KHN's 'What the Health?'

Episode Title: Manchin Makes a Deal

Episode Number: 258 Published: July 28, 2022

Julie Rovner: Hello, and welcome back to KHN's "What the Health?" I'm Julie Rovner, chief Washington correspondent at Kaiser Health News. And I'm joined by some of the best and smartest health reporters in Washington. We're taping this week on Thursday, July 28, at 10 a.m. As always, news happens fast, and things might change by the time you hear this. So here we go. Today, we are joined via video conference by Joanne Kenen of the Johns Hopkins [Bloomberg] School of Public Health and Politico.

Joanne Kenen: Hey, everybody.

Rovner: Sarah Karlin-Smith, of the Pink Sheet.

Sarah Karlin-Smith: Morning, Julie.

Rovner: And Alice Miranda Ollstein, also of Politico.

Alice Miranda Ollstein: Good morning.

Rovner: Later in this episode, we'll have my interview with my KHN colleague Dr. Céline Gounder about what we need to know about monkeypox and how worried we should be about it. But first this week's health news. So as usual, there is news breaking just as we go to tape. This week, it seems that the onagain, off-again, on-again-in-tiny-form, and now on-again-in-slightly-bigger-form that is budget reconciliation is, well, on again. Only Build Back Better is now called the Inflation Reduction Act, announced in a joint statement by Senate Majority Leader Chuck Schumer and West Virginia Democrat [Sen.] Joe Manchin, who announced earlier this week that he'd tested positive for covid. The bill has added back to its health and prescription drug provisions some tax and climate change provisions, too. What's new, if anything, on the health front of this bill, which could go to the Senate floor next week if all goes as planned?

Ollstein: So whether it goes to the Senate floor could depend on how many senators get covid. We had yet another one this morning. That could complicate things.

Rovner: Assistant Majority Leader [Dick] Durbin is now working at home.

Ollstein: Right. And, crucially, he is the whip. So it's his job to whip the votes for important bills like this one. So not the person you want to be out sick at this time. So really the only new thing on the health front is that the two years of Affordable Care Act subsidies [are] getting extended to three years. And that is important because there are a bunch of Senate Democrats who will be up for reelection in 2024 and did not want that hanging over their heads. So this all put that past that date at least. Originally. Democrats wanted to make those permanent so we wouldn't be doing this rigamarole every year. But that is really the only change on the health front until we get a ruling from the parliamentarian, which could happen later today, and that could change some of the drug pricing provisions, which are really the only other health piece left. I think it's interesting that because of this deal unveiled yesterday between Manchin and Schumer, so much climate and tax stuff was added back into the bill but not all of the other health stuff that Democrats had been fighting for for a long time, like home care provisions and Medicaid in states that didn't expand. So, all of that is still out, as far as we know.

Rovner: And, Alice, you had a story [last] week about the insulin provisions that are now floating on their own instead of being in this bill.

Ollstein: That's right. So Democrats are still ostensibly trying to pass provisions on capping out-of-pocket insulin costs, and they're ostensibly still trying to do that in a separate bipartisan bill. But everyone I talked to thought that was not really going anywhere. And patient advocates said that they really want it put back in reconciliation. It's time to cut bait on the bipartisan deal. They're not seeing enough support from Republicans to go forward. But it's unclear if that's going to happen. And there's really a clock ticking. And what's interesting was not only were the insulin provisions carved out and put in the separate bill but from the patient advocates' perspective weaker than what was originally in the bill — because in the party-line bill, it would have specifically directed Medicare to negotiate some insulin prices. And in the bipartisan bill, it doesn't negotiate the underlying price. It just caps out-of-pocket costs, which the advocates say and the [Congressional Budget Office] confirmed would actually raise the price of insulin. So ironically.

Rovner: So if you're not one of the people protected by that cap, you could end up paying more.

Ollstein: Yes, exactly.

Rovner: Yeah. Which has been a problem. So, if you'd asked me, I don't know, six weeks ago, I would have said that Congress was not likely to get the reconciliation bill through before the August recess but they were likely to get the FDA user fee bill done in time for the August recess, because they needed to do that. Otherwise, these layoff notices might go out. Sarah, they're not getting the FDA user fee done, are they?

Karlin-Smith: Right. It's stalled a bit right now. Sen. Richard Burr [of North Carolina], who's the minority chair on the Senate health committee is basically pushing for a clean user fee bill — so a bill that just is going to renew the programs without adding any additional legislation. And that's holding things up at the moment. I think it was also revealed a bit by some digging by Burr's office that maybe the FDA pressuring them to get this done faster is not necessarily necessary at this point. There's this fear that FDA would have to send out notices of potentially laying off employees if they weren't guaranteed to have this user fee funded by a certain date. But now it's clear FDA has a little bit of runway to work with. So Congress has more time. So we know that if Congress has more time that they're going to make use of it.

Rovner: I was just saying never tell Congress that they have more time for something.

Karlin-Smith: Right. So they're going to have to work out these differences in terms of how clean a bill will or won't get passed. And I think some of the drama that the FDA has found itself in in recent months and weeks over the infant formula shortage and so forth is playing into the willingness of various members of Congress in terms of interest in adding different reforms and so forth to these bills.

