specifically the six countries that H.R. 3 would direct the Secretary of Health and Human Services to use in setting American drug prices. What PhRMA found is that Americans have access to 86 percent of new drugs introduced between 2011 and late 2020. The average for those six countries: 52 percent. So, half of these drugs that the government is going to be setting prices for aren’t even available in some of these countries. In Australia, it’s 38 percent of those new drugs. Germany is the leader at 64 percent. We’re at 86 percent. We have access to 95 percent of new cancer drugs. People in those countries: 60 percent. For mental illness, Americans have access to 100 percent of drugs created since 2011. For those six countries: 31 percent. And when it comes to rare diseases, Americans have access to 96 percent of newly developed drugs versus 56 percent for the six reference countries. So, the first thing you have to think about when the government gets into the drug-price-negotiation business is this: Are some of these new drugs going to be available to Americans? Many of them are not available to the French or Brits or citizens of the other countries on this list. That’s the first consideration.

The second thing that I think we lose sight of is: Are new drugs going to be invented in the first place? This is not a question of access to a new drug, but whether a new drug actually is developed. The President’s Council of Economic Advisers (CEA) issued a 2019 report¹¹ that analyzed an earlier version of H.R. 3, one passed by the House in December 2019. They said that this would, using Congressional Budget Office (CBO) estimates, reduce pharmaceutical revenue by \$500 billion to a trillion dollars over 10 years. About 15 percent to 20 percent of revenue goes into the research and development in these pharmaceutical companies. So, if you take half a trillion or a trillion dollars away, you’re reducing R&D spending by 75 billion to 200 billion over a decade.

What does that mean? A company spends an average of about \$2 billion in research and development to get one new drug to market. A lot of that spending is on drugs that never make it out of the lab, or fail somewhere during the process. But if you divide it out, total R&D spending by the number of new drugs that are actually approved, it averages about \$2 billion in R&D spending per newly approved product.

If you take \$75 billion to \$200 billion out of pharmaceutical research and development, what you're going to get is fewer new drugs—up to 100 fewer over 10 years, according to the CEA. When you don't get these new drugs, people don't get treatments for diseases that they might otherwise have access to. So fewer people go to work, fewer people go to school, fewer people engage in productive activity. The CEA estimated¹² that H.R. 3 would therefore reduce economic output by \$375 billion to \$1 trillion over the next decade.

The CBO said that H.R. 3 would save the federal government \$35 billion annually. According to the CEA, annual economic output would drop by \$375 billion to \$1 trillion. The loss of economic output from H.R. 3 is thus somewhere from 10 times to 30 times the savings to the government, according to the CEA analysis. So, there are real costs associated with price controls. It can be hard to visualize the effect of having one fewer new drug, or eight fewer new drugs, or 30 or 100 not coming to market. To illustrate that, I would cite the example of COVID-19.

Where would we be as a society today if we were still relying on what public health people call non-pharmaceutical intervention—masks, lockdowns, social distancing—as our primary weapon against COVID-19? I would argue that the years of research and billions in spending that resulted in the development, production, and distribution of COVID-19 vaccines has made for a much better scenario than we would be in without that pharmaceutical innovation.

Peter Pitts: We all agree that the goal of smart reform is to broaden access to high-quality, cutting-edge health care. When people say, “my drugs are too expensive,” what they mean overwhelmingly, is that “my copay is too expensive. Why are my copays going up? Why are my out-of-pocket costs rising?” That is not exclusively a “greedy pharmaceutical company syndrome.” Why are the insurance industry and pharmacy-benefit managers getting off scot-free without a word in any legislation supported by the majority party or the President? Again, it's a complete lack of honesty in addressing an ecosystem problem minus an ecosystem solution.

Adam Mossoff: I'd be even more specific that the high costs of payments are also a result of cross subsidies mandated through Obamacare and many other pieces of legislation, such as the cross subsidies created by the fact that

Medicare and Medicaid already pay below market prices. So, if you are a producer or a hospital or a doctor, you have to make up that difference somehow. This has been an economic fact in our health care industry for decades now. And it's false to say, "Oh, the problems are patents." It's the patents that are making these drugs possible in the first place, as Doug and Peter have described. And again, it's the private investment that has made these possible as well.

