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## The Health Wonk Shop: Probing the Legal Arguments in the Drug Industry's Challenges to Medicare Drug Price Negotiations

**Larry Levitt:**

Hello, I'm Larry Levitt from KFF. Welcome to the latest episode of The Health Wonk Shop. About once a month we dive into timely and complex health policy topics with experts from a variety of perspectives. Today we'll be examining this slew of lawsuits that have been filed to try to stop the government from negotiating the prices of some drugs in Medicare.

The Inflation Reduction Act requires the government to negotiate drug prices reversing a ban that was put in place when a drug benefit was added to Medicare. This is a signature policy and political achievement for Democrats and one they will no doubt be trumpeting on the campaign trail over the next year. It's a foot in the door for a bigger government role in curbing drug prices and potentially healthcare prices more generally. That's precisely what concerns the pharmaceutical industry. If successful, the lawsuits filed by the industry could deal a blow to President Biden's healthcare agenda.

We're joined today by three experts to discuss these lawsuits from a variety of angles. We're going to try to help explain some of the complex legal issues for non-lawyers like myself. Dan Troy is managing director at the Berkeley Research Group. He was previously Chief counsel for the FDA and General Counsel at GlaxoSmithKline. Zach Baron is associate director of the Health Policy and Law Initiative at Georgetown, and he was previously health counsel for the House Ways and Means Committee. Tricia Neuman is the Senior Vice President at KFF and executive director of our Medicare policy program.

If you have questions, submit them at any time through the Q&A button in Zoom and we'll get to as many of them as we can. Also note that this session is being recorded and an archive version should be available later today.

Tricia, let me start with you. Give us a very quick overview of the IRA's price negotiation process, how it works, and what some of the key milestones are.

**Tricia Neuman:**

Okay, sure. I'll try to do that quickly. And hi, Larry, Zach and Dan, it's great to be here.

So as you just said, the Inflation Reduction Act put the process in play. It was very specific in terms of the number of drugs that would be selected, the criteria CMS would use to select drugs, the steps in the negotiations process, the factors to be considered in the negotiations process and setting a maximum fair price. And the timeline. So I'm not going to go over because I think people are pretty familiar with the criteria for selecting the 10 drugs and the 10 drugs that were recently announced. So I'm going to move a little bit to the next process in the interest of time.

So if you think about the timeline and the process, think of September one as the opening bell for 2023. This is the sort of first round of negotiations. This is the deadline for CMS to announce drugs that were subject to negotiations. And as we've seen, CMS has made that announcement and in fact, CMS beat the deadline and came out a few days early. But if September one is the opening bell of 2023, then you can think of September 1st, 2024 as the closing bell. That's the date when CMS will publish the maximum fair price for these drugs.

Between now and the closing bell, the timeline looks like this. October one, which is just a few weeks away, is the deadline for drug companies to sign agreements with CMS. Basically agreeing to negotiate with Medicare negotiations program. October two, a day later, that's the deadline for drug companies to submit a lot of information to CMS, that again was specified in the law to help determine the maximum fair price. Now that's including things like research and development costs, the cost of production and distribution, how much money in prior federal support went into the development of the drug and sales and revenues. This is also the time for drug companies and other interested parties to submit information about alternative treatments or the extent to which drugs are meeting unmet needs.

Next up in terms of timeline is October 30th through November 15th, that's a two week period for CMS to be hosting what they're calling listening sessions, one for each drug with patient groups and others to get input on this process. Now, the next big date, I think, is February 1st, 2024. That's less than five months from now. That's when CMS will be sending an initial offer to each company that is involved in one of these 10 drugs for the maximum fair price. The drug companies have an option, they can either accept the offer or they can not accept the offer and make a counter offer. And the timing for that is March 2nd. Then there's a back and forth that can happen between the spring and summer of 2024. But by August 1st, 2024, the negotiation period ends. By September 1st, 2024 that's the deadline for CMS to publish the negotiated maximum fair price to take effect January 1st, 2026. The process continues and repeats itself, the dates change a little bit, but that's kind of it in a nutshell.

**Larry Levitt:**

Terrific. So Zach, these lawsuits, the drug companies drug industry, did not wait for the announcement of which 10 drugs would be subject to negotiation. They certainly didn't wait for the publication of the maximum fair price, as Tricia said. So give us a sense of the legal landscape here. How many lawsuits have been filed? What's the timing of this? What are some of the milestones?

