Denver, Colorado.

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APPEARANCES

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3	Jennifer M. Johnson, Colorado Attorney General's Office, Ralph L. Carr Colorado Judicial Center, 1300 Broadway, Denver CO, 80203, appearing for the remaining defendants.
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8	Proceedings Reported by Mechanical Stenography Transcription Produced via Computer
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LO	* * * *
L1	PROCEEDINGS
L2	(In open court at 1:34 p.m.)
L3	THE COURT: Good afternoon. Let's take our seats.
L4	We're here for a hearing on a motion for a preliminary
L5	injunction in case number 23-cv-2584, Teva Pharmaceuticals,
L6	U.S.A. versus Weiser, et al.
L7	Why don't I begin by asking counsel to enter their
L8	appearances.
L9	MR. LEFKOWITZ: Good afternoon, Your Honor. Jay
20	Lefkowitz on behalf of Teva Pharmaceuticals. I'm here with my
21	two partners, Alex Russell and Cole Carter.
22	THE COURT: Welcome. Thank you for being here.
23	MR. NELSON: Pawan Nelson, Assistant Attorney General
24	on behalf the Attorney General.
25	MS. JOHNSON: Jennifer Johnson, Assistant Attorney

General on behalf of the remaining defendants who are members of the State Board Pharmacy.

THE COURT: All right. Thank you all for being here. So as I think we may have explained, at least in part, kind of the way I want to proceed today. There is, in addition to the preliminary injunction motion, there's a Motion to Dismiss pending. I want to at least give everybody a chance to address both of those, but mostly, obviously, the preliminary injunction motion is more pressing, given the timing.

So I think the way I want to proceed, essentially, give the plaintiffs about an hour, and the defense about an hour. Plaintiffs can reserve some time, if they want for a rebuttal, I'm not going to be super strict about it, but I think that should be sufficient for what we're going to do, in particular, because I did review, in addition to the briefing, I have reviewed the declaration and the deposition transcript, so you don't need to go through all of evidence that, again. You can assume that it's been reviewed, and admitted and just go ahead and start addressing what you think are the important parts of it.

I will just give you a little bit of an idea of where
I am, right now. I don't expect to rule today from the bench,
but I will get a written ruling out, at least on the
preliminary injunction question before the end of the year, one
way or another, maybe on the Motion to Dismiss, as well,

depending on how things go.

My current thinking is that I do think that there's probably enough of a threat or imminent enforcement or at least requiring the plaintiff to choose between various courses of action that — between either complying or paying money or giving away some of their product to probably satisfy the case for controversy requirement, although I do want to hear argument and explanation on that.

I'm not sure, though, that there's — that the same evidence is sufficient for the extraordinary relief of a preliminary injunction. The uncertainty surrounding how this will apply, at least, seems to call into question whether the plaintiffs can satisfy the, sort of, very high burden required to justify enjoining an injunction, particularly an injunction against a state law, when the context is a takings, where presumably, it can be remedied through payment of just compensation.

So that's, kind of, my thinking going into this. I do have an open mind, and I certainly have some questions, still, for everybody. So -- but I did think it was fair to at least give you a heads up about where I am, at the moment.

So if that makes sense, I think we can go ahead and let the plaintiffs begin their presentation, unless there's any questions. All right. Mr. Lefkowitz.

MR. LEFKOWITZ: Thank you, very much, Your Honor, and

I appreciate the Court's overview. I think I will probably 1 only take about 20 or 25 minutes to make my argument, take 2 obviously, as many questions as the Court has, and maybe ask 3 4 the Court for about ten minutes, at the end, just to respond. I don't know that it will require more than that. 5 6 THE COURT: Terrific. MR. LEFKOWITZ: And I think I will start -- I will --7 8 I will address, obviously, the key concern you have, which is, Is the remedy we're asking for appropriate, in the course of 9 10 the 20 minutes or so that I do want to touch on each of the 11 different components, if I may, since we have the time. 12 Just to kind of -- for brief -- very brief --13 background, this is a challenge to a statute signed into law by the governor in June, and it addresses affordability of these 14 15 epinephrine auto-injectors through two measures. The first measure is unobjectionable. It says that the carrier shall cap 16 17 the total amount that a covered person is required to pay for 18 all covered prescription auto-injectors, at an amount not to 19 exceed \$60 for a two-pack. It's essentially a price control. 20 The State wants to limit epinephrine pens from being sold for \$30 each, they are entitled to do that, whether the drugstore 21 22 or the manufacturer likes it. 23 The second part of the bill is to address uninsured

people, who are not covered, in a sense, by that first provision, and for them it says they can fill out an

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application at a drug store, and obtain their two-pack of auto-injectors for \$60. The constitutional problem is what happens next. The pharmacy can pocket that \$60 payment and then either make a request for a replacement auto-injector, the physical property of the drug company, the manufacturer, and if the drug company doesn't want to do that, the alternative, under the statute, is to pay the drugstore what it paid to get it.

Now, that's a little bit of a false choice or certainly a Hobson's choice with a thumb on the scale. Why? Because the drug company, in this case Teva, is a Delaware company based in Pennsylvania. They sell to three principle wholesalers around the country, and they sell their EpiPen®s, and then eventually those EpiPen®s make the way to the CVS or the Walgreens or the Joe's drugstore on the corner, through, obviously, at least, the one middleman of the wholesaler and perhaps through other middlemen. And so the price that the drugstore pays is invariably going to be a little bit more or maybe more than a little bit more than Teva receives.

So financially there is a choice, but it's always going to be the case that providing the actual EpiPen®, the actual physical property, is going to be the effect of this statute.

Now, that's the provision that we are challenging, and the provision is enforced by both a fine of \$10,000, for each

month of noncompliance, and the Attorney General is then empowered to bring a Deceptive Trade Practices case against Teva, or one of the other companies that would be subject to this, under the Consumer Protection Act, which carries with it a treble damages remedy. So this is very much a statute that has a lot of force behind it.

I want to start on just the substance of the takings question, then we will get to the injunctive relief, and we will finish with the Eleventh Amendment and a couple of the other issues, and certainly standing which I want to address.

As to the takings, I don't think there's any serious dispute, particularly after *Horne* that this reimburse or resupply requirement takes property without compensation, in violation of the Fifth Amendment. In fact, the Attorney General didn't even offer a merits defense at the PI, however, the Attorney General did offer a merits defense at the Motion to Dismiss, and so even though it's not technically before the Court on the PI, I want to address it anyway, because what the Attorney General says is there's no violation of the Takings Clause, because the State is just exercising its police power.

Now, the implications of that argument are enormous.

If the Attorney General were correct, the State could commandeer any medical product for anyone that the State deems worthy. It could commandeer hotel rooms in hotels for people who are homeless on a cold night. It could commandeer gas from

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gas stations, all without compensation, all without it being treated as taking, because the police power is essentially the plenary power of the state.

It's really a misnomer here to defend this as an exercise of police power, because the key question, under the police power is, does the government attempt to secure a benefit to the public or to prevent a harm to the public? And that is really the critical distinction. Police powers, when they overlap with takings issues, are usually in the areas of nuisance. If, for example, a hotel in Downtown Denver were emitting some toxic fume, the State could clearly use its police power and tell the hotel you have got to shut down until it's remedied, even though they would be losing lots of the value of the asset during the shutdown; that's very different from telling the hotel, You have to make a hundred rooms available every night for people we determine should get a free room. In fact, the Tenth Circuit case, Lech v Jackson, which the State relies on, basically, although it's not a published case, I want to address it, it addresses this directly, because it says what we're talking about is the police damaging a home while trying to apprehend a suspect. Yes, there's damage to the person's home, but that is a true exercise of a police power. Or in the District of Kansas case, Carrasco that they cite, cutting down a tree that could damage electrical wires. Those are proper exercises of police power. In those

situations, there's no Fifth Amendment violation, because the government is not taking property for public use. No one is using the plaintiff's property at all, even though there's a public benefit. We're stopping the fire. We're stopping the criminal. The plaintiff's property there is being destroyed or invaded in furtherance of some independent public safety goal.

Here, by contrast, the State is clearly taking Teva's auto-injectors for a public use; not to eliminate a threat to public safety, and therefore, I think it is clear that this violates the Takings Clause, and just to kind of punctuate this with the -- one of the classic takings cases, Penculum vs.

Mayhon as Justice Holmes wrote in his opinion, A strong public desire to improve the public condition is not enough to warrant achieving the desire by a shorter cut than the constitutional way, of paying for the change, and I think that's exactly what we have here.

