KHN's 'What the Health?'

Episode Title: Biden Social-Spending 'Framework' Pulls Back on Key Health Pledges
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Julie Rovner: Hello and welcome back to KHN's "What the Health?" I'm Julie Rovner, chief Washington correspondent for Kaiser Health News. I'm joined by some of the best and smartest health reporters in Washington. We're taping this week on Thursday, Oct. 28, at 10 a.m. As always, news happens fast, particularly today, and things might have changed by the time you hear this. So here we go.

Rovner: Today, we are joined via video conference by Joanne Kenen of Politico and Johns Hopkins School of Public Health.

Joanne Kenen: Good morning, everybody.

Rovner: Sarah Karlin-Smith of the Pink Sheet.

Sarah Karlin-Smith: Hi, Julie.

Rovner: And my KHN colleague, Rachana Pradhan.

Pradhan: Good morning, Julie.

Rovner: Later in this episode, Amy Howe of SCOTUSblog will help us break down what's at stake next week, when the Supreme Court hears oral arguments over that Texas law that has stopped most abortions in the state and its very peculiar enforcement mechanism. We'll also have the winner of KHN's Halloween Haiku contest. But first, this week's news, and it is breaking even as we speak. We will start as usual on Capitol Hill, where President [Joe] Biden is just wrapping up a meeting with House Democrats on a newly unveiled "framework" — and I put "framework in the biggest of air quotes — for the Build Back Better / reconciliation / social-spending program. Apparently, this is what the president has gotten moderate Senate Democrats Joe Manchin and Kyrsten Sinema to agree to. And it does *not* include most of the health proposals we've been talking about for weeks. What apparently *has* made this cut is a temporary expansion of the beefed-up subsidies for the Affordable Care Act and expansion of Medicare to cover hearing aids, but not dental or vision care, and a very vague way to help the people caught in the Affordable Care Act's Medicaid gap sign up for free marketplace plans instead. Anything I missed here that you guys have seen or heard?

Kenen: Well, I think that Julie always points out that between the time we record and the time people listen lots could change, and we have to sort of say that in, like, bold italics. I mean, the big three things: something about Medicare, ACA extension and something to address the Medicaid gap. They are all in there, as we'll talk about, I assume, in a minute. Prescription drugs is a whole other story.

Rovner: That's a whole other story. Yeah. Let's jump to prescription drugs, because one of the major ways Democrats were hoping to pay for the new health benefits is by lowering what taxpayers and patients pay for prescription drugs. But despite the fact that it is super popular with voters, including Republican voters, it's just as unpopular with drugmakers and it's proving harder to accomplish than it seemed only a couple of months ago. It appears that only a single prescription drug provision has made

it into the final package, a repeal of the so-called rebate rule. Who wants to tell us what the rebate rule does?

Karlin-Smith: I can take that. Ironically, it's actually something that the pharma industry *did* like, the rebate rule. So, you know, they maybe got a tiny hit but, for lots of reasons, I think that rule was never going to be implemented anyway. But it basically would have essentially banned these discounts drugmakers give to health plans unless the discounts were going, kind of, directly funneled to patients at the time you buy your prescription drugs. So the criticism of drug companies has been that they do give these huge discounts on their medicines to many health plans. But a lot of patients, including the ones who most suffer from the high costs of drugs, don't feel those discounts because what the plans do is they tend to take that savings and put it back into lower premiums for everybody rather than, you know, ensuring that the person with high-cost drugs feels that.

Rovner: Actually, yeah, actually pays less.

Karlin-Smith: But it's a pay-for now for this bill because of lots of, you know, congressional gimmicks, because if you implemented the rebate rule, it would have scored as costing the government money because, again, the government helps subsidize premiums for health insurance. So, if premiums go up, the government pays more. So therefore, they get a little bit of savings that they can pay for other elements of this bill. But, ironically, not really go into health care stuff.

Rovner: It's one of those weird budget math things. So Rachana, you pointed out that Politico is reporting this morning that there might actually be a slightly broader deal on drug prices that isn't in here for now, right? Right.

Pradhan: I mean, I think the biggest thing that people were looking for on drug prices, of course, was to what extent and if the deal would include any provisions allowing government intervention essentially in negotiating prices. And it seems like, what Politico is reporting is that there was an agreement between the president and Sen. Kyrsten Sinema, but the framework doesn't have any reference to any sort of negotiation. So it's really unclear. I guess it would suggest that there aren't the votes to get this thing through quickly. And so, for now, it may be left out as the pharmaceutical industry tends to be quite successful at beating back any sort of proposal that would allow for negotiating drug prices. So, I think it's really interesting. Of course, we have, there are so many details on health care that still have to be even fleshed out. One of the more significant areas that I'd been looking for was, of course, the expansion of benefits under traditional Medicare. It looks like we see something about expanding hearing coverage, but not dental and vision, which is going to be very much to the disappointment of Sen. Bernie Sanders and other progressive lawmakers.