**Zachary Baron:**

Great. Well first thank you Larry and the whole KFF team for having me join this timely discussion about the ongoing litigation. Thank you, Tricia, for that initial overview. And Dan, I look forward to your remarks.

So as of today, there are eight ongoing lawsuits brought by drug companies, their leading trade association pharma and other allies like the Chamber of Commerce seeking to block the implementation of the drug negotiation program. These cases have been brought across the nation from New Jersey to Connecticut to Delaware, Ohio, Texas and Washington DC and six specific drug companies have brought their own lawsuits, Merck, Janssen Pharmaceuticals, Bristol Myers Squibb, Novartis, Boehringer Ingelheim and AstraZeneca. So many of these lawsuits substantially overlap and bring the same or similar claims. I'm going to try and provide a brief overview of those claims. And for those non-lawyers, thank you for bearing with me and I'll try and stay high level here.

So various lawsuits argue that the negotiation program compels them to endorse speech that they disagree with in violation of the First Amendment. And here they point to requirements that they sign an agreement that communicates that the price of a drug is fair. Various lawsuits also argue that the federal government is taking their property, here, patented pharmaceutical products, without just compensation by requiring sales at below market rates. We also have various lawsuits arguing that the law denies drug companies the right to sell their products at market rate prices without providing them constitutionally sufficient safeguards. Here they point to the lack of rulemaking in the initial years of the program, the lack of judicial review in certain circumstances as well as the potential imposition of an excise tax if they don't participate in negotiation or abide by the negotiation process.

Related, a number of lawsuits argue that this negotiation program isn't really voluntary. They're being coerced into participating in Medicare and Medicaid by forcing them to give up their constitutional rights. And just briefly here, a number of companies point back to the Supreme Court's decision in NFIB in the major case that folks may remember more than a decade ago, challenging the individual mandate and Medicaid expansion as a parallel to the dynamics under the IRA. So if you thought you were done with that, you are not done with that case.

A few other claims, a few lawsuits have argued that the law gives the Department of Health and Human Services broad, unfettered discretion to set very low prices for prescription drugs. They bring what's called a non-delegation doctrine claim, which is really rooted in the constitution's separation of powers. And here again, they point to the lack of definition of certain key terms and the lack of safeguards when you talk about rulemaking and judicial review. I touched on the excise tax earlier, there are a couple claims that focus on the excise tax in particular. Various lawsuits argue that this tax violates the excessive fines clause under the Eighth Amendment, that it's really a penalty serving as a punishment and it's grossly disproportionate to the conduct designed to respond to. Related, some lawsuits argue that it's not really a tax at all, and because it's not really a tax it doesn't fall under the limited powers that the Constitution gives to Congress and because it's really a penalty, it's unconstitutional. Stepping outside the constitutional lane, there are also two lawsuits that bring statutory claims under the Administrative Procedure Act, and that's focused at specific pieces under the guidance that the administration put out.

So just briefly on timing this Friday, we actually have the first oral argument in one of these lawsuits in the Chamber's lawsuit, and that's because they move for what's called a preliminary injunction and what that really is trying to stop the government from being able to implement the negotiation program nationwide. They've actually asked for a decision by October 1st by before when these companies have a choice in terms of whether to sign, participate in the negotiation process. And if the chamber loses that case, we could see it quickly appealed up to the Sixth Circuit and even conceivably up to the Supreme Court. And just to clarify, it's actually only on one of their claims that they brought, which is a due process claim. So if it did proceed up through appeals, it wouldn't be on all the claims that they brought.

In the other cases, we have briefing schedules that the government has agreed to with different parties that generally run through towards the end of this year. In some cases we don't even have briefing schedules yet. It's always a challenge to predict when courts will rule on these cases, but the reality is between briefing schedules, oral argument, and the time needed to write these opinions in which, again, it's highly likely there will be some form of appeal. My guess is that it's not likely that we see district court decisions until the first quarter of next year sort of really at the earliest. And then it's always even harder to predict as things go up on appeal, what that timing may be.