THE COURT: So let me interrupt you, briefly, and just ask a couple of questions on things you have addressed so far. So -- is this -- is your view of police power, as it's being used in this takings context different than the sort of generic concept of the police power? Because I think, at least sometimes in my head, I view, when we talk about states have a police power, just as sort of -- to do whatever they feel like in -- for the health, safety and welfare of the citizens; whereas, contrasting that with the federal government, which

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only has limited granted powers. I think you could certainly, if you wanted to, say, Oh this is for the health, safety and welfare of the people of Colorado, right? And so is this a sort of term of art in this context.

MR. LEFKOWITZ: I think you have put your finger on it, Your Honor. It is a misnomer to just say anything that is an exercise of a police power escapes scrutiny under the Fifth Amendment. The police power is the plenary power of the states; that's the constitutional compact. The states have plenary power in pretty much every facette of life, with the exception of those powers that are provided through that constitutional agreement to the federal government, and then there are, not only is the federal government a government of limited powers, but there are certain powers in the Bill of Rights, particularly, that states, because of incorporation, are also now limited from. But other than that, what the state does is one way or another an exercise of its police power. It doesn't mean that they can take private property for a public use and that's why, whether you look at the way the Tenth Circuit described it in Lech or the Fifth Circuit in the case we cited in footnote four of our response to the Motion to Dismiss, which talks about the State not having to compensate, when it is an exigent circumstance or in some of the land-use cases, if a private party has land that is on the edge, for example, of a river or a wetland, they own that land with a

recognition that something might happen with the land that the State might have to exercise some regulation; that's a regulatory taking.

Again, all use of the State's police powers, but when you have something that constitutes a nuisance, then there's an understanding that the State can eliminate that nuisance without having to compensate you, but merely commandeering personal property is totally off limits, and I think the Supreme Court's decision in Horne amplifies this, as well as almost any other, but there are several others that address that. The Apfel case talks about it in the context of money, not even physical property. Horne talks about it in terms of a statute that required raisin farmers to simply set aside some of their raisins and not maximize the profitability of those raisins, and even though the Court recognized that maybe by taking some of those raisins away from the farmers, their remaining raisins would be more valuable. It didn't matter. The Court said that's a taking.

Again, that was a federal law. So I'm kind of giving you a mixed metaphor here, but the premise under state police power is states have enormous police power, but it's checked by the Fifth Amendment, as applied to the states.

THE COURT: Okay. Let me just ask you, before you move, on a couple of questions. So you have conceded that the other part of the -- the other part of the law is okay. The

part setting, as you called it, just a price cap, right? And so my question would be could — could the State for uninsured people, just require pharmacies or manufactures to not charge more than \$30 per injector, and would that raise any constitutional issues?

MR. LEFKOWITZ: If they applied the statute to pharmacies it wouldn't apply. It wouldn't raise any constitutional issues. If it applied — if it made the sale by the manufacturer to the — to the person manufacturer sells to, a violation of the law, then you have to look at where that sale takes place. This is actually a case I litigated, in connection with a Maryland statute, that, essentially, wanted to do exactly what you suggested, and they could have simply imposed a price cap on drugs, within the state, including sales within the state. But if you have an out—of—state manufacturer that sells out of state, then it raises a commerce clause issue —

THE COURT: There would be a jurisdictional problem -MR. LEFKOWITZ: Due process. We won that case in the
Fourth Circuit, but you certainly could effectuate that result
by simply saying, no CVS, or whatever the drugstore is, can
sell an EpiPen® for more than \$30.

Now, the market would either respond, because either the companies really don't need to sell for more than that, and they would still want to sell, or at some point you basically

disincentive people from selling a product, if they can't make money. But that would not raise a constitutional issue. We would be letting the market forces work.

THE COURT: All right. And then let me ask you, and this may come up in another part of the argument, but one quirk of this law, besides that, of the part you are challenging is that it — even though I understand your, sort of, finance/economic argument of why the other option is not a legitimate option that would ever likely be used. It is an option to pay money, instead. Could you view this as, essentially, a tax, that part of it as a tax, that you can pay either in money or by giving away some of your product?

MR. LEFKOWITZ: So, two parts to that answer; one, I don't think you could treat it as a tax, because the money isn't going to the government, and taxes are not -- you know, they don't go to third parties. They don't go to drugstores. You can't tax person A to pay person B, that is something else, but it's not a tax.

Number two, and I think even more important, given the way the statute is written, that would be a taking just as much. *Koontz*, the Supreme Court's case on *Koontz* 570 US, 595, it's 2013 case, basically says the government can't condition your right either on a depravation of property or on the payment of money. And in *Apfel*, the Court was addressing merely a taking of money. It was a statute that said some

company, new ownership of a company found that there wasn't enough money to pay old pensioners, because the money had run out, and they imposed this... you could call it a tax, but it wasn't. It was a requirement, by the statute, for the private party to pay money to a pension fund for these workers, and that was, again, deemed to be a taking. So I think that answers — I hope that answers your question.

THE COURT: Okay. Thank you.

MR. LEFKOWITZ: Let me move now to injunctive relief, and then I will save some time to talk about standing and ripeness and Eleventh Amendment.

So, look, I understand that this is, in my view, the heart of the issue, in the sense that I think it is very clear that we have a taking, and the question then is, what is the remedy here? I will address the pre-enforcement challenge part. I know the Court is very familiar with this from just dealing with it in Bella Health, so I will focus, right now, on just the guts of the issue is, do we have an adequate available remedy?

The Attorney General essentially says look, injunctive relief is inappropriate, because we have an adequate remedy of law, and I would agree if there were an adequate remedy of law, we would be in a different situation. We would require compensation, and then we would have to be doing it a different way because of Eleventh Amendment issues, here.

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They claim that Knick, the Supreme Court's 2019 case, essentially, sets forth a rule that a state's compensation program is always adequate. But actually Knick says nothing of the sort. It makes clear that when a program is adequate, a federal court won't enjoin a statute, and so where the rubber meets the road, really, is -- and where the action is, I think is, is this state compensation program adequate? And for that we look at traditional principles of equity which go all the way back to Terrace vs. Thompson. It's a Supreme Court case, literally a hundred years ago, and the test is, is a remedy at law adequate? And it is only adequate if it is as complete, practical and efficient as that which equity could afford, and that comes right out of Joseph Story's Commentaries, and that is a proposition that has been followed by the Supreme Court, by the Tenth Circuit, by Colorado courts, throughout, and I will address that.

The plurality of the Supreme Court applied this principle to a takings case in Apfel, when the Court enjoined statutory mandated payments, because the Court said forcing the plaintiff to recover its payments through damages suits, under the Tucker Act would entail an utterly pointless set of activities, and the Eighth Circuit, very recently, in the PhRMA case, dealing with almost an identical statute, dealing simply with insulin, instead of EpiPen®s, found that the state remedy, and there was a state remedy in Minnesota, was, quote,

incapable of compensating manufacturers for the repetitive future takings that will occur, and the Eighth Circuit relied on *Apfel*, which in turn relied on *Duke Power*, which essentially said the same thing, with respect to injunctive relief, when a compensatory remedy is not adequate for efficient, and that's the real question here.

Let me explain why it would not be adequate or efficient. Here, Teva would be required to bring damages every time it was forced to reimburse a pharmacy. Now, the State says, Well, you could just wait and do it at the end of two years. But, of course, you would have to constantly add new claims, you would have joinder, and it would be an utter mess, because you have maybe hundreds of different pharmacies and their — the costs that you have to pay each of them is based on their cost.

Well again, Joe's pharmacy may not have nearly as much buying power with, you know, Cardinal or McKesson or one of the wholesalers, so they may be spending \$400 dollars or \$300 or \$200. CVS or Walgreens may be paying much less. It's even more complicated than that though, because the really big retail drug stores, they end up getting rebates after two years, after like a two-year look back. They get a rebate that's based on all of the different things that they buy from that wholesaler. Now you have got to come up with a methodology to figure out of that X, you know, million-dollar

rebate that they got, how much of that is allocated to each EpiPen®? Because the State has got to figure out or some Court is going to have to figure out, how much we're entitled to get back.

THE COURT: Let me -- that makes a lot of sense to me, but let me just ask you why that's so different than your, sort of, more traditional takings case. Say Knick, for example, seems like it should be pretty straightforward, right? The town in that case says you have got to leave your -- your family cemetery open; but how do you value that? Why is that -- that's an ongoing, forevermore, you have to leave your property open. Who knows how much that's worth.

MR. LEFKOWITZ: Well, it's not -- it is ongoing, but it's ongoing in the same way that if my father's apartment, growing up in New York was condemned by Robert Moses, because he wanted to build the Cross Brox Expressway. He suffered that loss every day until he moved out to go to college, but it was a one-time event.

The lighting for the cemetery is a one-time thing.