Rovner: But very happy for the American Dental Association, which has been lobbying hard not to include dental in Medicare because, as we're seeing with the drug industry, if you're covered, then they're going to want to limit what you can charge.

Kenen: Big teeth!

Rovner: Yeah, big teeth.

Pradhan: Big teeth. There's a new one. We have to get that in a headline somewhere in a story. So but I think even on hearing, I mean, there are lots of questions that are still unanswered. We don't know

what year the new benefits are going to begin. We do have a cost estimate from the Biden administration. They say that it will cost about, looks like $35 billion. But I also wonder whether, did it get cheaper actually, because of a separate move recently for the Biden administration to have more competition on over-the-counter hearing aids. So it's just all … there's a lot still to be answered, I guess is what I'm trying to say.

Rovner: Yeah, I mean, and I should say that we all woke up to this framework in our inbox, which is a, you know, a three-page sort of fact sheet with zero details. And I think that it looks like, I mean, Joanne, you were saying that it seems that Biden really needed to have something that they looked like they agreed to because he's leaving for Europe, particularly for this climate change conference, right?

Kenen: I mean, I would point out that climate is also a health care issue, although not one that we have actually talked about as much on this program. But this is a framework, as Julie just said, it's not final. It's going to change. There's details that are going to be haggled over, the details that will come out, and there is probably more horse-trading to be done. The part I think that is probably fairly solid is the climate language, and it's a lot of money. It's almost a half a trillion. It's $550 billion. It's a big investment in climate. Biden needs to go to Glasgow with that. So I don't think that's going to get messed around with too much. I think that's probably pretty fixed because you really don't want the president to go … and he doesn't want to go and make a big announcement and come home and find out that Joe Manchin used his veto pen. I mean, I think that the Medicaid approach, you know, when it starts … I don't know the details, but I think that's how they're going to fix the Medicaid gap. It's not something that everybody's going to love, but it's doable. So I would be surprised if that changes too much. I mean, it's putting the Medicaid-eligible people who are frozen out because of the 2012 Supreme Court ruling, making Medicaid optional for states. There's still 12 conservative states that are resisting it, or two of them have Democratic governors, but very conservative legislatures, in North Carolina and Kansas. So there's like 4 million people who just …

Rovner: Right, who are not eligible for anything.

Kenen: Yeah, it's like 2.2 [million] or something who are not eligible for anything at all, and another 1½ million who are very limited and can't get what's really best for them. So, you know, there are about 4 million people who will benefit from this. Basically, it makes these people eligible for the exchange with really, really heavy subsidies. They will not be paying through the nose for this. They'll be propped up. But, I mean, Medicaid was designed … it is a different benefit package. It is a different system. But these people have been without anything for a number of years and they are poor.

Rovner: By definition, I mean, if you're over 100% of poverty, you're now eligible for a pretty generous plan under the Affordable Care Act. The problem was these people under 100% of poverty were originally all supposed to be covered by Medicaid. The way the Affordable Care Act passed, they were all going to be covered by Medicaid, and then the Supreme Court said: states, you don't have to do it. And so we have ended up with this.

Kenen: And some states have not.

Rovner: Right, we've ended up with this group of people who aren't eligible for anything.

Kenen: Yeah, they're too poor to get help, which is crazy. So, this is not the solution everybody looked for, but it is the solution that everybody's going to live with.

Rovner: So, it looks, I mean, the other thing that looks like it took a big whack is there is a home care provision that started out at, I think, $400 billion that now seems to be down to, like, $100 billion. And you know, the reason that all of these things that were in there were scaled back so much is because they're not actually going to get a lot of money from the drug industry. The drug industry wins again. Rachana, you're one of several bylines on a big piece that KHN just published about drug industry contributions to members of Congress. What did you guys find?

Pradhan: Well, so interestingly, so what we looked at was data that was submitted to the Federal Election Commission that covers basically lawmakers, individual campaign accounts and also what we call leadership PACs. So it's what the pharmaceutical industry is directly sending to members of Congress to kind of help their reelection chances. Interestingly, in the first half of this year, overall, the total that the sector gave was actually quite small relative to other prior years. We think some of that might have to do with the fact that the industry stopped giving to many Republicans who voted against certifying the results of the 2020 election. But that being said, you know, their giving really reflects that Democrats are in power. Democrats and Republicans were almost tied as far as receiving the amount of money that lawmakers in each party received and some of the top recipients for who got the most money, three of them are Democrats. They all sit on pretty powerful committees that control legislation that would very much affect the pharmaceutical sector's bottom line. And they have been sort of hesitant to back any sort of plan that would involve Medicare having the authority to negotiate prices. So, yeah, it's all really interesting. And I would imagine … we didn't have third-quarter data in our story, so that would cover, you know, July until October.

Rovner: When they were actually writing the bills.