**Larry Levitt:**

Super helpful. A lot to unpack there, which we'll come back to. Dan, let me turn to you. So Zach laid out the arguments the industry, including the Chamber, are

making. What in your view is the most compelling legal argument against the IRA and its drug pricing provision?

**Dan Troy:**

Okay, well first of all, again, thanks to all for having me. I have to state, I'm the managing director at Berkeley Research Group. The views I'm stating are my own and my company testifies on behalf of various branded companies. I have no conflict of interest here. I'm not being paid. I may work on occasion as an expert for some of these companies, but I'm not involved. And I particularly need to distance myself and be clear. I am on the Chamber Litigation Council's Advisory Board, but I've had nothing to do with the Chamber's suit.

**Larry Levitt:**

Great Dan, thanks for that.

**Dan Troy:**

I think Zach gave a very fair overview of the challenges and essentially the bottom line is this is not a price negotiation. These are price controls by other names. The companies really have no choice whether or not to participate. The negotiation isn't really a negotiation. They have to start giving information on penalty of at least a million dollars a day. If they don't participate ultimately, they can be charged an excise tax of 1900%, almost 20 times of not the amount of the revenue that they would make in the drug in Medicare, but the entire revenues of the drug in the United States, the CBO, when scoring this excise tax gave it a zero because they know that no one will be able to avoid participating in these, what I call, sham negotiations.

So the real question, ultimately I think that's going to drive whether it's a takings claim, I think that the CMS did some things to try and moderate some of the first Amendment issues after the Merck lawsuit when they put out their second guidance. But the real question is going to be, and I think again, Zach alluded to it, is do the companies have any kind of choice? I mean, the government's basic argument is sure you have a choice, you can just get out of Medicare. Well, there are at least two or three problems with that. One is by the terms of the statute, you need to give Medicare 19 months notice before you leave Medicare. Well, this law was enacted less than 19 months ago. So now CMS in its guidance says, oh, well, we have this special way where we'll let you out of Medicare within on three months notice. Not at all clear that that's legal. It's pseudo, as Zach will alluded, a subregulatory guidance. So there's no real choice.

And then the real question is, the government's going to say, you want to walk away from Medicare ultimately, fine. You can walk away from Medicare. And again, I think Zach put his finger right on the issue as in the Affordable Care Act case, is the government using basically its power to coerce people into giving up

their own their rights. So is it an unconstitutional condition? Is it a due process problem? I mean, the nub of the issue is the government overstepping in coercing these companies into giving the drugs, making them available at a lower than market price without any kind of process.

So my last point that I'll make and then I'll shut up I promise, is as Zach sort of said, there's no review of whether your drug is in, there's no review of the negotiation process and there's no judicial review of what the prices are. That's a very unusual regime when the government is taking your property. FERC, for example. Prices are regulated, but they have to be, "Just and reasonable," and you can appeal them to a court. There's no oversight here. HHS is the beneficiary, it is the judge, it is the jury, it is the executive, and it's the one that actually is dictating the prices and gets the budgetary benefit of these dictated prices. So I'll shut up.

**Larry Levitt:**

Thanks Dan. So Zach, you laid out the industry's arguments in the case of particularly on this issue that Dan is raising about coercion, that it's not a negotiation, it's effectively price controls. What has the government said so far in response to that claim or what do you expect them to say?

**Zachary Baron:**

So today we've seen government filings in both the Chamber litigation and actually just last night and Merck's litigation. I think as Dan alluded to, I think really one of the major touchstones in this litigation is going to be what is the nature of the Medicare program and what is the nature of the choice that these drug companies have to participate? And so the government pretty forcefully pushes back on these arguments by drug companies that there is no real choice and that this isn't a voluntary program. The government points to decades of precedent considering challenges to reimbursement rates under Medicare that have uniformly rejected similar takings claims. Courts have previously emphasized that the Medicare program may limit how much the government pays participating providers, and this doesn't require entities to surrender any form of property. And as the government outlines, these entities are not required to serve Medicare beneficiaries. And this has come up in a number of past cases.

As to this NFIB and the argument that the drug companies are making by pointing to Medicaid expansion as an analogy. Both before and after NFIB, the government points to precedent where courts have uniformly rejected the idea that the nature of Medicare and Medicaid is coercing private parties to accept any conditions. At the end of the day, like other participants in the Medicaid program, whether they be doctors, hospitals, nursing homes, if they don't like

the terms of their program, nobody is forcing them to participate. And there are a range of ways to both withdraw from the program and mitigate any impact.