It's the statute, and you now could tell, you go to a Court and you say, I have now been deprived of the use, the quiet enjoyment of my property, because I have got to keep the lights on forever, and someone does evaluation in the same way that nearly all of these eminent-domain-type cases are. You take a piece of property, you burden some land, and there is a way of

coming up with some economic formula. This is a series of independent repetitive, multiple takings, and they will go on indefinitely, which means that because there's only a two-year statute of limitations, under the Colorado Inverse Condemnation law, not only would you have to do everything I just described, in the first two years, but then you would immediately have to go and start doing it again for the next two years, and the two years after, and that, I think, is what the Supreme Court talked about in Di Giovanna vs Damden Fire, when it said, The avoidance of a burden of numerous suits at law between the same or different parties where the issues are substantially the same is a recognized ground for equitable relief in the federal courts.

And here we even have the more complicating factor, which is, the payments that we're making are to a third party. I'm not sure what the State's position would be if we sought, you know, relief/compensation from the State. They might say, Well, you have got to look to the pharmacies, they are the ones who have your property. I'm sure the pharmacies would say, We are commanded by the state. But if we had to go after the pharmacies, some of them might not even be in business in two years, but even beyond that, there's also this treble damages that we would suffer, if we don't comply with the statute, and for that, I'm not sure we could ever be made whole, because I don't think the State has waived sovereign immunity.

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THE COURT: My understanding is Teva intends to comply with the law, right? You don't intend to just say this is unconstitutional, we're going to -- we're not giving away our stuff?

MR. LEFKOWITZ: I don't believe that our witness said that at all. I think what the witness said is we intend to continue to sell the drugs, and moreover, we couldn't even avoid it if we wanted to, because we have already shipped so many EpiPen®s into, you know — to our wholesalers, who have, in turn, sent them to Colorado, that they will be sold, and when they are sold, we will then be forced to basically replace the EpiPen®s or not.

So, I don't know that Teva -- I think Teva intends to do exactly what we're kind of moving a little bit into standing ground but, Teva intends to do exactly that which will bring itself squarely within the ambit of the State's full authority, and once that happens, I think there are enormous complicating factors with respect to an adequate remedy of law.

Now, the Attorney General cites a couple of cases that he says Courts decline to grant relief in cases that also had what he calls potentially or theoretical indefinite takings.

But I want to look at the two key ones that he cites. He cites Gordon vs. Norton, a Tenth Circuit case involving the federal government's reintroduction of wolves in Wyoming, and then some of the wolves killed some of the cattle. Importantly, as the

Court noted, the plaintiff wasn't challenging the lawfulness of the government action. They weren't, as we are, challenging and seeking to enjoin the entire statute. They were quibbling with a certain aspect of the statute. How the State, under its regulations, was going to cull the herd of the wolf. Very different from a situation where we are trying to strike down or enjoin the entire statute, because the -- not the entire statute, the provision of the statute that we find unconstitutional. I apologize.

THE COURT: Let me just --

MR. LEFKOWITZ: Yeah.

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THE COURT: What difference does that make? Why is that any different? I mean, they thought a narrower sliver of the law was problematic. You think a broader one. Why is that dispositive?

MR. LEFKOWITZ: Because here we have this endless supply -- endless multiplicity of lawsuits. They were not challenging, as the Court observed, the lawfulness of the government action. We are challenging the lawfulness of the government action, and that is significantly different. The same distinction, actually even stronger distinction applies in the more recent case that they cite from the Tenth Circuit, Williams vs. Utah Department of Corrections. There the Court did reject injunctive relief, but it expressly said it was doing so for the reason that the plaintiff had named the wrong

defendants under ex parte.

But I would submit, Your Honor, that the Eighth
Circuit in the PhRMA case got it right. When a statute
authorizes an indefinite serious of takings, a suit for
compensation is not complete, practical and efficient, which is
what equity demands, and Colorado courts have a long tradition
of applying that very principle in nuisance and trespass cases.

I will cite the Court two cases, Colby vs Young, which is a 1984 case, where it recognized that where a trespass is continuous, the plaintiff's, quote, only remedy at law would involve a multiplicity of suits for each recurrence of the trespass, and therefore the remedy would be inadequate. And in 2010, Hunter v. Mansell, Court of Appeals decision also in Colorado, if as here, the trespass is continuing, the owner's only remedy at law would involve a multiplicity of suits for each recurrence of trespass.

This remedy at law is inadequate where further trespasses of the same kind are threatened and an injunction will lie. I really think, Your Honor, when the Eighth Circuit addressed this through the prism of Apfel, this is the body of case law they were looking for, and the case law, and the scenario where an injunction is not appropriate, is the situation where you have a taking, whether it's an exercise of power by the State, for a nuisance or eminent domain by a railroad or something, and you have an event and you can go to

court and someone can value that event. And sure, what you get in the compensation may not be as much as what you -- might not give you the kind of relief you really wanted, but the Court deems that adequate; the same way that if I'm injured in an accident, and I get damages, I may not get my arm back, but that's deemed to be adequate compensation. But this is not an adequate remedy, because we would have to be doing this, literally, forever, because this statute doesn't have a sunset provision.

that. But I do wonder why we couldn't -- say we didn't have the Eleventh Amendment issue here, and you were trying to get some money, in this case, and I said, Okay, I think this is a taking, but instead of telling you, You got to come in and prove exactly how many you sell and, you know how many, you sold to this particular pharmacy, or this particular middle man, I just say, let's do like you do in a land case, and make some estimates, get some economists and accountants in here and say here is a reasonable present value of the likely cost of these going forward in perpetuity, just like the town could -- the value of what the town did in Knick could change over time, But that doesn't mean that whatever they come up with in that case is inadequate.

MR. LEFKOWITZ: It's far more unworkable here. First of all, we're dealing with private parties, not the government.

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We're dealing with compensating all of these pharmacies, that we're obligated to pay. And also, we're in a world where, right now, there are two generic substitutes to the branded EpiPen®, and because of Colorado's very generous state substitution laws, they encourage physicians and pharmacies to dispense generics, always, because generics are a lot cheaper than the brand. However, we have no idea how many Teva is going to sell a year from now, two years from now, three years We don't know how many more generics may be in the market for this product. We don't know when some new product will come on the market that will modify the quantities being sold. There is no way -- it's not like when you are simply making a bet on how much my land would be worth, you basically value it based on the fair market value today. That is the measure in takings cases. That is the measure for just compensation. Because no other measure is really fair. here, to do the net present value, you have to make assumptions about the forever, which you literally can't make, because this is an endless series of takings, and even the inverse condemnation proceeding that takes place two years from now, is only one of many that have to take place. I just -- this actually is even more inadequate than the one that the Eighth Circuit found inadequate, because in the Eighth Circuit they didn't even have a two-year statute of limitations. It was a much longer period. They did have a statute of limitations,

but it was a good deal longer than we had here.

So, here dealing with the multiplicity of lawsuits, and figuring out what the pricing would be, the requirement of having to have various experts opine, look at different models, understanding that the, you know, kickback arrangements, I don't mean that in a pejorative way, the way drugstores get reimbursed, in a look back from the wholesalers, it's just impossible to really do this in any efficient way.

If I may, I would like to just touch briefly on the standing issue. And last thing I will just say about this one thing is, in Horne, there's actually a discussion about the longstanding Cherokee Nation rule about, you know, adequate compensation being appropriate, and the Supreme Court, just a couple years ago, in ** Horne -- a few years ago in ** Horne -- cited several cases, where it found that compensation was inadequate, even though there were compensation formulas available, and in those cases, found that injunctive relief was appropriate.

THE COURT: Let me ask you one last question, before you move on from this, because I think we both agree this is probably the heart of what we need to talk about, right now at least.

Knick, you would concede, says a lot of things that are helpful to your case, but then has one section that says,

Don't read anything we're saying today as saying that courts

can just start enjoining takings. It seems, explicitly, to try to say injunctions and takings, if not never, are rarer than injunctions in other areas, that we have to treat it differently, somehow.

MR. LEFKOWITZ: I think that's not -- that's not an
incorrect reading.

First all, that entire discussion was dicta, because there was no question in <code>Knick</code> about that. But because <code>Knick</code> was establishing, by overruling <code>Williamson</code>, that parties can come straight to federal court, and in that case, because it was not a state, it was just a municipality, you know, she was able to go straight to the court to seek her relief. What the Court was saying, <code>is</code>, <code>Look</code>, <code>don't worry</code>, <code>when there is an adequate remedy, <code>we're not going to be going around enjoining state action</code>, and we assume that there is, usually, going to be a state remedy that's adequate, because every state has some form of just compensation formula that they use in eminent domain.</code>

But it did not, in any way, say that it will never be the case, and the backdrop rule is clearly the rule that we apply in all equity, which is, is there an adequate remedy at law? And the Supreme Court was very clear to modify its, kind of, note to the state that says don't worry, you shouldn't expect lots of injunctions, by saying when there is an adequate remedy, and it certainly had the knowledge of *Duke Power* and it

had the knowledge of *Apfel*, when it said that, and it recognized that there are going to be times when a remedy wasn't adequate.