Pradhan: When they were really writing the bills and it really kind of hit a fever pitch like these negotiations. So, we'll be really interested to see how things sort of shifted, if at all, during that time. You know, in the coming weeks.

Rovner: I would just point out, and I think I point this out every time we talk about this, that during the Affordable Care Act negotiations, the Obama administration basically struck a deal with the drug industry. And there was a lot of criticism of that deal, you know, because the drug industry was going to get more money, more people were going to be covered. Therefore, more people will be able to afford their drugs. And there were accusations of the Democrats being in bed with the drug industry. But I would point out, if you see how hard this is, that the drug industry doesn't lose very often. And you either strike a deal with them or you end up where we are right now, which is you don't get what you think you were starting with when you need every single vote. So I will say again that this is so not over. I don't know whether this is the beginning of the end or the end of the beginning. I think I might call this the end of the beginning. But there's a long way to go on this, and I'm sure we will be talking about it every week for the next several weeks.

Kenen: Julie, can I just say one thing about the drug …?

Rovner: Yes, go ahead.

Kenen: I mean, Democrats have been campaigning on Medicare negotiation for years and years and years, and this sort of kicks that chair out from under them. Most Democrats do favor it. There's a 50-50 Senate. And what is it? A three-vote majority in the House?

Rovner: Yes, there's a three-vote cushion in the House.

Kenen: Teeny-weeny-weeny … so if you had more …

Rovner: And there's, ironically, three Democrats in the House who have been holding out on a lot of the drug stuff.

Kenen: Right. You know, if Pelosi just had a couple of more Democrats, I think this would have gone through. It's really sort of a bit of a core thing that Democrats have been screaming about since the late 1990s, early 2000s in the Medicare drug benefit debate. It was a big deal in 2003, and they lost it. George W. Bush was president, was more market-oriented … which Democrats have come to sort of, you know, they don't complain about it so much anymore. It has covered people, it's helped people. But they've wanted to add this.

Rovner: It was a Republican Congress too.

Kenen: They wanted to add this and they've wanted to add this for years. And I mean, I just think if there were five or 10 Democrats, it would have gone through. Most Democrats do, but I don't think they can … they can't talk about it the same way on the campaign, and they can't vilify the Republicans for refusing to do it when they just refuse to do it. So I think the status quo also has some political implications, not that they won't try to do it again. I think they will if they ever have a big enough majority, but you're not going to hear them talking about it as much.

Rovner: Yeah, well, we'll see. I'm still not convinced that this is the final package and that maybe …

Kenen: It isn't.

Rovner: And they may be able to get something in it.

Kenen: They're not going to announce something this morning and vote on it happily tonight and go off into the sunset, though … they're Democrats!

Karlin-Smith: I do think it is Rachana that brought up the Politico story about this potential deal that Biden and Sinema worked on and which was sort of seemed like a version of a Scott Peters bill as an alternative to tackle drug pricing. Peters is one of the House Democrats who hasn't supported the plan Nancy Pelosi has shepherded, but I kind of think it's interesting that they didn't just sort of accept that, because, I mean, a lot of Democrats have been calling that a fig leaf. It doesn't really do a lot. It would pretend to, you know, allow government negotiations but really, for drugs that we've already figured out ways to get competition and prices lower. So I think, to some degree, maybe that says something about, like, they're not just willing to check the box and tell the American people they tackled drug pricing. If they're going to do it, maybe they really do want a chance to kind of go big and not just say we did it and move on.

Pradhan: Right. Because the big difference, of course, as you reference, like, the Peters bill really does not address prescriptions and really the most aggressive proposals that have been out there recently to actually have a Medicare drug negotiation would be in Part B, which is prescription drugs and not drugs that you are, excuse me, expensive, of course, but that you get in a doctor's office or in a hospital.

Rovner: All right. Well, we will definitely come back to this because there is definitely more to this story. But it's another big week in the abortion wars. After we finished taping last week, the Supreme Court once again refused to block the Texas law that has stopped almost all abortions in the nation's second-largest state. But the court did agree to hear the case brought by the Biden Justice Department on a very fast track next Monday, in fact. That's a month earlier than it will hear the Mississippi case that we all assumed the court's anti-abortion majority would use to water down or overturn *Roe v. Wade*. Later in this episode I'll break down the Texas case with Amy Howe of SCOTUSblog. Spoiler alert: The court does not have to directly address *Roe* in the Texas case. It's more about the unique Texas enforcement mechanism that lets individuals sue people who, quote, aid or abet those getting an abortion. But I wanted us to talk a little bit about the politics of this case. Gallup has an interesting piece out this week pointing out that while the public opinion overall favors abortion rights in most cases, that is not the case in Texas, nor in its surrounding Southern neighbors, which kind of makes sense. These states wouldn't be passing these laws if voters didn't send lawmakers to the statehouses who basically agree with them. We keep assuming that there would be this big backlash if the court overturns *Roe*, but maybe not in these states that are pushing these very restrictive laws.