I think also part of what Dan touched on in terms of the ability to terminate as well as the scope of the excise tax is also going to be a key point in this litigation. The government, in its filings, I think has really alleged that the drug companies are pretty fundamentally misunderstanding the nature of the excise tax as well as the ability to withdraw. Both they've outlined that it's fairly straightforward to withdraw from the program. Also, certain companies can assign the interest in particular drugs if they want to be able to sell other drugs to Medicare. And also with respect to the excise tax, rather than this 1900 number that's been thrown around the government in guidance that it clarified that parties can rely upon even before there is final rulemaking, that the tax is inclusive of the rate and it only applies to the drugs being sold to Medicare beneficiaries and not the total number of sales.

So I do think on this issue about whether it's voluntary and the potential harm, if they chose that to negotiate, I think the government has a very different view than the drug companies.

**Larry Levitt:**

Tricia, let me bring you back in for some non-legal policy context here. And we've had a number of questions about how Medicare works for other types of healthcare. This is a new negotiation process with drug companies, but Medicare has, and it's not even called a negotiation, Medicare sets prices for other types of healthcare. Right?

**Tricia Neuman:**

Well, thank you for letting it slip in that I'm not a lawyer that's really important. So I don't want to speak to the issues floating in the courts, but I will say that Medicare has a long history of setting prices. If you look back over decades, in 1983, Medicare established the prospective payment system that was under President Reagan. Since then, Medicare has established formula driven payment systems for physicians, for skilled nursing homes as Zach said, for home health agencies and actually for Medicare Advantage plans. And the deal is providers and plans can accept the payment that comes from Medicare or they can decide they don't want to do business with Medicare.

We recently looked at physicians because physicians have the option to opt out of Medicare, and you kind of hear about physicians grumbling about Medicare fees. But what we found is only 1% of physicians in this country have elected to opt out of the Medicare program. So this whole issue is, in some ways the drug industry has been given very different treatment by Medicare than every other provider group so far. And so this is in some ways getting closer to what

Medicare does with hospitals, doctors, nursing homes and others. But it's not even the same thing because they don't have quite the same process for maneuvering to come up with a maximum fair price. And so whether it's a true negotiation, there is a process for negotiation. And your New York Times article, I think referred to it's negotiation though the government has a big stick. That's true. But in this case drug companies have a choice just as providers do and they can decide to take the fee or not.

**Larry Levitt:**

Yeah, my guess is we can all agree that the government has a big stick in the negotiation here. Dan, so what makes this different from a legal perspective from the way Medicare has historically treated doctors and hospitals and other providers?

**Dan Troy:**

I mean, I think that absolutely will be one of the most critical questions. I'm going say two things. The quote from the Affordable Care Act case is when such conditions take the form of threats to terminate other significant independent grants, the conditions are properly viewed as a means of pressuring the states to accept policy changes. So the question is going to be, is it reasonable to say, because you won't accept this price your only other choice is not to not sell that drug to Medicare, but actually to be excluded from Medicare entirely.

I mean, I was the general counsel of GlaxoSmithKline, we dealt with price controls in European countries. There were times when we said, sorry, we're not going to sell you that drug at that price. There isn't really that choice here. And that's I think going to be a big part of the action.

The other thing I just want to point out is there was a very interesting case by a liberal panel two weeks ago out of the DC Circuit. And I say liberal panel, one judge was appointed by President Carter, one was appointed by President Obama, and this is what was at issue in the court. The owner of a copyright work has to deposit two copies of a work with the Library of Congress within three months of publication. And the deposit requirement basically is enforced by issuing demand letters. And if you don't comply with that, you either have to deposit copies or pay a fine. And the court found that that was a taking, overturned the district court decision. And two, again, very well respected, but judges normally considered a little more liberal than center found that that was a taking.