Rovner: Yeah. And we'll come back to that FDA reorganization in a minute, but I want to move on to covid. Last week, we began with the breaking news that President [Joe] Biden tested positive for covid and he started on Paxlovid. This week, the president's already testing negative. He's out of isolation, back in the Oval Office, and holding himself out as an example of what vaccines, testing, and treatment can do to keep this infection less serious. But I have to wonder: Has the White House been too no-big-deal about this? Might it have the unintended consequence of making vaccinated people think that it's actually OK if they get covid and maybe they shouldn't need to take any other precautions right now while the BA.5 variant is surging in many places.

Ollstein: So the biggest criticism I have seen is that like many other government officials who have gotten sick, there was this big show of working through it. And a lot of advocates point out that working while

infected and not resting enough is a risk for developing long covid, longer symptoms. And so a lot of people are saying that the president should model for the American people that if they get sick, they should rest and not work through it. But it's also understandable why he and others are making a big show of putting on a suit and posing with some papers while they have covid.

Kenen: Besides, he might have had pajama pants on.

Rovner: That's right. But we can obviously see that Manchin was working through his covid.

Kenen: But it's the same dilemma that we've been talking about for weeks, months, that, yes, we're not in 2020, but, no, we're not out of it. So what is that balance of protecting yourself and others around you versus ... We don't need a "shutdown." We don't need to go into March of 2020. But what's getting lost I think ... The White House is trying to say, "We can manage this with the following tools." And yet the country is not taking the tools. Voluntary masking when it's a smart thing to do. Vaccines and boosters. The booster take-up is very low. And the racial gap — which was pretty close to closed or with some groups definitely closed during "full" vaccination, the first-year shots — is wide again with boosters. And even people who know about Paxlovid — not all doctors do. It's being prescribed on the coasts more than the interior. You hear all sorts of things from doctors about who needs it and who doesn't. There's some youngish, healthy-ish people who get it and older, sicker people who are at risk and don't. So the administration is saying, "Yeah, we still are in the pandemic, but everything's OK." And it just makes a murky situation even murkier. The clarity of, "Yes, we have the pandemic, and we have tools to cope," which is what they're trying to say is not coming through with that crystalline clarity.

Karlin-Smith: I think it also shows a little bit like how out of touch the White House is to some degree on the hurdles for the average American to get covid versus the president of the United States, right? Not every American can pop open their laptop in bed and work from home. And Biden probably has somebody cooking his meals, taking care of everything else he needs to do, right? He's the president. And so parents, if their kid gets covid and they get covid, they're having to both balance being sick and dealing with sick children. They may not have paid time off from work, all this stuff. So even a manageable infection that isn't going to kill you can be economically devastating for somebody. Again, we still have the risks of long covid. We have hospitals and health care workers we know that are, again, already feel burned out and are still bearing a huge brunt from this wave. So there's a lot of consequences that even though things are better I think people want addressed, and we don't want widespread transmission just because less people will die. And I think that's where the White House hasn't been doing a great job of saying, "Yes, we know things are better and we want to highlight that, but here's what we're going to do to get them even better." They seem to be having trouble pivoting to that next step of, "OK, well, what else are we going to do to push this to an even better situation?"

Rovner: So one group that seems to be taking precautions less seriously than public health might have hoped are parents of the youngest children, who are finally eligible for vaccines. The latest KFF Covid Vaccine Monitor finds that more than 40% of parents of children ages 6 months through 4 years say they will "definitely not" get their children vaccinated. And more than half say they think the vaccine is a bigger risk than their child getting covid. Is this a public health failure, or is this parents making logical choices with the information that's currently available?

Ollstein: I mean, I think it really reflects poorly on the decision to wait this long to open it up to that youngest group, because there was a lot more high demand. And I think the longer the wait, the more doubt and misinformation [were] able to creep in and influence people. But I want to hear from Sarah, as the parent of young children.

Rovner: That's right. On this panel, the one who fits this demographic.

Karlin-Smith: I think it is a tricky situation. It is true that for most young children, covid is not as much of a threat as it is for older people. I mean, there's data to back it up. That said, as people have pointed out throughout this, children are not supposed to die, right? We expect children to handle illnesses differently than an 85-year-old. So even a much smaller amount of death or serious illness in young children is seen as problematic. And I think [the Centers for Disease Control and Prevention] and others have pointed out we certainly vaccinate children for other diseases that cause a lot less harm. Now, thankfully, due to the vaccine, and even before the vaccines for covid ... But I think there probably is a lot of confusing information out there because it's been so long, a lot of children have had covid, so parents may not understand the benefits of vaccination even if your child did have covid and did well with it. The changing nature of the pandemic — I know some folks have criticized the types of studies FDA required to get the childhood vaccines authorized, saying they haven't demonstrated that these vaccines essentially help with clinical outcomes of covid in children. They've just done what are known as immunogenicity studies, basically to show they work equivalently in children and adults. And I think that's been used as well by people to try to push people away from getting vaccinated. And I'm not sure if FDA or others have done a good job of explaining this is a traditional way of approving vaccines in different age groups after you have established that it does work in these huge — tens of thousands of people have been studied in adults and so forth. So I think there definitely, as Alice has mentioned, there's been a lot of bits of information that anti-vax actors have been able to exploit. And if you give them any little hook to hook onto, they will do it. And that seems to be part of the problem here.