Karlin-Smith: The Gallup polls certainly show that there's a sort of a majority of Texas that favors these types of heavy-handed restrictions on abortions, but it's not the overwhelming majority, so it's like a little over 52%. So if you think about a state the size of Texas, that's going to be millions of people that don't agree with it. So I think when you think about how divided the country is, even states, right, like Texas, where you think about being red and being, you know, having these sort of more conservative values, there are still huge portions of the population that would want to go the other way.

Kenen: I never anticipated abortion rights turning Texas blue. I mean, you know, if Texas ever goes blue and they, you know, the Democrats keep saying, “Next election we will!” and they don't. It's going to be for other demographic reasons and changes in the population of Texas, you know, which is a deeply conservative state. Not only do they elect Republicans, they elect really conservative Republicans. There's some diversity of ideologies in their state legislature but look at who their senators are. Look at who their governor is. They're electing very conservative people. That Texas is an anti-abortion rights state, it's really not — more than average? — it’s not a surprise.

Pradhan: It's important to note, you know, even with demographic shifts, it's not just white, conservative voters who are anti-abortion. There are certain racial and ethnic minorities like Hispanic people and even certain Black Americans who are very conservative when it comes to social issues. And so I agree with you, Joanne, that things that would change the kind of the shift in voting patterns would not necessarily be driven by this particular issue.

Rovner: I guess my question was, you know, if we think about how if suddenly *Roe v. Wade* doesn't exist anymore, whether they'll be sort of this strong Democratic backlash. Maybe, and that's what you were saying, Joanne, maybe not in some of these Southern states where there may not be enough people, you know, it may mobilize people in bluer states to come out and vote. But I'm wondering whether there's enough people in these red states that it would mobilize.

Kenen: Texas is still a conservative state. And, you know, whether some of the Latino vote actually shifted toward Trump last time. I think that, you know, it is a state that has pockets of change, including some of the tech companies moving in. There are changes in Texas, there are demographic and economic changes in Texas. I still would be surprised to see, well, I mean, we're all waiting to see what

Beto O'Rourke is going to do. But in terms of the governor's race … I don't think even if we see Beto O'Rourke win the Texas governorship, it's going to be because of abortion.

Rovner: This will also definitely shake things up as we go forward. All right. Let us turn to covid. The big news this week is the impending approval of an emergency use authorization for kids age 5 to 11 for the Pfizer vaccine. Sarah, this really is a game changer, right?

Karlin-Smith: Yeah, I mean it would open up another huge swath of the American population to have access to covid vaccines. And, of course, people are really hoping that would make a big difference in terms of schooling and life, kind of returning to some semblance of normalcy for this population with children that age still have a lot of worries about just them even doing kind of things that people are vaccinated now feel much more comfortable doing. An FDA advisory committee earlier this week voted 17-to-0 with one abstention to recommend FDA approve that authorization, and they're expected to do that later this week. Next week, what will happen is the CDC's Advisory Committee on Immunization Practices will also sort of have to sign off on it as well. The thing I'm going to be watching for is that while the FDA advisers did sort of unanimously ultimately decide this should go through, there were a number of people who raised concerns about whether every child in this population really needs to be vaccinated or has a favorable risk-benefit profile here, particularly because there are some concerns in terms of side effects of the vaccine. So it will be interesting to see how CDC deals with that because they have more sort of discretion to sort of say, OK, we feel like this population of children should definitely get it. We feel like maybe this population of children might want to get it, but you might want to kind of talk with your doctor kind of about your individual health profile and whether it makes sense. It'll be interesting to see if CDC does anything like that there or if they just kind of do a straight, you know, "all kids 5 to 11 should get it."

Rovner: Which sort of blends into my next question, which is: Late last week we got final approval from FDA and CDC for boosters, but the whole booster thing is really confusing, particularly with the mix-and-match policy and, again, who's eligible for a booster, who *should* get a booster? Is there any sort of quick way to explain this? I know a lot of people who are really confused by the booster thing.

Karlin-Smith: I think Bloomberg actually did a really nice flow chart that I was saying, like, the White House or somebody should borrow for their campaigns because it kind of, it's like, yes, no, you know, you kind of go down it and figure out whether you qualify or not and for which product.

Rovner: One of those little algorithms things.

Karlin-Smith: Right. The simplest place to start is with people who got the Johnson & Johnson vaccine, which is basically everybody 18 and older who got that, which you had to be 18 to get it, initially, is now eligible for a second shot. They basically opened that up to everybody because the sense has kind of been the J&J vaccine probably should have been a two-dose vaccine all along. It has slightly less efficacy compared to the mRNA two-dose versions. But then when you get back to the other two vaccines, Pfizer and Moderna's mRNA vaccines, the population who qualifies for a booster right now is a bit more complicated. Essentially, if you are older than 65, get a booster, and then if you're between 18 and 64, there's two other main ways you might qualify. One is essentially if you have an underlying medical condition that might put you at higher risk of, you know, a breakthrough infection or severe outcomes from a breakthrough infection, which includes people with various types of cancer and pregnant women. They recently actually added mental health illnesses to that list. So it's a pretty broad list of health conditions that might qualify you. And then the third category of folks who qualify is people that

either live or work in some kind of institutional setting that puts them at higher risk of covid. So that includes everything from people in long-term care facilities to prisons to people that work in hospitals or perhaps teachers. You know, anybody who feels like they are kind of out there exposed to the public and, you know, have more risk. So I think CDC estimated that's about 60% of all adults really qualify for those mRNA boosters right now. So that's a decent amount. And, of course, this is all self-attesting.