THE COURT: So Apfel, in particular, you have said a couple times here that what you trying to argue is that this is un— this action is unconstitutional, this is an unlawful provision of the statute, but that that same part of Knick seems to me to — well, let me strike that. Going back to where I was saying. Normally, a taking is, sort of, by definition, a lawful action on behalf of the government, other than that they have to then pay just compensation. One way of interpreting what you are saying, and certainly what you are asking for, an injunction on this law, is that if a taking is coupled with this inadequate remedy, it is unlawful, period. There's no way of complying with the Fifth Amendment, at all; is that right?

MR. LEFKOWITZ: I think that's fair. And remember, there used to be a doctrine with the Court where states, as long as they provided a remedy, you didn't even suffer the constitutional harm until after that inverse condemnation thing happened, and then a Court made very clear, about 15 years ago, no, you actually suffer the constitutional depravation the minute the taking takes place; that's actually why Knick says you have right to a 1983 action, instantly, immediately. You don't have to go and do your compensation program with the

State, because you are suffering the injury immediately. So the only question is, if you recognized, from a standing perspective, that we have an actual live case in controversy, which we will talk about in a minute, then the question is, as of January 1st, we will be suffering this Constitutional depravation, and if we don't have an adequate remedy, then it is perfectly appropriate to grant the injunctive relief, because otherwise there's no way to unscramble that egg.

THE COURT: Okay. Thank you.

MR. LEFKOWITZ: I will be much briefer on the standing and ripeness issues. I do want to, just briefly, address them though because I know the State has made a big deal of them.

First of all, I don't think there's any dispute that

Teva is facing a credible threat here. Basically, there are
only really three different, you know, assumptions, that go
into this. One, that some Coloradans will use the program; two
that some Teva pens will be sold; and three, that pharmacies
will seek reimbursement.

I want to first address their legal argument, then I will go to what's in the record. They argue that the credible threat standard is restricted to First Amendment cases. First of all, Susan B. Anthony, although it was a First Amendment case, makes clear that the credible threat language that it was articulating, relates to the injury in fact requirement, and therefore it applies to any preenforcement challenge. I know

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this Court applied it in the free exercise clause recently. Chief Judge Brimmer applied it in a Second Amendment case recently, and interestingly, he denied -- he rejected standing in another gun case, because in that case the plaintiffs didn't allege they intended to engage in the conduct forbidden by the statute. So there, there wasn't credible threat. But there's no question that in the Second Amendment context, it's been utilized by the Tenth Circuit, as well, both when it affirmed that initial injunction of Chief Judge Brimmer earlier this summer, and in Colorado Outfitters vs Hickenlooper, which was a Second and Fourteenth Amendment challenge, again in 2016. One of the key lessons of Knick, and this is what the Court specifically says, there's no reason why the taking clause should be relegated to the status of a poor relation among the provisions of the Bill of Rights.

We know, for example, that we have Second Amendment cases where this standard applies, First Amendment cases, and of course, when it applies to a state, it's actually just applying through the Fourteenth Amendment. So there's no reason to single one of the Bill of Rights out from the others. For years this preenforcement challenge applied in abortion cases which, depending on your view of the world, either involved five or six different parts of the Bill of Rights or involved none, but it certainly doesn't just involve the First Amendment, and so, from my perspective, there is a credible

threat, and there's no basis to say that the preenforcement challenge can only apply in a First Amendment case.

Now let's look at the facts. Teva supplied 14,000 epinephrine auto-injectors to Colorado. This is from the declaration, in the deposition, at page 21, Mr. Galownia says, Teva plans to continue shipping the auto-injectors to Colorado. He said, the next page, Even if the act goes into effect we will continue to sell EpiPen®s in Colorado, and then on page 20 he said, There's already inventory in Colorado, and its customer contracts require Teva to provide any notice of stopping sale, which we have not done.

Moreover, the Colorado laws on generic substitution make it clear that these EpiPen®s are going to be sold, and Teva has a 37 percent share of the market; that's on on page 29.

So, I don't think there's any question that Teva satisfies the case in controversy requirement for a pre-enforcement challenge both on the law and the facts.

I want to touch, very briefly, on ripeness and make two points. The Attorney General has two ripeness arguments. I think both are meritless. First, he claims that Teva's claim is unripe because no taking has yet occurred, but the Tenth Circuit just said, two years ago, in 303 Creative, that in the context of pre-enforcement challenges, quote, Standing and ripeness often boil down to the same question. And then, the

Attorney General argues that Teva's claim doesn't satisfy the finality requirement for takings, but the finality requirement applies only to regulatory takings not per se takings, like this, and it almost always arises in the land use context, where a plaintiff has to get a variance before filing a lawsuit, in order to make clear — he has to seek a variance, in order to actually ascertain what the force of the law is.

We know what the force of the law is here. That citation is Pac. Tel. vs. City and County of San Francisco, 141 Supreme Court, 2226 it's a 2021 case.

I won't even address, unless the State raises this, the question of the whether the defendants are now the proper parties. I think everybody agrees that we have now sued the proper parties, and I will simply close by addressing, briefly, the Eleventh Amendment. The Attorney General's argument on the Eleventh Amendment is a little confusing and circular. He argues that if Teva reframes the claim as one for just compensation, the Eleventh Amendment, Sovereign Immunity would bar the claim. But Teva will not reframe its claim as one for just compensation. It doesn't believe just compensation would work here, doesn't believe it would be adequate or prompt or efficient, and it is not like all of these cases that they cite, the EEE Minnesota case, the Ladd vs Marchbanks case, Williams vs. Utah, Los Molinos, all of those cases are basically cases where injunctive relief is disquised as a

request for just compensation. That's not what we are doing here. We only seek an injunction preventing enforcement of the reimburse or resupply requirement, and therefore, I think our case falls squarely within <code>Ex parte Young</code>. The State has a lot of options if it wants to make <code>EpiPen®s</code> available to Coloradans, insured or uninsured, cheaper. It can impose a tax on the sale of <code>EpiPen®s</code>, and then use that tax as a dedicated fund for people who are uninsured. There are some states, municipalities that have adopted that. They can simply impose a price cap and see what the market forces do. They could subsidize it more broadly, in other ways.

I guess, the State could even decide it wants to enter the generic business and develop its own EpiPen®s. The one thing that it can't do, is it can't take this private property, which is clearly for public use without just compensation, and when there isn't an efficient, practical remedy, as the Supreme Court has articulated in *Terrace*, as the Eighth Circuit has just made very clear in a statute almost on all fours, injunctive relief is warranted.

THE COURT: Can I just ask you one question before you sit down?

As I have read *Knick* and the *Apfel* case, and the *PhRMA* case, I haven't seen any of those — it was a little hard to tell, exactly, what was going on, procedurally, in *Knick*, but, *PhRMA* and the *Apfel* case seem to be not pre-enforcement cases.

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Do you have any pre-enforcement takings cases where a Court has enjoined before a law went into effect? Because what Knick does say, you are right, once we -- even if there's possible compensation, that constitutional flaw, the constitutional right is infringed once the property is taken, but what happens -- you are asking me to do something before that even. Do you have any other cases doing that? MR. LEFKOWITZ: I will think about that while I listen to the State's argument, and I would gladly accept an injunction that went into effect on January 1st, which would satisfy that concern, but doctrinally, I actually don't think there's a difference, if we have standing. In other words, if -- if we are imminently threatened, there's all sorts of case law that makes clear, you don't have to wait for the government to effectuate punitive action on you before getting your relief in court; that's the standard for all of these pre-enforcement challenges that we've seen over the last decade, mostly, again in the abortion context, but in a lot of other context as well. Certainly in the gun context, here in Colorado, just recently with Chief Judge Brimmer's opinion, but I will think about it, since I know I will have a little bit of time in the takings --

THE COURT: This is not really a question, just a summary of my big question for everybody, is, to me, Knick, as you pointed out, does suggest and say, in some ways, that

basically, takings cases should be treated just like other constitutional cases, and that, obviously, is the heart of your argument. But then it has the one section that says, but wait, there's -- don't read us as thinking we are going to start handing out a bunch of injunctions in federal court for takings cases, and there's something just different about takings, the Takings Clause, than the Second Amendment and the First Amendment, which is, those typically -- those cases involve a prohibition on doing something and here, you are allowed to continue everything you just said; they are allowed to continue selling; they are allowed to do this; but when they do, they've got to hand over some of their property, and there's just something different about that, isn't there?