The latest number we have from 2018 was \$129 billion¹³ in private funding of R&D in the biopharmaceutical sector. And that was in comparison to \$43 billion¹⁴ in public funding provided by the National Institutes of Health (NIH). First, you already have more than a three-to-one ratio of private to public funding of biopharma R&D. But this public funding has to be put in context, too: It's all for upstream basic research. A recent study¹⁵ found that the more than 23,000 NIH grants in the year 2000 are linked to only 18 drugs approved by the FDA as of 2020. This confirms that the NIH grants are for very far upstream from basic research. These public grants aren't going to the development of the actual pharmaceutical treatments that are being created by the pharmaceutical industry and put into the health care market that are benefiting all people's lives.

Peter Pitts: To paraphrase H. L. Mencken, for every complicated problem, there's a simple solution that's wrong. H.R. 3 and the International Pricing Index are wrong in many of their basic assumptions. The non-interference clause, that protects market competition and patient access by prohibiting the government from interfering in negotiations among insurers, drug manufacturers, and pharmacies, was written by then-Senator Ted Kennedy (D-MA) and then-Senator Tom Daschle (D-SD). These two "liberal lion" Senators understood the complexity of the American health care system. So, not only dealing with facts, but also looking back at history might do some Members of Congress a world of good in terms of developing plans for broader access to health care for all Americans.

Marie Fishpaw: You're pointing out that there's been a bipartisan consensus over the years. While there will always be trade-offs in public policy, what we want to get right is to balance the need to make sure that people can access the fruits of innovation. That requires a culture that encourages innovation and encourages the necessary investment—and that requires getting the government policies right.

While we celebrate the successes of policies that have created space for a culture of innovation that led to developments like the COVID vaccine, we also acknowledge where there is room to improve policy.¹⁶

Doug, you have written about a constructive action that Congress could take to lower prescription drug prices. Briefly walk us through that.

Doug Badger: Let me focus strictly on the Medicare Part D program where there is bipartisan consensus on how it needs to be reformed. The program has been very, very successful. The premiums are lower today, in 2021, than the Centers for Medicare and Medicaid Services Actuary predicted they would be in the year 2006. Fifteen years later, they're lower on average than the experts predicted they would be in the first year. The major reason for that is the program's reliance on private negotiation between pharmaceutical benefit managers and the manufacturers. There are two areas where Part D needs to be improved. The first is payments for high-cost drugs. These costs are very burdensome for seniors. Congress should establish an out-of-pocket maximum on spending by beneficiaries. Once they've hit that threshold—\$2,000 a year or \$3,000 a year or whatever Congress establishes—they should be held harmless. That would do a world of good in that area.

The second thing is that the way the program is structured now, pharmaceutical manufacturers and the Part D plans bear the risk for spending below the catastrophic level. But above that threshold, taxpayers bear 80 percent of the cost. So, what's happened? Part D spending below the catastrophic level—the area where the private-sector manages costs—has actually declined. The program spent less on drugs below the threshold in 2019 than in 2006: \$11 billion in 2019 versus \$18 billion in 2006. Above that threshold, where the government picks up 80 percent of costs, we've gone from \$6 billion a year in spending to \$46 billion a year in spending. The solution is to realign the incentives in the catastrophic tier. Instead of the government paying 80 percent of catastrophic costs, manufacturers and the pharmacy benefit managers should pay 80 percent of those costs. Let them butt heads, let them negotiate, while holding the beneficiary harmless.

Marie Fishpaw: Peter, anything you want to add from your experience at the FDA?

Peter Pitts: What the Biden Administration can do to empower the FDA to do a better job in bringing new therapies to market quicker and more safely is to nominate the next FDA Commissioner. It's shocking to me that we're this late in the game and it doesn't seem to be on the Oval Office's front burner. Obviously, the agency will continue to function, but a confirmed Commissioner with a goal and a mission can inculcate senior staff with a vision of the future and move that vision forward.

On the Part D front, I think the lesson to be learned here is that when you allow government to partner with industry and partner with health care providers, amazing things happen—for patients!

Occasionally politics gets in the way. When Part D initially passed, then-House Minority Leader Nancy Pelosi said, We're going to run on this. We're going to kill the Republicans on Part D.

Well, that was a bad call. Part D has 95 percent-plus approval ratings and, as Doug mentioned, its costs are going down.

That's real free-market competition. And it works.

Marie Fishpaw: What's needed, then, are ways to build on what's working and continue to refine it for future success. Now we're going to hear questions from our audience.

Question 1: Why would the Biden Administration take the threefold approach to setting prices? What is your sense of what this will do for prescription drug prices?