Kenen: I think so many kids have had it that parents either don't understand the risk of reinfection or they're not worried about it: "Well, he was fine last time, he'll be OK next time." But I think the point Alice made is actually a double-edged sword. There was more of a sense of urgency. We needed these vaccines for our kids a few months ago, as she pointed out. But, also, if they had done it too quickly ... If anyone in the government ever got the messaging right, they could have said, "We took a long time to get these pediatric vaccines to the little kids. We understand how nervous you are, parents, about your 6-month-old. That's why we spent so many months. We did it a year later." Again, it's not like they can't message at all, but they can't message A+. And you need A++++. I don't think [CDC Director] Rochelle Walensky has any grandchildren yet. But you need somebody. You need Tony Fauci. Well, that won't work. He's too toxic. You need somebody with all their grandkids on their laps, with their Band-Aids on their arms or something.

Rovner: Bring back C. Everett Koop.

Kenen: The problem is that in a society this divided, nobody is able to message to the entire country. I mean, everybody can only message to half the country.

Rovner: We miss Mr. Rogers.

Kenen: Mr. Rogers. Right. They just haven't been able to get this across.

Rovner: Which is a perfect segue to my next topic, which is reorganizing the federal government. If you can't message right, at least move the chairs around. So in trying to address how the federal government fell down in trying to address covid, the Department of Health and Human Services has announced a reorganization, including elevating the Office of the Assistant Secretary for Preparedness and Response to the same level as the CDC, reportedly in an effort to stem the turf wars between the two. The ASPR is in charge of the national stockpile. There have been all kinds of butting of heads, both in the Trump and the

Biden administration about this. Will this really fix things, or is this just an effort to dilute some of CDC's power rather than fix what's actually wrong with the CDC?

Kenen: Just the name — it's the clunkiest. Even in a government full of clunky names, it's a really clunky name. Like nobody knows what that means or can remember what the initials are. So I think they should have rebranded it as well.

Rovner: As I demonstrated, I couldn't say it. The assistant secretary for preparedness and response.

Kenen: I mean, there have been calls for more of a point agency within the government, within HHS. Because the CDC is part of HHS, but also a thing unto itself. So there have been commissions and so forth, including a recent one that former FDA Commissioner Peggy Hamburg led — sponsored by Commonwealth and I think it was revealed at the Bipartisan Policy Center. They call for something like this. I haven't read the details of exactly the structure they call [for] versus how this one is going to work. But something like "We're in charge and we got this." It's sort of a coordinating function, etc. And authorize with ... But I don't think anyone yet understands what's different. And does it solve turf wars, or does it create new turf wars? And also, frankly, the federal stockpile has been a disaster for years. In Democratic and Republican administrations, there were things that were not in there that should have been, including ... turns out we don't need as many ventilators as we thought they did. But they were in terrible shape. They weren't usable. There weren't masks.

Rovner: And not enough PPE [personal protective equipment].

Kenen: Not enough anything. And what there was was more oriented toward bioterror rather than a biological pandemic. So that needs a whole rethink.

Rovner: Yes. Well, we will definitely talk about this more in August when there is less news.

Kenen: Don't be so sure about that, Julie.

Rovner: When there should be *slightly* less news. Meanwhile, the FDA is getting a potential overhaul of its own. FDA Commissioner Rob Califf has ordered a, quote, "external review of the offices of food safety and tobacco regulation." Those are two different offices. Sarah, what does this even mean? Is it like double secret probation?

Karlin-Smith: I wouldn't really call it that. The Reagan-Udall Foundation for the FDA, which is doing this review, is a very FDA-friendly organization. They work with them more as a partner than as a ... they're not an OIG [Office of Inspector General] or an oversight body in the sense that they're really out to get FDA. So they're hopefully going to take a good look at can they improve their tobacco/food functions by somehow reorganizing FDA. But this is sort of a friendly exercise, if you will.

Rovner: It's like bringing in your hand-picked consultant.

Karlin-Smith: Correct. Exactly. And perhaps ...

Rovner: It *is* bringing in your hand-picked consultant.

Karlin-Smith: Right. I think the other thing is, you know, we'll see what they find and they conclude. Particularly, I think, on the food side, FDA is not a heavily taxpayer-funded agency, and particularly on the food side, where they don't get money from industry as they do in the much more well-funded drug device areas, what may end up being the problem — I wouldn't be shocked — is they just don't have enough

people. They just don't have enough funding to do the incredible amount of work we expect them to do. So it will be interesting to see, can the Reagan-Udall Foundation find solutions that are doable within the current budget and staffing constraints they have? FDA often does lots of different reorganizations. ... Every commissioner likes to reorganize things. But at the bottom line, you can only do what you can do when you have a certain number of people and a certain number of millions of dollars.

Rovner: And Alice, this pertains directly to your extra credit this week. So why don't you go ahead and do it? Because this is another perennial FDA problem.

Ollstein: Yes. I think it's important to remember with all these reorganizations and reviews, nothing that we've seen recently gets at a problem that's been around for a long time under all different parties and administrations, which is the revolving door between government and the private sector. And we had a pretty egregious example of that this week when a top FDA official in charge of regulating tobacco left for a job with Philip Morris, the big tobacco company. And so this is a piece in The Hill by Nathaniel Weixel about this. And one of the ethics issues at play, besides the obvious, is that the agency said that this person was recused from decisions related to the tobacco industry during his job search, but they wouldn't give exact dates on when that took place. And so ...