Rovner: So pretty much anybody who wants to get a booster can, right?

Karlin-Smith: Right. If you really want a booster shot, it's probably not very hard to get it. It is sort of the bottom line. I mean that the reason for the hesitancy, I think, to clearly recommend it for everybody in the younger-age range is again going back to the potential heart risks from these mRNA shots and the question of, we know there is some benefit to the booster, particularly for older populations, but there's still a lot of questions as to how much extra added benefit you get and whether, again, younger people may be really sufficiently protected with the two shots. So why risk a negative heart event if you're perfectly well protected with the current vaccines?

Pradhan: And on top of that, it wasn't unanimous, but a lot of scientists and infectious disease experts said, you know this, if you do recommend boosters for all adults, it really sends the wrong message about how safe and effective the vaccines are to begin with. And we still have a very dire need to vaccinate a lot of people, even in the U.S., with first doses, let alone globally. So, but I agree. I feel like at this point with the booster recommendations, it's pretty much, like, if you want one and you look like you might fit the age category, no one's going to ask you for medical paperwork to verify your underlying health condition. You will probably be able to get one successfully.

Rovner: Yeah. Well, while we have Sarah with us, there have been some other interesting happenings on the prescription drug beat. First, the FDA last week approved, I'm not sure I can even say this, Cyltezo. I hope I'm saying that right. It's the first so-called biosimilar for Humira, a widely used and super expensive biological drug used to treat rheumatoid arthritis, ulcerative colitis and other inflammatory diseases. There were no copies of biologic drugs like these until the Affordable Care Act authorized them — something else, I think, the vast majority of people have no idea was in the law. I know this is not the first biosimilar, but it's the first one of a really widely used drug, right?

Karlin-Smith: So this product actually was first approved by FDA in 2017 as just the sort of standard biosimilar. What happened last week was FDA said it can be interchangeable, which is a higher standard and essentially means that your pharmacist can kind of give you the hopefully cheaper version of the product without getting your permission or your doctor's prescription.

Rovner: So essentially, it's a generic biosimilar?

Karlin-Smith: Right. It's auto-substitutable, and that's what's made the generic industry successful and work, is those auto-substitution laws. The catch here, of course, is that AbbVie, who makes Humira, has long built up its sort of patent armamentarium around this drug, which, you know, makes billions of dollars every year, and this product can't actually launch and hasn't been able to launch until at least 2023. There's still some litigation and other issues to sort out, which means it could be even longer. Well, I think there's some celebration about the fact that this sort of policy milestone actually happened; the way they went about doing this, it sort of sets the stage where I think this product should help other companies figure out how to get interchangeable biosimilars. There's a lot of questions and concerns about just how long AbbVie was able to keep a monopoly on this product — well over 20 years by the

time we'll get competition. There's also a little more concern than with the small-molecule generic drug industry about how much these copycat biologics will be able to lower the price, particularly if we don't get a few competitors in the field yet.

Rovner: Yeah, that was my next question. We've seen with the small-molecule generics that when you get the first one, it doesn't really lower the price all that much. It's not until you get multiple competitors that the price starts to come down. One would assume that may be the same with these more expensive biologics.

Karlin-Smith: Right. That's generally the thought process here. The other problem with biologics is, while Humira is a drug that you can get sort of at your pharmacy and creates different issues around that but, sometimes what these brand drugmakers have been able to do with these biologic products is kind of strike deals with insurance companies to block competitors from getting on formularies. So there's a lot of gaming in the system we have to look at before we do a celebratory dance that, you know, we figured out how to lower costs in this area. So yeah, as always, with the drug industry and drug pricing, as we talked about before, it's complicated and a hard one to kind of solve.

Rovner: These people who are smart enough to invent wonderful new drugs are also smart enough to figure out how they can continue to make money from them. Something else you pointed out …

Kenen: It's not the same people, though.

Rovner: It's not the same people! But they have a lot of smart people. I don't know. In some cases, it could be. Something else you pointed out last week, Sarah, the FDA actually revoked the approval of a drug that had been approved under the agency's so-called accelerated pathway. This is how it's supposed to work, right? That a drug that gets what amounts to a conditional approval, if it's not shown to work, then the approval gets revoked.