MR. LEFKOWITZ: I don't actually think there's --

there's something different, because factually it's different, but I think that doctrinally it's not different, because the job, I think, that a Court has in this situation, is to make an assessment now, as to whether the compensation program is going to be a full and efficient remedy. If it is, then, yes, what is different about the Takings Clause is, it allows the taking, if there's going to be just compensation, but based on the record we have, and I don't think there's anything more that is needed, and certainly the State could have taken discovery, if it thought it needed additional discovery, based on what we know now about the way in which this inverse condemnation

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proceeding would have to work and how it would be endless and repetitive and involve thousands or hundreds of different drug stores with different price formulas. I think we can say -not we -- I think the Court can say, at this point, I can look and I know that this is not going to satisfy the demands that equity imposes in the test for equity versus law, and so as long as there's standing, I think it is appropriate to grant that injunction. THE COURT: All right. Thank you. MR. LEFKOWITZ: Thank you, Your Honor. THE COURT: I will let the State -- I'm not sure, Mr. Nelson? Right, yeah, please. MR. NELSON: Good afternoon, Your Honor. THE COURT: Good afternoon. Go ahead. MR. NELSON: Pawan Nelson, I represent the Attorney General, but today I will be arguing on behalf of all defendants. Teva's motion for a preliminary injunction should be denied and i's case should be dismissed. Colorado enacted this program to give all Coloradans access to lifesaving medication that they need in an emergency, in the face of price gouging. It has not gone into effect yet, and it's clear Teva dislikes the policy, because it may affect them, perhaps, in the future. But what Teva is trying to do here, and I think the Court mentioned this, was exact -- was specifically prohibited in

Knick. Coming to federal court to try to get an injunction to prevent a taking from happening in the first place, that should not be allowed.

For three principle reason the preliminary injunction motion should be denied and the case should be dismissed.

First, Teva has an adequate remedy at law, and I think we all understand that's probably the heart of the dispute right now.

Second point is, Teva has filed a suit prematurely, and we can get to that standing and ripeness arguments, and finally, the police power argument.

But I would like to start with the adequate remedy at law argument, because it is really, I think, the heart of what we're talking about here. And a few things are not in dispute, Your Honor. No taking has occurred, because the program has not even gone into effect yet. But if that ever does happen, there are adequate compensation remedies in Colorado state court for them to get just compensation.

And it's well established too that in the Fifth
Amendment Takings Clause context, no injunctive relief is
available where a suit for compensation can be brought,
subsequent to the taking.

In the face of these, you know, facts and well-established principles, Teva makes its argument that, But wait, it's not adequate, because we will have to have these repetitive suits, and therefore it's not adequate, and I think

that's wrong for two principle reasons; it's wrong as a matter of Fifth Amendment Takings Clause Doctrine, and it's wrong as a practical matter.

So we're talking about Fifth Amendment Takings Clause. Since the *Cherokee Nation* case, in 1890, all that's required to satisfy the Takings Clause is reasonable, certain and adequate provision of obtaining compensation some time after the taking, and I think that's a line of precedence for 130 years that make that clear, and it was reaffirmed in *Knick*.

A compensation remedy does not become inadequate simply because multiple suits may be, theoretically, necessary. And I think where Teva and the Eighth Circuit took their wrong turn is by not looking at how the Takings Clause has been, sort of, developed and enforced over the years. They are trying to import equity concepts into this context when they've really never occurred in the Fifth Amendment Takings context at all.

We can look at the Tenth Circuit for that. You know, the Gordon case, the one involving the wolf pack. There, theoretically, would have been a taking any time the wolf pack got hungry, right? Yet, in that case, the Tenth Circuit said, Nope. You don't get to come to federal court, get injunctive relief. You have got to use a Tucker Act. I think the Williams case illustrated this principle, as well. I mean, interest accrues, literally, every day, right? Still, Tenth Circuit said, Nope. You have got to go use your state court

remedy. Even more than the Tenth Circuit, since Knick, multiple federal courts have rejected the argument Teva is making here; that somehow we get an injunction, because, Hey, you didn't give us just compensation ahead of time; multiple Courts have rejected that argument.

So I think that the idea that somehow there's a multiplicity of suit exception, that we can import from equity into the Fifth Amendment Takings context, it really doesn't have any basis in the case law.

THE COURT: What about the Apfel case?

MR. NELSON: So the Apfel case, essentially, what the Court found there was that the Tucker Act didn't provide a compensation remedy at all, given, sort of, how the Cole Act worked.

So the holding of that case wasn't based on some sort of multiplicity of suit rationale. It was simply that, Hey, listen, given how Congress constructed the Cole Act they did not mean the Tucker Act to be the exclusive remedy to get compensation.

THE COURT: Right. And I mean why wouldn't that same analysis apply here? State of Colorado clearly didn't intend for the state to subsidized these pharmaceutical manufacturers, right? I mean -- and maybe you can take a step back and just tell me, if I agreed with you, what you think -- how would this play out, if I just dismiss the case and deny it? What do you

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think they should do? Assume that it's a taking, for purposes of this question.

MR. NELSON: Sure. If you assume it's a taking, whenever there's a final decision; that is, whenever a pharmacy comes to Teva and says, Hey, I need to get reimbursed for this. Send me an EpiPen®. Okay. That would be what would be considered the taking, right? And at that point Teva could come to state court, in Colorado, and say; A, either after they give them the EpiPen® come to Colorado State court and say state you owe us for a taking; a taking has happened. So you owe the wholesale acquisition costs for the EpiPen® that we give, right? Or if the Board tries to enact some sort of enforcement proceeding against them, Teva could make a Fifth Amendment Takings Clause defense to that, in Colorado state court, and would have the same sort of fight, which is, you know, Hey, is this a taking? And if it is, You owe us the money.

So I guess I hope I answered your question,

Your Honor; the taking -- the taking needs to occur, and once
the taking occurs, they go to state court and get their
adequate compensation.

THE COURT: So then was -- do you dispute

Mr. Lefkowitz' description of how complicated that would be,

and maybe even setting that aside, even if we could do the math

without all of that much complication, doesn't that sound a lot

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like -- I mean, the math in Apfel was pretty simple. But the Supreme Court said, Well, that's pretty pointless, because the law is clearly intended not to have the government basically paying these private companies who then pay it to someone else, which is what you are saying would happen here. And the Court said, Well, that's not what anybody had in mind. So if the statute is set up to do that, you can get an injunction Isn't that the holding of Eastern Enterprises vs. instead. Apfel. No, Your Honor. I think you asked a few MR. NELSON:

questions there --

THE COURT: Yeah, probably. You can pick -- pick them off one at a time.

MR. NELSON: I would like to answer all of them, but in a particular order.

First of all, I do dispute the notion that somehow this is going to be mind-bending complicated damages question, right? The reason I say that is because the way the program works is the pharmacy asks the manufacturer for replacement, and then the manufacturer will send it straight to them. it's not going through the chain of commerce. It's not going, first, to the wholesaler, who marks it up, but then gets some kickbacks from them, and so that price changes, who then sells it to the pharmacy, at a markup, other types -- no. None of that is happening in the program, the way the program works.

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Once the pharmacy asks for reimbursement, Teva ships it, and Teva can say, We would have sold that at 300/350 wholesale acquisition costs. You guys owe us now. So I dispute the notion this is somehow some complicated question, right?

And then I think talking -- you asked me about the Apfel case, and you know -- but again, I don't think the plurality in Apfel, the notion of money damages, I don't think that was really the basis of their holding. The basis of their holding was, we presume Tucker Act applicability unless congress unambiguously says it doesn't apply. In the Cole Act we believe it said that it didn't apply, right? And then you need to look at it, again, in the context of how the Tenth Circuit has dealt with similar questions in the past, right? So if we look at the Gordon case, again with the wolf pack -- I believe, during his argument he mentioned -- Teva's argument, mentioned that as a practical matter, what this program is going to do is Teva is going to give the physical product. we are not talking about money, as a practical matter here at all, based upon what they said in their oral argument. We are talking about them shipping a physical product, and I think that falls squarely into the Gordon v Norton realm. Tenth Circuit, you know, distinguished Apfel, they said, No, we're talking about discrete physical products. Apfel wasn't talking about that, Apfel doesn't have applicability here.

So, to answer your question, Your Honor, I would say, it's — this is not some complicated damages question; and two, since we are talking about physical products, really shouldn't be talking about Apfel at all.

THE COURT: On the first question, so is your view, that no matter who requests, no matter which pharmacy is at issue, the dollar amount attached would be the same for Teva, that none of the middleman stuff makes a difference or none of the pharmaceutical — who makes the requests from them, it wouldn't matter?