If that's a taking, then I think this court, the Supreme Court, I think is going to be very interested in some of these takings arguments. In one of the other cases, I don't think the manufacturers have yet cited this case because it came out two weeks ago, but one of the key cases that they're talking about is a case called



Horne, where essentially these raisin manufacturers were told, if you want to sell your raisins, you have to give basically 40% of your raisins to the government. And the Supreme Court said, that's just too much. The taking here cannot reasonably be characterized as part of a similar voluntary exchange. In one of the years at issue here, the government insisted that the Hornes turn over 47% of the raisin crop in exchange for the benefit of being allowed to sell their remaining 53%. The next year the toll was 30%.

So that's really going to be the issue. I mean, how coercive is this? How much freedom do the manufacturers have to walk away when at least 40% of the entire US drug market is Medicare? So as a practical matter, again, nobody thinks that anyone can really walk away from this and that's why it's viewed as, pardon me, coercive and not voluntary.

**Zachary Baron:**

So if I could just briefly, I think both to the copyright case that Dan touched on as well as the Horne raisins case, which actually the direct companies do heavily rely upon the raisins case and the government has started to directly confront. And so I think, as Dan alluded to, one of the key issues that courts are going to have to grapple with is whether this is a physical taking or not. And again, in the raisins case, and similarly, when you think of the copyright case in terms of physical property and the government literally taking something out of your hands, for lack of a better phrase, here the government has argued that there is no type of physical appropriation like there was in the Horne raisins case and similar to the copyright case.

As what happened in the raisins case, the government literally sent trucks to their home to take away raisins. That's not happening here with drugs. Again, they have a choice in terms of whether to participate and access this market. There are all types of business decisions that companies have to make. And there are a range of options even within here in terms of if they'd like to continue selling other drugs to Medicare and Medicaid. And again, in terms of the scope of the excise tax and how it would actually impact them. I think the government has pushed back and said that, look, at the end of the day, if we side with the drug companies here, does that mean that any company that participates in a federal program gets to dictate the prices? And it means there can be no effort in which the government can try and leverage its authority to constrain certain costs that it can pay. And what would that mean in other aspects of the Medicare program, as Tricia alluded to, in which that is the norm, and again, in which there have been past legal challenges that have rejected such claims?

**Larry Levitt:**

So I suspect we're going to be talking a lot about raisins in the next couple of years. So we've had a bunch of questions about process and timing. So let me turn to those. So first, a preliminary injunction. So for Zach and Dan, number one, what might we expect in terms of timing when a decision about a preliminary injunction might occur? And then two, how would that work? So is it possible that a preliminary injunction would just stop the process dead in its tracks? We had the opening bell, we won't get to the closing bell as that Tricia talked about. Walk us through how to think about this.

**Dan Troy:**

So Zach, I'm going to defer to you on the very easy and non-nettlesome question of potential nationwide injunctions.

**Zachary Baron:**

Yeah, we could spend a whole separate talk on that, but just briefly. So I think as I mentioned, the Chamber requested a decision by October 1st. It's now fully briefed. There's oral argument on Friday. And so I would expect there will be a decision within the next few weeks on that preliminary injunction motion. Though again, the decision could technically just be on the motion to dismiss. And so it could just be on different procedural grounds and they may not reach the merits. As I think we've all seen in other high profile cases lately, and this is of course hotly disputed amongst even different members of the Supreme Court and certainly other federal judges. But we have seen both in constitutional challenges as well as statutory challenges, a single judge can enter a nationwide preliminary injunction to block any enforcement of a federal program or of a federal regulation. Some of this, of course, would depend on how a judge would craft particular relief, and there was a lot of discretion there.

But, the reality is that there are a range of possible outcomes in this litigation, including a potential pause on any type of enforcement by employees at HHS and CMS and stopping this negotiation process right in its tracks. Then if there were appeals, it could then be un-paused. And there are a range of potential opportunities. Of course, some of the drug companies, the specific relief that some of them have asked for include both declaratory judgements that certain provisions are unconstitutional, but also request that the government be blocked from enforcing the terms of agreements just with respect to them. That is certainly one possibility. But I think to the extent, if there are any listeners here that have been following the litigation over the ACA preventive services provision, it can be unpredictable in terms of different forms of relief that judges can fashion. So all the more importance to continue following the litigation as it proceeds.

**Dan Troy:**

Yeah, I mean, I will say the fact that these prices don't go into effect until 2026 does, I think, make it more likely that these cases will be more fully litigated.