Rovner: And also, if he was recused from doing things related to tobacco, that was his job.

Ollstein: That's his entire job!

Rovner: I can't imagine what else he was doing.

Ollstein: So basically, he was paid by taxpayers to look for a job in the tobacco industry. And that's the best-case scenario. The worst-case scenario is he was influencing tobacco regulation and policy while seeking a job in the tobacco industry. So not good all around. Obviously, this gives a lot of fodder to groups that have been pushing for reforms and cooling-off periods before government officials can go work for the industries that they formerly regulated.

Kenen: And this is a city of revolving doors, but this is like when Marilyn Tavenner went from CMS [the Centers for Medicare & Medicaid Services] to running the big insurance lobby. And this is not as high-level as that. She's not running Philip Morris. But in terms of just, like, *What?!* This is up there.

Rovner: Or when Billy Tauzin left Congress to go run PhRMA (the Pharmaceutical Research and Manufacturers Association). I mean, we've seen it in both parties in many branches. All right. Well, let's turn to abortion this week. I actually want to start with contraception, since at the moment it seems inextricably linked. The House last week passed a bill that would guarantee access to contraception, effectively writing into law the Supreme Court's decision in *Griswold v. Connecticut* and *Eisenstadt v. Baird*, which established the right to contraception for married and unmarried women, respectively, many, many years ago in 1965 and 1972. And no, I was not old enough to have covered those. A companion to that House bill was blocked in the Senate on Wednesday. The Senate last week blocked a different bill that would also have effectively reauthorized the Title X Family Planning Program, which, I point out every couple of weeks, abortion-related fights have prevented from being reauthorized since 1984. Also, I wasn't there then. Are Democrats going to be able to exploit the very popular right to contraception here? Or is this just another thing that Congress is not going to be able to get done?

Ollstein: So I think it's been interesting that they have been doing these as voice votes recently. If the goal is to highlight Republican opposition, it's just interesting because all it takes is really one Republican to

stand up and say, I object. Rather than forcing all of them to go on the record and potentially making things uncomfortable for those who are up for reelection, etc.

Rovner: And I've noticed that Joni Ernst is who just got reelected.

Ollstein: Right. Exactly.

Rovner: She's the one who's been standing up and objecting to these things.

Ollstein: Right. And so I think it doesn't have the political punch that a roll call vote maybe would have. But I also think they've done so many of these at this point that I think the more you use the hammer, the less impact it continues to have. And so I think that the public is broadly aware of which party is in favor of abortion rights right now. And I don't know if each subsequent vote ... if anything, it allows individual lawmakers who are running in tight races to cut an ad saying, "My opponent is against you having birth control," which I'm sure is the entire purpose of the exercise.

Rovner: Yes. Although, I mean, they are — particularly in the Senate — in this odd position of possibly being able to pass with 60 votes a bill to enshrine gay marriage, which isn't technically yet in the Supreme Court's sights, but not able to do anything about contraception. And I wonder if that could end up backfiring, just making Democratic voters who are already frustrated even more frustrated. I mean, not that they wouldn't be happy about enshrining gay marriage, but the idea that they can enshrine gay marriage and not be able to enshrine contraception seems a little odd.

Kenen: I think one of the phenomenons [sic] that's gone on is abortion — public opinion on abortion has been pretty locked in for 50 years and public opinion on gay marriage changed so dramatically in the last 10 or 15 years. Amazing. I mean, I'm not saying that there's no discrimination. Obviously, there is. But where the needle is on that and that abortion became secretive, abortion became shameful, abortion became something people don't talk about. When a public figure talks about an abortion, it's news. When a public official gets married to someone of the same sex, it's "let's send them flowers." So it's really striking. And then the contraception debate, it's partly how are they going to ... It's not that every Republican wants ... It's not that Republicans are against all forms of birth control. There are certain controversial forms of birth control, which the four of us on this conversation know that scientists say are birth control. But some conservatives say they are actually forms of early abortion. That's where the Republicans have gotten themselves tied up in knots. I don't think they want to send a message to American families: We want you to have zero tools. But they also don't want to be in the situation where they voted for contraception and then someone on the right-to-life side says, but wait a minute, we can't allow this anymore, you know, Plan B or IUDs or however they're going to grapple with this. I think that's where some of the political conflict is. I mean, they don't all have 800 children. I mean, clearly, a lot of these people have used family planning at one time or another. Most of them have one or two or three kids, right?

Ollstein: I also think it shows the success of the framing of the marriage-equality debate. And so, decades ago, there was a real decision to prioritize marriage rights and really to develop rhetoric to appeal to conservatives and change their minds. And it was all about: We're just like you. We just want to marry and have a stable family unit just like you. It was a framing that really appealed to conservatives. And I think the number of Republicans who are now supportive of this and stand poised to vote for it really show the success of that. Of course, the decision to pursue that area at the expense of other areas of equal rights for LGBT people is and was controversial. I mean, you can still be fired for being gay or trans. You can still be denied housing for being gay or trans. The decision to focus on marriage rights rather than those things is

still a subject of hot debate. But it's undeniable that it has been successful in winning over conservatives and changing minds in that way.