Karlin-Smith: Right. So FDA has this pathway and it started during the AIDS era. But you can essentially show that your drug works on a marker, like your tumor's shrinking, but we don't yet know if it increases your survival. You get a faster approval on the idea that you know people with cancer don't have time to wait until we get those final results. But the condition of that is always supposed to be that you should pretty quickly figure out whether it really does provide that ultimate benefit, and if it doesn't, you should leave from the market. Unfortunately, what's happened over the years is that many drugs take years, sometimes decades, to actually complete those trials so that we really know whether patients are getting the true benefit they want from these products. They often, going back to drug pricing, get charged thousands upon thousands of dollars without having that confirmation, and FDA has tended to not take much action. My colleague Sue Sutter over the past few months has actually chronicled some pretty big attempts by FDA to try to change this trajectory for at least for a number of cancer drugs. And the one that just happened is pretty impressive. It came off the market. It's going to come off less than a year after being on. And, I mean, she did a table with other products. And so this one is pulled in about 239 days. The closest one after that was closer to 653 days, and then it just goes up and up for years. So if FDA kind of follows through with this and really holds companies' feet to the fire, I think that's a good thing for public health, for, you know, financial issues and for really finding out the answers we need to know. The question will be: Does this trend continue? Because so far this has been the exception, not the rule, in how FDA has regulated these kinds of approvals.

Rovner: And I would point out that despite our little spurt of news last week about naming an FDA commissioner, it is Oct. 28 and the Biden administration has still not named an FDA commissioner. So that story will continue also. Well, that is as much time as we have for the news this week. Now we will play my interview with Amy Howe about the Texas abortion law at the Supreme Court. Then we will come back and do our extra credits. We are pleased to welcome back to the podcast Amy Howe of SCOTUSblog and "Howe on the Court." Thanks for joining us on short notice this week, Amy.

Howe: Thanks so much for having me. It's always great to talk to you.

Rovner: So, we've been talking about abortion in this term at the Supreme Court for months since the court agreed to hear a case about Mississippi's 15-week ban in early December. A case we expect the anti-abortion majority will use to roll back or even overturn *Roe v. Wade*, but now they're hearing this Texas case first. Everything about this Texas case is irregular when it comes to the Supreme Court, right? Starting with how fast these oral arguments are happening.

Howe: Yes, 10 days from the point at which the justices announced that they would hear oral argument until the oral argument, which is one of the quickest in recent memory. You'd have to go back to *Bush v. Gore*, back in 2000, which for us seems like it was just the other day. But for some of our other listeners, may seem like that was a long time ago, to find one that happened faster than that.

Rovner: How fast was that one?

Howe: That one, I think the second one, *Bush v. Gore*, as I remember, I think they announced that they would hear oral arguments on Saturday, heard oral arguments on Monday and issued the decision on Tuesday night, as I recall. I was involved in that case as a member of Al Gore's legal team. A bit player, to be sure. I was 12, obviously, at the time, but it was kind of all a blur. So I may have the exact dates wrong. But it was fast.

Rovner: I was at NPR and I remember it was like, "Oh my God, it's December and we don't know who the president's going to be" — which in 2000 seemed very odd somehow. And 2021 doesn't seem as … everything, everything else is even odder. But let's go back to the beginning of this Texas case. What does it actually do?

Howe: The Texas case before the Supreme Court. Well, that is an interesting question, actually, in terms of precisely what is before the Supreme Court: *United States vs. Texas*, the Biden administration's challenge to the Supreme Court. The Biden administration came to the Supreme Court last week, asking the justices to reinstate a decision by a federal trial judge in Texas that said that SB 8, the Texas law, was unconstitutional and putting the law on hold. But that is not what the justices agreed to decide. The justices told the Biden administration to address a separate question, which is whether or not the United States can bring a lawsuit in federal court and obtain relief against Texas and state officials to prohibit the law from being enforced.

Rovner: For the people who have not been following this as closely as I hope many of our listeners have: How does the Texas law work again?

Howe: So the Texas law bars almost all abortions after the sixth week of pregnancy, which is a point in which many women do not yet know that they're pregnant. Sometimes these are referred to as "heartbeat bills," and there have been several of these heartbeat bills around the country. Many, if not