Doug Badger: This is a politically popular issue. President Trump certainly saw great political benefit when he said the pharmaceutical industry is getting away with murder. It was an unfortunate choice of terms since pharmaceuticals actually save lives. But that kind of rhetoric works. A second reason is fiscal. As you know, the Biden Administration has been spending money fairly freely. It is proposing to "pay for" its next round of spending. If you put price controls on drugs, the CBO will say that you're saving the federal government a lot of money. Drug price controls can be used to offset a lot of new spending. So, price controls yield political and fiscal benefits. Unfortunately, as Peter and Adam have well pointed out, there are costs to approaching that issue this way. And they are considerable, and they are great.

Peter Pitts: We haven't talked about a Medicare for All proposition. Recently, Senator Patty Murray (D-WA) and Representative Frank Pallone (D-NJ) sent a letter to health care policy experts asking for their thoughts on Medicare for All. Not surprisingly, Murray and Pallone didn't mention that insurance companies can't recognize a national economy of scale. They can't sell policies across state lines as Medicare can. If you really want to allow people to pay less for access to health care, think about insurance reform. Let Medicare compete fairly against the private industry and let's see what happens. Here's a prediction: When there's a level playing field, government rarely wins.

Give people choices. People want them and are responsible enough to make their own decisions. The hard Left doesn't think people are smart enough to make choices. They think that government knows best—and that's a major point of philosophical difference.

Marie Fishpaw: Medicare for All, of course, would outlaw most private insurance and put us all in a government-run plan, so talk about taking away choices.

Question 2: It seems like the patents are just very complicated schemes. Can't we have a simpler way of encouraging more drugs to the market without letting companies monopolize or raise prices through the roof?

Adam Mossoff: There's a very common misconception about patents that we just have patents to incentivize invention. And I can see how some people might infer this from our discussion here about the extensive R&D expenditures required to create these drugs. But what we're talking about here is not just the invention of the drug, but also the ultimate commercial deployment of a therapeutic treatment that works for patients. And this is where the patent system achieves things that no other invention-promoting system does. A country can incentivize invention through lots of different mechanisms other than patents. It can grant prizes, subsidies, or have a patronage system, which is what was done for most of human history.

The United States took a very different approach. The Founders said in the Constitution, Congress is authorized to protect innovators and creators by securing to them copyrights and patents, and that these are property rights—an exclusive right. We were the first country that took seriously this idea that patents are property rights. This isn't just a label. This meant that innovators could go into the marketplace with them: You could transact with them, you could license with them, you could use them as collateral for venture capital investment. That's what the patent system achieves. It creates a bridge from the lab to the marketplace, by making possible the investment in, and ongoing development of, all of the innovative commercial mechanisms by which real-world drugs and therapies are given as treatments to people to benefit their lives.

This is what our patent system achieves. This is why the United States wasn't just unique historically in securing patents as property rights, it also took the lead when the rest of the world hesitated in securing biotech innovation. Starting with the decision in *Diamond v. Chakrabarty* in 1980, we said: "Biotech innovations, genetically modified organisms and other types of discoveries of medical innovators, are protectable in the patent system. As a result of that court decision, billions of dollars flowed into R&D investments in new drugs and other therapeutic treatments, and into the development of the necessary market structures to make these new discoveries benefit patients, like the licensing agreement between BioNTech and Pfizer, where BioNTech had the innovation capital and Pfizer had the skilled labor workforce and the infrastructure to deploy its innovation in the marketplace—which BioNTech didn't have because it's just a little startup. And this is a very common type of commercial agreement in the biopharma industry. There're tons of information-sharing agreements and other types of licensing

and commercial arrangements between hundreds and hundreds of different biotech companies and biopharmaceutical companies throughout the entire industry. It's all developed on the foundation of property rights.

As a professor, I teach my students that the content of contracts and commercial agreements is property. This is the story of the success of the U.S. innovation economy generally, and of the U.S. model for the rest of the world for the past 200 years of how to protect IP rights.

Peter Pitts: That question is very important, because it makes it sound as though patents raise costs in Europe. In the U.S., by volume, over 90 percent of the drugs we take are generic drugs. In Europe and Canada, generic drugs cost more than they do in the U.S. If patents are the problem, that doesn't jive with the reality.

Marie Fishpaw: Thank you. You have made clear to us the facts of the situation: Our laws impact the operating environment faced by those whose come up with new cures and new treatments to help patients and families have the care they need. You made clear the potential negative transformative consequences of President Biden's agenda and why the country should reject it.

I want to thank our panelists and our audience for joining us today. To continue the conversation and learn more, please feel free reach out to our panelists.

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Endnotes

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