Rovner: Well, speaking of conservatives, Alice, you're off to Kansas, where there's going to be a big election. Tell us about that.

Ollstein: Yeah. So, on Tuesday, the state is voting on a referendum on whether the state constitution does or does not support abortion rights. It'll be the first real test, the first time voters will be able to weigh in directly on this issue since the Supreme Court overturned *Roe v. Wade*. And so there's a lot of attention on this and a lot of watching to see what this could mean for all of the other states that are set to vote on similar referenda this fall. Of course, every state is different in its political makeup, and the wordings of the actual language of these different constitutional amendments are all different in different states, but it could be a harbinger of what is to come more broadly. It's also important because Kansas has, as abortion rights have crumbled in so many states in that region, it's become a real destination. So tons of people have been going from Texas, since they implemented their ban even before *Roe* fell. More recently, since Oklahoma implemented their ban, more and more people have been going to Kansas. And so, if Kansas falls as well, people will have to travel even further and further. And the resources in the states that remain supportive of abortion will be strained further.

Rovner: Yeah, just ... I mean, following up on exactly that, something that was predicted but that we're actually now seeing is that bans in some states are backing up appointments in adjacent states, meaning that not only women in states where abortion is banned are having difficulty accessing abortion. So are women in neighboring states where the wait may be three weeks or more, which is pushing some women into later, meaning more potentially dangerous and expensive, procedures. Is there anything those nearby states can do? I mean, if Kansas falls, then everybody is presumably going to go to Illinois. Are we seeing efforts in these, quote-unquote, "sanctuary states" to beef up availability? Because that obviously, that's an issue right now.

Ollstein: Yes. So we definitely are. And that's taking different forms. Some abortion clinics in states that have just implemented bans are picking up and relocating. We've seen a lot from Texas relocate to New Mexico. We have seen others looking at relocating to especially southern Illinois, which is becoming a real destination for people around the country. Something I also reported on a couple months back is efforts in progressive states to change their laws so that nurses and midwives and other non-physician health care workers can perform abortions. Because, really, the real crunch is not a physical clinic. It's the number of people who can actually do the procedure. And a lot of states have allowed non-physicians to do abortions for a long time, but more states are looking to join those ranks to meet the demand.

Rovner: Well, because there is really nothing that's new, the Affordable Care Act is back in court in Texas, of course, and before Judge Reed O'Connor. Joanne, remind us why Judge O'Connor's name rings a bell and what this latest lawsuit's about.

Kenen: You know, ringing a bell might not be the right metaphor. He's very anti-ACA. He OK'd the last case from Texas that was really a stretch. He said that because the individual mandate existed, even though it no longer had any penalty and it wasn't enforced and it was meaningless, that that in itself made the ACA [un]constitutional. ... It went all the way to the Supreme Court yet again. I mean, he's never, I mean, I think we would all be surprised. He's very, very, very, very anti-ACA. He is not bothered by things like standing, which was an issue in the last case. And we expect ...

Rovner: And may be an issue in this case, too, apparently.

Kenen: Right. We expect him to act. We expect ... and it's a different Supreme Court. But even the arguments, like saying, well, the U.S. Preventive Task Force isn't, they're not appointed by the Senate, but they are ... under HHS, where the secretary is appointed. There's these technicalities of saying, well, they don't have the right to define preventive benefits. They do.

Rovner: And we should point out, I mean, that this case is not challenging the entire law. It's just challenging preventive care benefits.

Kenen: The most popular thing in it! Which people don't realize. I mean, preventive care, the well-child, the colon cancer screenings, mammograms, all the preventive care, which includes contraception, the free, no copay contraception is part of this bucket of preventive care, which is one reason why it's so controversial. But these are all sorts of things that, I mean, I think half the people who get them don't even realize it's because of the ACA, because you don't have to be in the exchange, you don't have to be getting a, quote, "Obamacare plan." You go to the doctor on your, you know, whatever you're getting from work, or Medicaid, or what you bought yourself, and you get these free preventive care benefits, these screenings and cancer checks, etc. Well, baby, all these things ... and yes, that's because of the ACA. If people knew it was from the ACA, it would be the most popular thing in the ACA. Talking about messaging failures, you know, this is a clearly a Democratic tradition. So it's really popular, but I think we're going to have another year or ... I don't know how long it'll take to get to the Supreme Court. After it goes through Judge O'Connor, it still has to go through the Texas Court of Appeals, and they may ...

Rovner: The 5th Circuit.

Kenen: The 5th Circuit, which is the full ...

Rovner: ... federal case.

Kenen: Yeah, very conservative. It's why these cases go there. It is extremely conservative, but they may not, just because one judge, one really anti-ACA judge who is fairly predictable, it might get stopped before it gets to the Supreme Court, although I doubt it.

Rovner: I'm just curious, though. I mean, if it does get to the Supreme Court and there is a likelihood that it will, I mean, you know, we've seen the Supreme Court now on three different occasions refuse to strike down either the entire law or big parts of the law, basically because they would say this would be too big a jolt to the system. Well, we now see that this Supreme Court doesn't really care about jolting the system. I mean, so could we end up with a different outcome?