MR. NELSON: I mean, based upon what I think their declarant testified, I don't see how it wouldn't, because again, it's not going through the chain of commerce. So, you know, Teva would set its price. We think you owe us this, right? There's no markups, there's no kickbacks, there's nothing like that. So I don't think it's as complicated as they are making it out to seem.

So I think, you know, this multiplicity of suit exception really has no basis in Fifth Amendment Takings Clause jurisprudence. The Fifth Amendment was not designed to limit governmental interference with property, per se. It was just designed to secure compensation. The Fifth Amendment does not require compensation be paid in advance or contemporaneous with the taking. There just needs to be a mechanism for reasonably just and prompt payment after the fact, and the Colorado

compensation remedy does it here.

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I don't think they've really disputed that, at all. So the Court should reject that argument.

Now I want to move to the practicalities. We have talked a little bit about the pricing argument they made. The argument that we raised in our reply in support of our Motion to Dismiss. Another practical problem with their argument is preclusion, right? We were really -- since this is a discrete identical physical product, with the same price, no matter which formulation we're talking about, all we really need here is a single suit to hash out our differences in Colorado state court, and then depending how that court went out, there would be preclusion would apply. And so if a state wins there's no taking, you know, the program goes into effect, right? If Teva wins and there's a taking, I could see two things happening, right? A, there's legislative changes; or B, all Teva needs do now, after -- anytime an EpiPen® is made or is taken under the program, all they need to do is send us a letter says, Hey, State now you owe us this amount of money, and I don't think anyone in my office is going -- if they lose the first case, is going to try to dispute that in court, because how preclusion principles work.

So, as a practical matter, I don't think this argument that somehow they don't have adequate remedy really holds water, and what does that mean, right? If they have adequate

remedy, the Eleventh Amendment bars their suit, right? Because they can't get injunctive relief against the state. And it also means, if they have an adequate remedy, they have not made a strong showing of the need for a preliminary injunction.

So, because this is the case, Your Honor, I would say the State would ask you to, you know, reject Motion for Preliminary Injunction and dismiss the case.

THE COURT: Let me ask you what do you make of Knick's discussion of how -- I mean, it sounds very familiar, what you are asking the plaintiff to do here, which is going to state court, once you have had your property taken and ask for compensation, and the Supreme Court says that's not the requirement anymore. There's no state exhaustion requirement. You can go straight into federal court and the taking occurs the moment that the property is taken and you can go straight into federal court. And I think it's a fair analysis of Knick to say it, basically, was trying to say takings cases should just be treated like every other constitutional case. Do you dispute that?

MR. NELSON: I do, Your Honor, because I think that the Tenth Circuit addresses it in Williams. Knick was not -- did not involve state defendants, right? And Knick did not abrogate the state's sovereign immunity under the Eleventh Amendment. So, since they have decided to sue the state defendants, the Eleventh Amendment applies here, and you know I

think as the Tenth Circuit said in the Williams case, given that the Eleventh Amendment applies, you can't bring a taking claim against state entities in federal court, if there's an adequate remedy available in state court.

So, no, I don't think this is reimposing the Williamson County state litigation requirement. It has a separate font where it's coming from, and this is the Eleventh Amendment, and not only has the Tenth Circuit found that, it's multiple circuits have found that the Eleventh Amendment applies in takings cases, when you are dealing with state defendants in federal court.

THE COURT: But do you think -- Williams seems a little different. I mean, they clearly are not trying to use this to get compensation. I mean, they want to block the law from going into effect, and the Eleventh Amendment, generally, doesn't apply to those sorts of requests, right?

MR. NELSON: So, you know, I cited a number of cases in the reply in support of our Motion for Dismiss, where federal courts have dismissed these types of claims, under the Eleventh Amendment, because they found that inadequate remedy applied. They could get adequate remedy in state court. So, I would not agree with Teva's argument here. Knick, you know, Knick didn't apply in the Eleventh Amendment context. Williams held that the Eleventh Amendment applies and Fifth Amendment Takings cause -- cases, and multiple federal courts since then

have kicked out cases exactly like this one, under this principle.

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I don't see, really, any way, in this case, that there would be money paid in the way that the Eleventh Amendment usually — there would be damages coming out in this case.

So — do you see — do you see a way that there would be damages that would, sort of, be the equivalent — or some kind of payment that would be what, typically, triggers the Eleventh Amendment, or are you just saying that, sort of, there's — maybe based on this preclusive effect that you get an injunction in federal court, then you can — even if you can't get direct damages in federal court, that you could take that in and have a preclusive effect somehow? Or is it just a different rule for takings cases?

MR. NELSON: I think it's a different rule for takings cases when you are dealing with state defendants. I think, because of the Eleventh Amendment issue, literally, the only type of remedy they could get in federal court would be perspective injunctive or declaratory relief. Really, that's the only one possible. But given the nature of the Fifth Amendment, which is the remedy is compensation, right, as long as there's a remedy where they can get compensation, no, they can't come to federal court. That's what the Williams case held.

So, you know, although they may not be seeking it, and

I think they are not seeking that, in this case, given Ex parte Young, that's been well established, as a practical matter, given what we discussed before about being an adequate remedy of law, it's not available, at this point.

THE COURT: So that leads to, kind of, this question I brought up towards the end with Mr. Lefkowitz, which is their argument essentially is, if there's not an adequate remedy, that the law is just invalid. It's not that, you can somehow figure out compensation. But if you can't figure out compensation in an adequate, efficient way, then you can't do this at all. Is that right? Or do you think that -- so, I guess what I'm saying is so, your position is this is not a taking, but if we assume it's a taking, and then we assume that it's too complicated for this ongoing, constantly changing market, then the only -- there's no remedy, no compensation available. So the law just is invalid. And that is the kind of thing that you can get, despite the Eleventh Amendment, right? You can get a federal court to say law is invalid going forward.

MR. NELSON: So, I think the only cases that have -going back to the principle in Cherokee Nation, which is you
need adequate -- I want to get the exact language, so let me
leaf back. Yeah. So, you know, given Cherokee reasonable
certain adequate provision for obtaining compensation, and
again, after the fact. You know, I think the way that's been

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applied in federal courts, over the years, is the instances where's they found it didn't apply, was where a plaintiff couldn't get compensation at all. Simply couldn't get it, at all.

There's, you know, this Clajon case, it's Tenth Circuit, 70 F3d, 1566. This wasn't cited in the briefs, and it's was about ripeness, but in that particular instance, Tenth Circuit evaluated a Wyoming law governing the allocution of hunting licenses, and there the Tenth Circuit held, because the plaintiff couldn't bring inverse condemnation suit under Wyoming law, it wasn't adequate. So, I think if you actually look at the case law, how it's developed over the years, and the Fifth Amendment Takings Clause context, it's not because it's complicated. It's that if there's no remedy at all. And I think that's what I'm saying here. I'm saying simply, A, I disagree, as a factual matter, that this is a complicated question to begin with; but B, we can hash that out; that's what courts are for. Hash out these complicated questions, come to a final decision, and really that's all we're saying is necessary in the Fifth Amendment Takings context.

Unless the Court has any additional questions on this point I would like to move to the standing question, now, and I think that the -- at the end of Teva's argument, the Court asked an interesting question, which was, can you point me to any pre-enforcement takings clause case? They have not cited

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in it, but --

any in their briefs. I haven't been able to find any in my research, and that's not a mistake, that's because of the uniqueness of the Fifth Amendment Takings Clause to begin with. And I think if we look at Knick, they explain the uniqueness of this Takings Clause. It repeatedly says, you know, Fifth Amendment isn't designed to limit government interference with personal -- with property. You don't need to pay compensation ahead of time. Just because you enact legislation doesn't mean that's a taking. And I think as Knick said, repeatedly, the Fifth Amendment Takings Clause occurs at the time of taking; that's when the plaintiff can file suit, and I think there was a suggestion that that's all dicta, but that wasn't dicta, Your Honor. What the Supreme Court was doing in Knick was overruling a well-established law, and in response to that, the dissent argued, Hey, listen, you are establishing a rule where people have to pay for compensation ahead of time. And what the majority did, was repeatedly assured, dissent and the public, that's not what we're doing here, right? The violation occurs when there's a taking. So why am I emphasizing that, right? I'm emphasizing that because there's been no taking in this case, right? You know, they want -- they want you to assume that there's going to be a taking in the future. Maybe, maybe not. I think it's also possible that don't get wrapped up