all, of them had been struck down or blocked by courts. Because *Roe v. Wade* and *Planned Parenthood v. Casey*, the Supreme Court decisions establishing a constitutional right to an abortion, say that there's a right to an abortion up until the point at which the fetus becomes viable, which is somewhere around 22 to 24 weeks. So, a law that bans all abortions starting around six weeks under the Supreme Court's current precedents is unconstitutional. So Texas added this unusual enforcement scheme. It said that the state is not going to enforce the law. Instead, it deputizes private individuals to file lawsuits with up to $10,000 in damages against anyone who provides or "aids and abets" abortions. And so it's this unusual enforcement scheme that is at the heart of the second case that's going to be before the Supreme Court on Nov. 1. It was brought by a group of abortion providers in Texas. The case is called *Whole Woman's Health v. Jackson*, and many of your listeners are probably familiar with this lawsuit because they came to the Supreme Court trying to block the law from going into effect back at the beginning of September. And at that point, the Supreme Court, a divided Supreme Court by a vote of 5-to-4, allowed the law to go into effect. Chief Justice John Roberts is one of the dissenting justices, and he wrote a dissenting opinion that really, in many ways was kind of the jumping-off point for the case that's now before the Supreme Court by Whole Woman's Health, which is whether or not a state can insulate a law from federal court review. And so the Supreme Court didn't make any changes to the question that Whole Woman's Health had asked the Supreme Court to review. That case went back to the lower courts. The U.S. Court of Appeals for the 5th Circuit is supposed to hear oral argument on whether or not that case can go forward in early December. But the abortion providers asked the Supreme Court to leapfrog — that's a very technical term — the proceedings in the 5th Circuit and go ahead and hear oral arguments right away and the Supreme Court agreed to do so. And there's a lot of debate among the Twitterati law professors and lawyers about whether or not, in a subtle way, the constitutionality of SB 8 is before the Supreme Court because the question that the abortion providers asked the justices to hear is whether or not a state can insulate from federal court review a law that prohibits the exercise of a constitutional right. And so there is, in some ways, a challenge to SB 8 baked in there.

Rovner: Because the court will have to decide whether or not it's a constitutional right in deciding whether or not this kind of novel enforcement mechanism can be used.

Howe: That is the question. And so I'm actually going to be really interested that the Supreme Court's going to hear oral arguments 10 days after it announced that it would do so. Both sides are filing their briefs at the same time, which because everything is so fast-tracked it's a little bit of an unusual move by the Supreme Court. Normally, one side files its brief 45 days after the justices announce that they're going to weigh in and then the other side files its brief 35 days later. So I'm really curious to see what questions Texas and the abortion providers and the Biden administration think the Supreme Court is going to be addressing. And then we'll find out, I guess, at oral argument, exactly what the justices think they're going to be addressing.

Rovner: In theory, though, the Mississippi case remains the case where the court has clearly put *Roe v. Wade* on, you know, on trial, if you will, that that they are, that in that case, in the 15-week ban, they're going to look at whether or not states can actually institute abortion bans earlier than viability, which, as you pointed out at the beginning, is the current Supreme Court precedent that says they can't, and they're going to look at Mississippi and decide whether maybe they can roll that back. That's not necessarily what they're trying to do in the Texas case, right?

Howe: That's exactly right. And I think an important point is that when Texas filed its briefs last week telling the Supreme Court why it should stay out of these disputes at this point, one of the things it said was: If you decide to go ahead and take up these cases, leapfrog the 5th Circuit, you should treat our

filings as what's known as a conditional cross-petition and decide whether or not to overrule *Roe* and *Casey*. And the Supreme Court didn't give any indication that it was going to do that.

Rovner: But it could.

Howe: All bets are off at this stage. Everything about this is so unusual.

Rovner: So here's the biggest question: How soon do we expect to hear a decision in this case? Before Mississippi or with Mississippi next June?

Howe: It's hard to tell. You know, I have made so many predictions that have proven to be wrong. When I was getting ready for the court's order on Friday, last week I had various pre-rights and the one scenario I had not anticipated was, of course, the one that they ultimately came up with. But given how quickly they are acting in this case, I would expect them to act relatively quickly in issuing an opinion. I would bet. And again, you know, I'm often wrong, but I would plan on them issuing opinions before the Mississippi case and before things are supposed to happen in the 5th Circuit in early December as well.

Rovner: We could all be working on Thanksgiving.

Howe: Last Thanksgiving, they issued an opinion shortly before midnight on the Wednesday before Thanksgiving. It's hard to top that one, but there's always room for improvement.

Rovner: All right. Well, Amy Howe, thank you very much and I'm sure we'll be coming back to you to explain this when we get a decision.

Howe: Whenever that is. Thank you so much for having me.

Rovner: OK. We're back, and it's time for our extra credit segment where we each recommend a story we read this week we think you should read, too. Don't worry if you miss it, we will post the list on the podcast page at khn.org and in our show notes on your phone or other mobile device. Joanne, why don't you go first this week?

Kenen: Mine was something in Nature by Emily Waltz: “COVID Vaccine Makers Brace for a Variant Worse Than Delta.” I had been wondering, you know, with all those variants that have emerged and the fear of them, you know, why are we getting the same boosters? You know, why didn't they reformulate them? And the answer, according to this article, is that, you know, the shots are good. They're still effective against the vaccines, but everybody remains worried about the next one or the one after that. And it's sort of like the vaccine companies are sort of like doing dress rehearsals. They're not reformulating it. Our boosters are going to be the same as our last shots, but they're getting ready so that they can be very agile and fast if, in fact, they do need to reformulate them for whatever when we run out of the Greek alphabet and go on to whatever is, you know, pig Latin or whatever, I don't know. I mean, there's going to be variants. This virus has shown us it is going to keep mutating. So that was sort of a good, explainable, understandable piece. Answered my questions.