Kenen: It could be a different outcome. I'm not sure, because of some of the technical things here. There's not a radical move to eliminate preventive care in this country, first of all. People are pro-cancer screenings in general, right? And also because some of these arguments, there are some legal arguments about standing and who these, quote, "unnamed bureaucrats" are, etc., etc. I mean, the Commonwealth Fund has a pretty good brief on why other judges who might not like the ACA themselves could still throw this case at or defeat this latest effort.

Ollstein: The government's main defense here is these people aren't being harmed in any way by health insurance paying for STD screenings. You know, if anything, their premiums are lower because preventive care catches things before people end up in the hospital with serious conditions. So, you know, we've seen the standing argument protect the law before and it could again here. I also think it's important that this case has two tracks. It has two arguments. One is this religious freedom argument that's just about STD screenings and HIV prevention drugs and whether insurance plans should be required to cover those. And

then separately, there are these more technical arguments about all of the preventive care mandates and how they were developed and whether they should be enforced. And so, we could see a narrower ruling just on the HIV and STD care rather than wiping out all the preventive services. I will say that comes at a time when we have record STD rates in this country. It would not be great for public health to lose that. And then, more broadly, it would not be great to lose coverage for all vaccines in the middle of a pandemic with some new epidemics on the horizon.

Kenen: And the STD screening isn't the most controversial part. Alice has been covering this, but I think — she'll tell me if I'm wrong — PrEP is a drug that prevents the spread of AIDS, HIV/AIDS. It's very expensive, but it's also a really effective drug that is actually being underutilized in this country and the rest of the world because of its cost and some educational issues. So there's also these two factors in the STD thing. One is the screening, and then the other is, should the government be paying for this drug to prevent the spread of HIV/AIDS, making that free for people? There are still people who are, as we've just noted, are really opposed — that there *is* discrimination and there's also opinions about premarital sex or extramarital sex, etc. Why should we be paying for, you know, they should just not be doing this.

Rovner: People for whom this violates their religious beliefs. So. Well, speaking of things that are likely to end up before the Supreme Court, and this is our final piece of news for this week. The Biden administration announced a long-awaited reversal of the Trump administration rule that had weakened anti-discrimination protections included in the Affordable Care Act. The new Biden rules, which are proposed and still open for comment, not only restore the old protections, but seek to expand anti-discrimination protections for women seeking reproductive health services and teens seeking gender-related treatment. So only a little controversial here, right?

Ollstein: Yes. I think, like so much else, this is going to be challenged. We can almost guarantee this is going to result in a lawsuit and a legal battle. So, full employment for health care lawyers and health care journalists.

Rovner: Yes, absolutely.

Kenen: [Supreme Court Justice] Neil Gorsuch actually voted with the more liberal wing, which surprised some people. You may remember in oral arguments, which I think was more than a year ago now, he was speaking about, on one hand this is Congress' job, not the court's job. And then he also said but, you know, given what Congress is doing right now, Congress is not functioning in a way that they could do this protection rights, and maybe it is the court's job, and eventually he decided it was. So, I mean, in many cases, we're going to look at [Justice Brett] Kavanaugh as the one to watch on cases where [Chief Justice John] Roberts would side, would need one other conservative ally — we're talking about Kavanaugh, which obviously didn't happen with *Roe*. I would be interested in watching where Gorsuch comes down on some of the gay rights cases because his civil rights expansion vote was really quite significant.

Rovner: Kavanaugh and Gorsuch are becoming the Kennedys of this court, as it were.

Kenen: Well, they're way to the right — way, way to the right of Kennedy. But I mean, if, to the extent that there's three swings, is there this bloc — and they're not ... none of them are liberals.

Rovner: Yes, this is why it's always dangerous to predict what the Supreme Court's going to do.

Kenen: It's not always going to be 6-3.

Rovner: Yeah, that's true. All right. Well, that's as much news as we can get in this week. Now we will play my interview with Céline Gounder. Then we will come back with our extra credit.

I am pleased to welcome to the podcast Dr. Céline Gounder, an infectious disease specialist who is also a senior fellow and editor-at-large for public health at KHN. Céline is also creator and host of our sister podcast, "American Diagnosis." And you've probably seen her on the airwaves, most recently on CBS. Céline, I'm so excited to have you join us both at KHN and here on "What the Health?" Thank you.

Dr. Céline Gounder: Oh, it's great to be here, Julie.

Rovner: I am particularly glad to have you on this week because we haven't really discussed monkeypox on "What the Health?" because I don't want us to get the science wrong. So please help us understand what this is and how concerned we should be. Let's start with the basic basics. What is monkeypox and how is it different from smallpox?

Gounder: Monkeypox is a virus. It is a cousin of smallpox. But it does not cause nearly the level of death or disease as smallpox. That's not to say it's a mild disease, but it's not nearly as deadly.

Rovner: So monkeypox is hardly new. It's been endemic in parts of Africa for years. Why is it spreading now outside of Africa?

Gounder: What we've seen is monkeypox being transmitted locally in West and Central Africa for years. It has spilled over into populations of men who have sex with men. And, unfortunately, in many parts of Africa, gay sex is illegal. So a lot of this has gone under the radar where these men are not necessarily presenting for medical care. It's not being tracked by public health people to the same degree as if this were out in the open. And, of course, people move around; they travel. And so it was only a matter of time before this was going to spill over into additional populations. And that's essentially what we've seen happen — is transmission in Europe, in the United States, other countries. And because the sexual mode of transmission is so efficient, we've seen this really spike up in the last several weeks.