And at least in my day, when I was at the office of legal counsel many years ago, the government was able to argue different positions in different circuits, and that's how you got circuit splits that came to the Supreme Court rather than one judge making a decision for the entire country.

**Zachary Baron:**

I think that's right. And to Dan's point, again, the standard for preliminary injunction is supposed to be higher here in terms of irreparable harm to a plaintiff. And I think to Dan's point, and this has certainly been what the government has said in response. Look, again, as Tricia alluded to, there are so many milestones left to go in the negotiation process and with prices not taking effect until well years down the road. And so part of it to Dan's point, is where is the urgency here for a court to, again, block enforcement nationwide? As Dan explained, the practice in the past was that's in part we let this process play out through different circuits and judges, and ultimately, whether it's at the appellate court level or even at the Supreme Court, they benefit from the judgment and wisdom of different judges in different circuits.

**Dan Troy:**

Now, if I could jump in. That said, and these are more policy points, there are a number of CEOs already said that the IRA, the drug price controls, negotiation are distorting and affecting their investment decisions. Now, I don't even know though, that they've made that as a case for irreparable harm. But in the real world this is already affecting investment decisions, that's number one. Number two, the other, again, there's a part of policy argument, the fact that one of the things that they're not allowed to submit information on is about the other drugs, the thousands and thousands of drugs that fail for each one that succeeds does undercut the entire pharmaceutical industry business model, which is that you have a few successes to subsidize all these failures. But again, those are not necessarily the kinds of things that certainly the first one that the courts would necessarily consider irreparable harm recognizable at a preliminary stage.

**Zachary Baron:**

And I think to Dan's point, I mean, we've seen some CEOs talk about harm and then we've seen other investment advisors others say, well, look, the exposure is pretty limited in these initial years for some of these companies. And of course, I'll defer to Tricia on the weeds, but given the way in terms of if there are other competitors entering the market and what that might mean for some of these drugs being selected, that also gets a little bit at the uncertainty of what the harm is. And I do think some of those considerations will be presented for the courts.

**Tricia Neuman:**

If I could just weigh into here a little bit, I do think there is a legitimate question without certainty about what the drug companies are actually saying about

what the impact is going to be. I don't think there's been a clear message with regard to their own specific investments, at least not yet and at least not for most drug companies. When policymakers who are very concerned about research and development and investment in drugs that could cure cancer and Alzheimer's disease look at this, they've turned to the Congressional Budget Office, and the Congressional Budget Office has cast some doubt on whether or not the negotiations provisions, in fact the drug provisions of the entire law, will impact R&D. And I think in their estimate, they said something like less than 1% of the 1300 drugs expected to come to market over the next three decades will not come to market potentially as a result of the law.

And what they didn't say is, are these the breakthrough drugs that we're all waiting for, or are these me-too drugs? But it's a very, very small number. But the truth is, it'd be hard to know what goes on inside drug companies decision-making. And there is the concern that's out there, there's just not a lot of evidence yet on what the impact will be or if there will be a negative impact.

One quick last thought about this is, drugs that are subject to negotiation must be covered by all the Medicare plans. So it is conceivable the utilization will go up even if the negotiated price is less than the price that drug companies would wanted to get without the negotiations provision. So there could be some balance with the old price times queue formula in terms of total revenues.

**Larry Levitt:**

Well, and also if the lower prices will in some cases benefit patients as well, which may lead to greater use and adherence to these drugs.

Zach, let me turn back to you. So we had a number of questions around the point that Medicare has for many years set prices for doctors and hospitals and other providers. I think you mentioned that that has been litigated in the past, so presumably it's been upheld. If the government loses in this case, are there potentially implications for how the government pays for other types of healthcare beyond drugs?

**Zachary Baron:**

Absolutely. I think depending on the nature of any decision, and if any drug company or chamber of the pharma are successful, there could be pretty sweeping ramifications for the rest of the Medicare program. And the government actually makes that point in their filing last night in Merck to say, again, if this is a taking, what does it mean for how it approaches reimbursement rates for providers and for hospitals? And again, thinking about various efficiencies that that Medicare is able to promote while also being able support the needs of beneficiaries. And so I do think any success here from the challengers could have broad implications for Medicare, and frankly, it could

have pretty broad implications for the commercial market as well, and certainly other measures that both federal and state policy makers could try and take to contain costs.