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It seems pretty likely, highly likely to THE COURT: me, can given that they sold 14,000 of these into Colorado, that at least one will fall within this provision sometime reasonably soon. And so what -- and they clearly have to --Teva clearly has to, sort of, decide. They are being put to this choice of what to do here, soon, right? Starting on the 1st. And normally, if a law is putting someone to the choice of complying with a state law or violating it, and they think it is unconstitutional, normally, as long as it seems likely that they are actually going to be subject to the law, that's typically enough for standing. I mean, there hasn't been any -- this is not like some of the other cases I have had here where the state has said, Oh, we're not going to enforce this, until there's a rule making, or We're not going to enforce this for a certain period of time. Like, it's going into effect in a couple of weeks, and it seems to apply to their business, and normally that seems to be enough. Am I wrong? MR. NELSON: Well, that seems to be enough in, again, the First Amendment, due process, equal protection context, right? It's not accidental that we don't find cases in the Takings Clause context where this happens. And again, it's for this principle that I'm saying from Knick which is, the

Takings Clause context where this happens. And again, it's for this principle that I'm saying from <code>Knick</code> which is, the violation occurs when there's a taking. I think you mentioned too, Your Honor, <code>Knick</code>, <code>Horne</code>, <code>Cedar Point</code>, they brought suit after there was arguably a taking that happened, because that's

when you can bring suit, at all, and that simply is not the case here. And, you know — and I think the difference between the First Amendment context, the due process, equal protection context, is people have a right to act in a certain way, right? And arguably the law that prevents them from exercising the rights that they already have. And the Fifth Amendment Takings Clause, people do not have a right to avoid a taking. Under the Fifth Amendment they just have the right to compensation, and I think that's where their arguments about standing and ripeness all fall down, given the difference between this unique context and the context they are trying to import here.

Again, it's not accidental that we don't find these pre-enforcement challenges in Takings Clause cases.

THE COURT: But isn't that partly because this is an unusual type of taking? You know, it's different when the state or local government wants to build a road across your property, sort of know what's happening there. This is sort of ongoing, they never really know quite -- it could be suddenly they get in a -- two weeks from now they suddenly get 200 of these or they get none for a month, but they have to sort of change their analysis of how to do business. Now, it seems, and it's just a different kind of regulation or different kind of taking, isn't it?

MR. NELSON: I don't think so, Your Honor. I think the message from Horne, right, is that you know land-use cases

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and takings of personal property, they are analyzed the same. You know, they are different when you to get the substance, when you get to the Penn Central factors, obviously. It's kind of the same, they are governed by the same standards, and you know -- and I think the message from Knick is, there needs to be a taking in order for a violation to occur, right? And so, no, I don't think this is somehow unique because it -- you know, it requires or might require Teva to give an EpiPen® some time in the future to a pharmacy. Fifth Amendment Takings Clause jurisprudence can address that perfectly well, and I think that's all we are saying. THE COURT: Say in Apfel they brought a pre-effectiveness, pre-enforcement challenge, it's not totally clear to me, exactly, what kind of a challenge that was, based on my recollection, but say they had, what would have been the difference of bringing it two weeks before that law went into effect or the day after? MR. NELSON: So, I think it's also important to recognize in Apfel it wasn't a pure Takings Clause case. was also a due process case. And if you look at the reasoning in that case, the due process element loomed large in their

was also a due process case. And if you look at the reasoning in that case, the due process element loomed large in their decision. So, I mean, arguably could they have made a due process pre-enforcement challenge there? I think, sure, right?

But not Fifth Amendment Takings Clause, right. So that -- I think that's the best way of dealing with that.

THE COURT: Okay. Fair enough. Thanks.

MR. NELSON: And just -- I just want to highlight a few points from their witness' deposition, which again I think highlights that there are too many unknowns in this case for the Court to really adjudicate, at this point, right?

Teva can't say how many of its products were sold in the past to individuals who might be in the program, right?

They were not able to say how many of their EpiPen®s were dispensed to people on Medicare or Medicaid. How many EpiPen®s were dispensed to people who have private insurance with a cap. And they have not been able to say how many they anticipate will be — people will be eligible for the program in the future.

There are multiple generic manufacturers in this market. There are four versions of generics EpiPen®s on the market, including Viatris, who prices their product the same as Teva, has the same AB Rating as Teva. And Teva was able to say how much market share has in Colorado. It was able to say nationally. And nationally is not the majority of the market, right?

So, I don't think, given what we have before us, this claim is ripe, because no taking has happened, and I think it would require the Court to make a bunch of assumptions that are not warranted or allowed under the Fifth Amendment Takings Clause jurisprudence.

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I mean, Teva -- you are right, we don't THE COURT: know for sure what the Colorado market share is, but you don't have any reason to doubt that it's similar to the whatever 30-something percent that they said it was nationally, if I'm remembering right. There's no reason to doubt its significantly different than that. They sold 14,000 of these into Colorado last year. Obviously, some of those could have been shipped out of state, but probably not all. So that part of your argument, I'm not all that persuaded by the idea that they may not send any into Colorado that would be subject to this. The arguments about not knowing how many people are going to participate, how much -- how many pharmacies will bother to go to the trouble, that seems a little bit more problematic, to me. But if -- I mean, what do you think would actually have to happen for them to have standing? You think -- it's not enough, in your view, that the law just goes into effect; is that right? MR. NELSON: Correct. THE COURT: And would it be enough if one -- one pharmacy submitted the demand to them? MR. NELSON: Yes. So, they could either -- the demand comes, the pharmacy could say, Give us an EpiPen®, they give the EpiPen®, ripe. Or they could say, We are not giving you

the EpiPen® and maybe the board will do some enforcement

action, maybe not, but if they do, they can say, Takings Claim,

ripe. That's what the Fifth Amendment Takings Clause law shows.

THE COURT: Okay.

MR. NELSON: So, first all, I think this case isn't properly before this Court, because of the Fifth Amendment, but if the Court rejects that, it's not ripe for adjudication yet, and so it should be dismissed. The preliminary injunction denied, and the case dismissed on that basis.

And finally, and again, I don't think the Court again, because of the Eleventh Amendment, I believe this question properly belongs in state court, but I want to end on the police power question.

There was interesting back-and-forth, you had with counsel about the price controls, right? And I think what they said was it would be constitutional for the state to just impose a price control as long as it was in the proper chain of commerce. I think that's what I heard. Right? And again, what would be the source of that authority? Right? It's the police power, right? It's the power Colorado has to regulate the sale of drugs for the public good, right? And I think what the Lech case, the Lech case, I think, the Tenth Circuit attempted to give the line between takings and police power, and the line that they drew was use of property for the public good, police power. Use of property for public use, eminent domain power, Takings Clause. And I think what our argument

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here is, is this is necessary, life-saving medicine for a lot of people in the state, who, unfortunately, have been priced out, given some pricing practices that -- some pricing practices, which some people call price gouging, right? The state has the power to ensure that people have access to life-saving medication and I think that is exactly what the Affordability Program is attempting, here. So there's lots of discussion about where you draw the Slippery slope? No. What we're talking about here, is something that is necessary for people to live in an emergency. THE COURT: I definitely don't contest that. I definitely find the pricing of some of this, I understand why the State and other people feel the need to get involved, but you could make that argument with the most obvious, sort of, traditional taking, right? We need to build a hospital on your property or We need to build a road through your property, because it's dangerous up here. That doesn't -- that's still a taking, right? MR. NELSON: But it's not -- I would say it's not for the public good, right? And I think that's the distinction that Lech was talking about. I mentioned this is in the reply, in support of the Motion to Dismiss. You know, we have laws in this country

where hospitals can't turn away people from emergency rooms,

based on their lack of ability to pay, right? And it's the

same concept we're talking about here, Your Honor, right?

People shouldn't be denied access to emergency medicine, in an emergency, simply because they can't pay, and so, you know; whereas, I don't think there's any discussion that a law like that, that you can't turn away people from the emergency rooms who need help, is squarely within the police power, and I think merely just we are just drawing a line from that to the Affordability Program here, squarely about safety.

THE COURT: Yeah. I think I agree with that, but there are some ways you can do certain things, and some ways that require paying compensation. The hospital one is definitely an interesting analogy, but here you are making one private party give away their property to someone else. You are not imposing a price cap. You are not subsidizing people directly. You are -- you are saying to Teva, in this case, in order to help us solve this problem, we're going to make you provide your property to someone else, and isn't that just different, at least in terms of this part of the constitution, than any of the other examples you have given? The motivation may be the same, and maybe the effect is the same, or at least similar, but the method of getting there triggers a different constitutional problem for you.