Rovner: So what does it mean that the World Health Organization has declared it a public health emergency of international concern? Should we be worried it's going to spread the way covid has?

Gounder: It's really important to understand that monkeypox is not covid. These are very different viruses. They are transmitted very differently. Covid is transmitted through the air, and it infects the upper airway, the lungs preferentially. Monkeypox is transmitted through direct contact from person to person. Sexual contact, in particular, appears to be especially efficient, and it causes a different kind of disease. So it's largely skin lesions, as well as lesions on mucosal surfaces — that could be inside the mouth, inside the anus, on the genitalia. Monkeypox has been pandemic for at least several weeks now because it is a novel virus that is spreading on multiple continents. And it's a novel virus because these are populations that have not previously been exposed to monkeypox. A pandemic is very different from a public health emergency of international concern. That is more of a regulatory kind of declaration. It's really also to get countries to collaborate and coordinate over policies, over resources. It doesn't always work the way we want it to. If you look at covid vaccinations, we haven't really done a good job of sharing covid vaccinations, vaccines with the rest of the world. Only a quarter of people living in Africa have gotten even a single dose of covid vaccine. So clearly there's not been a lot of sharing there. But in theory, it should help share resources to where they're needed most.

Rovner: So on the one hand, we keep hearing that this is spreading primarily among men having sex with other men. On the other hand, I'm old enough to remember when we thought AIDS was just a gay man's disease. How concerned should we be if we're not in what's currently considered the highest-risk group?

Gounder: I think you have to separate how worried you should be about yourself right now from how worried should we be speaking more broadly about public health and about yourself in the future. So right now, this is actively spreading among men who have sex with men. However, it could spread into other populations in the future, as did HIV. And the populations we really worry about with monkeypox are pregnant women, the fetus or newborn, little kids, and immunocompromised people. And we've already had one case of monkeypox in a pregnant woman here in the United States. This could be deadly to her. This could be very dangerous to her pregnancy, could even cause a miscarriage. So we want to contain this before it spreads to additional populations, especially those that are most vulnerable and where this could be most dangerous.

Rovner: I've seen lots of anecdotes about people outside those high-risk groups who have had monkeypox symptoms and either been brushed off or actively misdiagnosed by medical professionals. How hard is it to get tested for monkeypox and how fast can we make that easier?

Gounder: Initially, the challenge was that labs just didn't have the capacity to do a large-volume testing. We're now at about 80,000 tests per day that could be done, but the new bottleneck is really the providers, the people seeing these patients on the front lines. And many of them are not educated about monkeypox. Some of them don't know it exists. Even if they know it exists, they don't quite know how to screen for it, how to test for it. And there are some hoops to jump through to do that in terms of paperwork, in terms of knowing what lab to send it to. Things *have* gotten easier. More commercial labs are online, commercial labs like Labcorp and Quest [Diagnostics] and some others — that should make this a little bit easier, more routine. One common misconception I've seen is sexual health providers or other providers who will test somebody first for all the common, older STDs before they test them for monkeypox. And that's really not the right approach here, because we actually see a lot of people who have multiple infections. So just because somebody tests positive for chlamydia or gonorrhea or syphilis does not mean that they can't also have monkeypox. So that should really be part of the battery of tests, not a second-line test.

Rovner: And what about vaccines? People who are old enough to have been vaccinated against smallpox are already protected, right?

Gounder: That's right. And smallpox vaccination phased out, depending on where you lived in the United States or around the world, over the course of the Sixties and Seventies. Smallpox was declared eradicated in 1980. So there is no question anybody born after 1980 has definitely not been vaccinated for smallpox — unless maybe they worked in the lab with smallpox or something like that. But for people who were vaccinated for smallpox, one sign of that is you might have this round scar on your upper arm. If you were vaccinated you should be, even now, pretty well protected against monkeypox.

Rovner: But there are vaccines for those who have not been, right?

Gounder: There are vaccines. The vaccine that we're using preferentially here in the United States against monkeypox is the Jynneos vaccine. This vaccine is much safer than the older smallpox vaccine, but it's also in more limited supply. And that's been the challenge, is getting enough supply from the manufacturer, Bavarian Nordic, which is in Denmark, and being able to, of course, then distribute it.

Rovner: Which leads me to my last question. What has public health learned from covid that we can apply to the monkeypox outbreak? Or, conversely, what haven't we learned that we should have?

Gounder: What I think public health officials are really aware, very well aware of what the problems have been during covid, and many of these problems we were aware of even before. The problem really is, are people in a position to fund public health — are *they* learning the lessons? Are they understanding you actually have to provide funding and workforce and empower public health officials to do the job? I'm not sure that those lessons have been learned by the people who could really make a difference here. You know, and that actually includes the general public as well. If they are worried about this, it's not just about what can I do for myself in terms of protecting myself and getting vaccinated. It's also about letting your elected officials know this is an issue I'm worried about. Please do something about it. I'll give you a couple examples of where we are continuing to see issues. So one is around data — we heard all throughout the covid pandemic about public health officials needing to fax their results to maybe the state health department or to the CDC to have that data compiled. That problem has still not been solved. There are still a lot of issues with reporting data between local and state health departments to the CDC.

Rovner: The last vestige of fax machines.