**Tricia Neuman:** Can I just pile on a little bit more to say it could have enormous implications for Medicare spending, which means it would also have implications for the federal budget and the federal deficit, the Hospital Insurance Trust Fund, for Medicare premiums, for cost sharing. So if this were to broaden beyond prescription drugs, it could have enormous implications for beneficiaries, the federal budget, and for taxpayers.

**Larry Levitt:** So turning back to the process, a number of questions about Supreme Court. Dan and Zach, you both mentioned that these lawsuits have been filed in different circuits. Zach, you rattled off all the states. I will never remember all those states. So what does this mean in terms of this ultimately potentially going to the Supreme Court? Is it virtually certain that this is going to end up in the Supreme Court, and when might that happen?

**Dan Troy:** Well, as Zach said, it's very hard to predict timing. It would be foolish to say with any degree of certainty that this will end up in the Supreme Court. I do think that if any court or court of appeals strikes it down, holds it unconstitutional, then I would bet a lot of money that the Supreme Court will take it up. If all of the courts reject all of the claims, unclear to me whether the court would take it up. I do think that there are a number of justices on this court that would be extremely intrigued by some of these arguments. Let's say Gorsuch, with the non delegation point and the lack of separation of powers. I think Thomas would be interested in the takings arguments. So I do think that if it gets to the court, it's going to get a very serious airing slash hearing. But again, I think it would be foolhardy to predict that it will with certainty or what would happen if it got there. But feel, [inaudible 00:42:20] Zach.

**Zachary Baron:** No, I think I agree with all Dan's-

**Larry Levitt:** Going to be foolhardy here Zach? You going to-

**Zachary Baron:** No, I think I agree with all Dan's points. I think a few things to note is that generally, again, the Supreme Court is taking fewer and fewer cases now than in the past. And I agree with Dan that certainly if any court issued any type of nationwide relief here, I do think we would see pretty quick, depending on the posture, whether it's up for an emergency stay of that decision or something like that. But to what he said, certainly if the drug companies and industry are unsuccessful here, it's not clear to me that the Supreme Court would then reach

down and say, oh, we do need to take this. I think to Dan's point, certainly a number of the justices have been trying to advance some of these more aggressive constitutional theories, talk about non delegation doctrine in which the Supreme Court hasn't used to strike down a statute of Congress since the Great Depression era, but Justice Gorsuch and others, and even a recent Trump appointee on the Sixth Circuit said, it's time to stop tiptoeing around that. So there is some energy from certain judges that you could see that want to engage in that issue. And so part of this, of course, will depend on how it proceeds up on appeal and what appellate panels end up with these cases.

**Larry Levitt:** And Zach, you are tracking this. Georgetown has a litigation tracker, which I would recommend to everyone. Very useful. What cases, which circuits would you suggest we keep an eye on? Which of the circuits do you think maybe are most likely to overturn the IRA?

**Zachary Baron:** Well, the Chamber decided to file their lawsuit in Ohio, in which, if that were to be appealed, if we go up through the Sixth Circuit, which does have a number of newer Trump appointees. Certainly I think for those that have been following other healthcare litigation, whether it be challenges to the Affordable Care Act or access to mifepristone, the Fifth Circuit has been a hotbed of litigation and tends to be pretty hostile to aggressive regulatory attempts, new types of federal programs. Pharma chose to file their lawsuit in Texas, and so I would certainly be watching those cases as they proceed through appeals. The others, again, whether it be in DC that would go up through the DC Circuit and others in the Northeast that have become, I would say, more balanced in recent years. So I think certainly it's [inaudible 00:45:17] so, I would say follow all the cases and we'll have to see as they proceed. But certainly I think the Fifth Circuit and Sixth Circuit in particular to keep our eyes on.

**Larry Levitt:** Well, thanks. Certainly plenty to watch in the courts, in the campaign as the process unfolds, as Tricia described. I'm pretty sure this is a topic we're going to want to come back to. We're unfortunately at the end, in fact, over our time now. But thanks to Dan, Zach and Tricia for a great discussion. And thanks to all of you for listening in and asking great questions as well.

**Dan Troy:** Thank you for hosting us. We really appreciate it. Thanks, Zach.

**Zachary Baron:** Thank you.

**Dan Troy:** Thanks, Tricia-

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