Rovner: Yes, because as Rachana pointed out, we're busy giving ourselves boosters while the rest of the world still lacks first shots.

Kenen: But the United States has actually just said they're going to send some, what is it, 33 million doses of Moderna? That's enough for about 16 million people that we would have gotten to the U.S. And there was also good news this week on the Merck drug being affordable to other countries, but we can come back to that another time. The covid pill, there's progress there.

Rovner: All right, Rachana, since I name-checked you, why don't you go next?

Pradhan: So my extra credit is a story that ran in KHN by Susan Jaffe. It's related to a handful of states, or three states, I guess, are taking these unprecedented measures to require nursing homes to spend a certain percentage of their funding on residents' actual care as opposed to other sorts of expenses. So the three states that are doing so are Massachusetts, New Jersey and New York. So they have been told, I guess, how to spend money coming from private insurance, but also, of course, government programs, which they are heavily reliant upon for their day-to-day operations. I thought this was really interesting. It reminded me of, of course, when the Affordable Care Act was passed. It included first-ever requirement on insurance companies to spend at least 80% of premium dollars on medical expenses, and it limited how much could go to administrative costs and limiting their profit, essentially. And so I wonder if, over time, if you see more activity in the nursing home space sort of in a similar vein across the country, would it also lead to a federal sort of groundswell of support for similar federal legislation? And I guess it's really something to watch. So I thought it was really interesting after the pandemic that these states decided to take those measures.

Rovner: Sarah.

Karlin-Smith: I looked at a piece by Jenny Gold of Kaiser Health News, called "Down to My Last Diaper: The Anxiety of Parenting in Poverty." It talks about how 1 in 3 American families can't afford enough diapers to keep their infants and toddlers clean and dry. And I think it brings up a point many people don't appreciate, which is you cannot use a lot of forms of federal or state government assistance to cover diapers such as, you know, your food stamp money won't let you buy diapers and it's just incredibly expensive. And these families are making choices such as whether the mom eats versus can diaper her baby. The sociologist at California State University-Fresno she interviews for this piece, Jennifer Randles, has this incredibly powerful story at the end about a dad who was incarcerated because he wrote a bad check. And, you know, he basically said he had a certain amount of money and they needed diapers and milk for the baby. And, he said, I didn't make a good choice, but I made the right one. You know, essentially he ended up in prison for, you know, trying to keep his baby, you know, both clean and fed. And you know, I think this sociologist is trying to get to some of the underlying issues of this struggle for parents and parents in poverty, in the ways that various, you know, government programs and services kind of have failed them.

Rovner: Yeah, I feel like this is a classic case of when we talk about social determinants of health. This is a big social determinant of health. It was a really thought-provoking story. I learned a lot. My story is from the Rewire News Group, which covers reproductive health issues, and it's called "When a Miscarriage Becomes a Jail Sentence" by Caroline Reilly. It's about a growing trend, alongside states making abortion harder to get, which is states arresting, trying and incarcerating increasing numbers of women who lose their pregnancies. Mostly involving pregnant women drug use, but sometimes not. Quote "the criminalization of adverse pregnancy outcomes," as the story refers to them," has led to more than 1200 cases since 2005, in which a woman's pregnancy outcome was a determinative factor in her loss of liberty. That's a threefold increase over the number in the 30 years prior to that." I covered a case some years ago about a woman in Indiana who tried to commit suicide and failed, but who lost her

fetus that she was carrying and ended up in jail. Some of these stories like that one have gotten a lot of media attention, and some of the women were eventually released, including that one. But many have not, and women are literally being held legally responsible for the outcomes of their pregnancies. So it's a trend that definitely bears watching. OK, finally, this week the winner of KHN's annual Halloween Haiku Contest. For those of you who aren't regular visitors to KHN's homepage, khn.org — and you should be, you can also get to the podcast directly from there — we feature a reader-submitted health-related haiku every weekday, and a couple of times a year we run holiday-themed contests. Our Halloween winner this year is from Carrie Moores, who sent along this: "The motel sign blinks / 'Vacancy for the Unvaxxed.' / Norman Bates walks in." So that is our show for this week. As always, if you enjoy the podcast, you can subscribe wherever you get your podcasts. We'd appreciate it if you left us a review — that helps other people find us, too. Special thanks, as always, to our ace producer, Francis Ying. Also, as always, you can email us your comments or questions: We're at WhatTheHealth, all one word, @kff.org. Or you can tweet me; I'm @jrovner. Sarah?

Karlin-Smith: I'm @SarahKarlin

Rovner: Joanne.

Kenen: @JoanneKenen

Rovner: Rachana.

Pradhan: @rachanadixit

Rovner: We will be back in your feed next week. In the meantime, be healthy.