MR. NELSON: And again, I understand what the Court is saying. I would just, again, point to Lech and be given the line there. You know, the cases I also cited in support of

that, you know, it was taking of people's property for safety 1 2 reasons, and I think the same holds here. But again, this really isn't a question for this 3 4 Court, given the Eleventh Amendment bar, given that they have 5 an adequate state remedy, you know, and given that this case is 6 premature, I think. I would ask the Court to deny their Motion for Preliminary Injunction, and grant our Motion to Dismiss, 7 8 and let's take this to the Colorado state courts where this 9 belong. Unless the Court has any further questions from me? 10 THE COURT: I have one question that's probably 11 unfair. This is for both people. In Knick there was a part 12 of -- the plaintiff asked for all sorts of relief, including 13 injunctive relief, and lost in the lower courts, and then won 14 in the Supreme Court with no real distinction about what 15 happened, and we've tried to look at what happened on remand after Knick, just because I'm curious about how important this 16 17 sort of exception for injunctive relief is. 18 Does anyone know what happened in Knick after it went 19 back down? I told you this was an unfair question. 20 MR. NELSON: I wish I knew. THE COURT: Well, if you can find it, let me know. 21 22 Okay. I don't have any other questions. Thank you. 23 MR. NELSON: Thank you, Your Honor. 2.4 THE COURT: Mr. Lefkowitz. 25 MR. LEFKOWITZ: Thank you, Your Honor. I just have

six or seven very brief points I will try to rattle through. I will start with the last question, and neither my colleague nor I know what happened on remand in *Knick*, because the injunction issue really wasn't at all relevant at the Supreme Court. The Supreme Court really was just deciding the question of do you have a right to go to federal court the minute there's a taking.

THE COURT: Right.

MR. LEFKOWITZ: And they were overruling Williamson. Everything else that they talk about, which we have been talking about, is actually not even part of the holding.

I will say we're not going to end up in state court here, because, I guess in theory, you know, we would just — the first time we got a letter from a pharmacy saying, You owe us money, pursuant to this law, we would be right back here renewing our request for injunctive relief, but that, of course, just demonstrates why it is ripe now, and we have standing.

We are entitled to injunctive relief, and I want to start with what you asked me about before. Apfel, itself, was essentially a pre-enforcement challenge. The Cole Act, obviously, had gone into effect, but the Cole Act didn't, in any way, implicate directly how much this company would have to pay. The minute they got the assessment, before they paid, before they did anything, they brought the lawsuit, and they

didn't pay the premiums. They requested a declaration and an injunction. And importantly, the Supreme Court citing *Duke Powers*, said, and I quote, "The declaratory judgment act allows individuals threatened with a taking, to seek a declaration of the constitutionality of the disputed governmental action before potentially in-compensable -- I'm mangling the word -- damages are sustained."

Now, to be clear, in usual takings cases we do have adequate remedies. So usually this does not happen. The key language from the Supreme Court's decision in Knick says as — this is at the flip between 2176 to 2177, As long as an adequate provision for obtaining just compensation exists, there's no basis to enjoin the government action effecting a taking. And to the same point, Justice Thomas concurring, says a couple of pages later 2180, Injunctive relief is not available when an adequate remedy exists. So that's what we're talking about here.

Now, adequacy. I don't understand the argument about why this is not complicated. The statute says, Reimburse the pharmacy in the amount that the pharmacy paid, for the number of epinephrine auto-injectors dispensed. Each pharmacy is paying something different. There's no doubt about that, and even were Teva, and it doesn't plan to, but even were Teva to turn over its physical property, the value of that property to Teva changes all the time, because the average wholesale — the

average wholesale price, this formula that they were talking about, is adopted for different wholesalers in the same way that wholesalers change it for different retailers. It's constantly fluctuating.

The declarant testified, in his deposition, that there are rebates for wholesalers too, just like for pharmacy. So there's no avoiding the difficulty in calculating the value of the EpiPen®s to Teva as time goes on and different wholesalers are involved.

Now, the Attorney General says, We shouldn't import, those are his words, equity principles to the takings context, but it's a whole one context. This is an equity case. We are here seeking equitable relief, and as in Knick traditional equity principles apply, and not one of the other federal cases that the State cites involved an alleged multiplicity of lawsuits. Read the cases that they cite. The argument was never made, because the cases didn't involve statutes that authorize repeated indefinite takings.

The Gordon case, which they rely on, involved the introduction of wolves, but the introduction of the wolves was not a taking. All the plaintiffs there were seeking was an alteration of the policy and the Court said, No. You don't get to do that. If you have been injured, you can try to get compensation. Here, by contrast, the statute, itself, necessarily effectuates a taking.

I just want to finish on the police power point. The scope of their argument is breathtaking. We're not dealing with a regulation governing the way a hospital that has a special license to operate in the state, has to conduct itself. How many hours it has to be open, who it has to take, those are regulatory issues, and to the extent they want to frame it as a taking, it is a regulatory taking. It is not a, per se, physical taking that we have here. Very different situation.

All of the other things that you suggested that you alluded to are absolutely true. On a very cold night in Denver, there are people who are going to freeze, who are living on the streets. If they want to have a policy that says, for the public benefit we want to put them in hotels, the way they did in New York, during COVID, they commandeered some of the hotels on the Upper West Side and they put homeless people in those hotels, but they have to provide compensation, because that is the essence of a taking for public use, and it is completely different, and if you read the Lech case, even though its not a published decision, it couldn't be more clear.

All of the examples they cite of the police power when it is not a taking, are when they are knocking down trees because they are causing harm; they are breaking down the front door of someone's house, because they are chasing after a felon. Sure they — that conduct also is beneficial to the public, but that's not a taking for the public benefit. That

is, the use of the police's emergency police powers.

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I will conclude, simply, Your Honor, unless you have questions, because I think I answered your question about Apfel and the procedure in which Apfel arose, and the way in which they cited Duke Power for exactly the proposition we are asking this Court to enforce, I will close simply by reminding the Court, again, of what Justice Holmes said, which is, there are lots of things that a state, in its infinite wisdom, wants to do, but it can't take shortcuts through the Constitution. takings claim is not the poor stepchild in the Bill of Rights. To be sure, when there's adequate compensation available, then injunctions are not appropriate, but here, with ongoing multiplicity of suits, the way in which Colorado has treated these trespass cases for generations, including, very recently, give us all of the precedent that we need to know that this is that unique case where we are not going to be able to get a clear, efficient and complete remedy.

We certainly can't get a complete remedy because we are going to have to do it every two years, and we are going to have to bring together all of these different pharmacies and all of their pricing information, and it's going to be a never-ending set of economic calculations, and that is what makes equity appropriate, here.

THE COURT: Can I just ask you, I think, one question?
If I'm -- say I'm unsure whether there's an adequate

1 compensatory remedy available, and I just can't figure it out, right now, who do I hold that against? Seems to me I might 2 hold it against you, for purposes of the preliminary 3 injunction, but against the State for purposes of the Motion to 4 5 Dismiss. Am I wrong? MR. LEFKOWITZ: I think if we have -- I think we have 6 7 clearly established that we have a likelihood of success on the 8 merits, in the sense that this is a taking, this violates the 9 Constitution, and clearly the public interest favors the State 10 obeying the Constitution, that's standard in all of these 11 The question is, do we have an adequate remedy? We 12 have, now, provided evidence, not just my argument, but 13 evidence in the record, they examined this witness, they could have tried to do whatever they want and show any evidence, but 14 the record, in the evidence, suggests that we actually have a 15 16 stronger case for injunctive relief than the Eighth Circuit 17 found in PhRMA, relying on Duke Power, relying on Apfel. I 18 think there's ample evidence in the record to suggest that 19 there's no adequate, efficient, complete remedy available. 20 THE COURT: Okay. All right. Thank you. 21 MR. LEFKOWITZ: Thank you, Your Honor, very much, and 22 thank you for accommodating us on the scheduling, and I 23 appreciate the State accommodating us on the scheduling, as 2.4 well. 25 THE COURT: You are welcome. Thank you for your time.

1 Mr. Nelson, did you want to respond just to that last question? Did you have a position on whose burden it is, if it 2 differs? You can just stay there. You don't have to come up 3 4 here. 5 MR. NELSON: It's their burden. 6 THE COURT: Okay. All right. Your position is it's 7 their burden. Their position is they've met their burden, so I 8 probably should have anticipated that would be everybody's 9 position. 10 MR. LEFKOWITZ: We disagree. 11 MR. NELSON: Our position is they have not met their 12 burden. 13 MR. LEFKOWITZ: We all agree, it's your decision. 14 THE COURT: Well, good. Good. Me too. All right. 15 Thank you. I appreciate everybody's efforts in this case. 16 It's been, in my view, well briefed and well argued and that, 17 unfortunately, in this case, doesn't necessarily make it any 18 easier, but will make a better analysis, and so I do appreciate 19 it. 20 As I said, I will be getting an order at least on the preliminary injunction out before the end of the year and 21 22 perhaps also on the Motion to Dismiss. 23 If there's nothing else, we will be in recess. 24 you. 25 THE COURTROOM DEPUTY: All rise. Court is now in

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