Gounder: The last ... [laughter] health care and public health? Yes, this is the last vestige of fax machines. Another example here is, remember, in the early days of covid, you had vaccination websites crashing and it was "The Hunger Games" to get that appointment for a covid vaccine. We have seen that happen all over again with monkeypox vaccination scheduling, with websites crashing. These problems have still not been fixed.

Rovner: Well, I guess it's time for the public health funders to get on this. Céline Gounder, thank you so much for joining us. And please come back as this progresses.

Gounder: Oh, my pleasure.

Rovner: OK, we're back. 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 links on the podcast page at khn.org and in our show notes on your phone or other mobile device. Alice, you've already done yours. Sarah, why don't you go next?

Karlin-Smith: Sure. I took a look at a piece by Sydney Lupkin at NPR called "Drugmakers Are Slow to Prove Medicines That Got a Fast Track to Market Really Work." And it's a look at FDA's accelerated approval program, which started due to HIV/AIDS quite a while ago now, but basically created a pathway for FDA to approve drugs before they actually are shown to extend your life or provide some other clinical benefit. But, basically, they improve some kind of laboratory marker that makes FDA fairly confident they will likely be of a benefit. And what's happened over the years is that the program has gotten very, very popular, particularly in cancer. And companies have been very slow to do the back-end confirmation trials to really show they're extending people's lives or improving quality of life. And recently, FDA has actually started to crack down on this a bit in cancer, because cancer drugs tend to be very toxic. And in a few cases, they've actually seen that drugs they've granted accelerated approval are not only not ending up with the benefits they've seen, they've actually ended up harming patients more than the alternatives. So this is a really deep-dive story into the program. And I think it also does a good job of highlighting that even among family members of people that were seriously harmed by some of these drugs and felt like they weren't, it wasn't appropriately conveyed to them just what was known and not known about these drugs, many of them still talk about how they didn't have many other options and how even if they had been more informed, they still might have tried these drugs. So I think it also demonstrates some of the tension here in the U.S. and culturally that people, particularly facing really serious deadly illnesses, still do want these options. And we mentioned briefly earlier in the podcast the FDA user fee bill. There are some reforms to accelerate

approval in there. But even there, I would argue they haven't really gone very far. And I think that's because the bottom line is there are a lot of flaws, I think, the policy people have pointed out in this program, but it's so popular, it's very hard to touch.

Rovner: The bottom line is the bottom line, as it were. Joanne.

Kenen: This is a really extraordinary piece in Nature — excuse me, in Science — called "Blots on a Field? A Neuroscience Image Sleuth Finds Signs of Fabrication in Scores of Alzheimer's Articles, Threatening a Reigning Theory of the Disease," by Charles Piller. And it's about allegations of falsified data — or falsified images, actually — involved in Alzheimer's research. And the reason it's so important is there's been a huge debate in the field about what is the cause of Alzheimer's. We actually don't know. But this whole amyloid beta plaque theory, which has been the dominant theory for many, many years, and yet lots of drugs have been developed with an aim of addressing it. And we don't have a cure or a great treatment. Well, it turns out that the foundational work 16 years ago — 16 years and, you know, millions and millions and millions of research dollars, some from the NIH [National Institutes of Health] and some from foundations and some from private enterprise. And all those hours may have all been built on a study that was falsified, that the blots on a field this headline refers to — actually, the images of the plaque — might have been manipulated, pieced together, collages of different pictures to make it look ... it's not just like somebody allegedly doing something really wrong. It's had an enormous impact in where we have spent our time and energy on this disease that is a terrible disease in an aging population becoming more and more of a burden by the second.

Rovner: And it's what led to the whole Aduhelm fight.

Kenen: Yes. Yes.

Rovner: Because that was based on this whole amyloid plaque.

Kenen: So in addition, yesterday — where it is reported, maybe others, in addition to Reuters—I saw a Reuters story saying that a company that's involved with developing a drug out of this research and closely involved with the circle of people is now being ... there's a criminal investigation. So it's a really good piece of detective work. You know, some young scientist just got suspicious, and there is such thing as forensic pathology imaging experts. I forgot the exact title, but there's this scientific field where people look at medical images and figure out if they're legit. So it's a detective story with, you know, incredible implications for biotech and families around the world. I mean, maybe, we just spent 16 years maybe looking at ... it's not just one person. This research was foundational. So much that has been done in the last 16 years was based on this research.

Rovner: You know, I imagine this is the first of what we will be hearing a lot about of this particular story. Well, my extra credit this week is from Carrie Feibel over at NPR. And it's called "Because of Texas Abortion Law, Her Wanted Pregnancy Became a Medical Nightmare." And it's a hard story to read and even harder to listen to, but so important. It's about a young couple who got pregnant, set up their nursery, saw everything go fine. Until it didn't. Elizabeth Weller's water broke early at 18 weeks, basically dooming the baby and threatening her with life-threatening infection. And yet it took more than a week before she could get the care her doctor wanted to provide because everyone who was supposed to be taking care of her was scared that her life wasn't endangered, quote, "enough" for them to not get caught up in Texas' abortion ban. I know my extra credit was a similar story just a few weeks ago. I just wanted to make the point that this is not that rare and we're likely to see it more and more in places other than Texas now that that abortion is leaving medical providers to wonder what is legal for them to provide and what happens

when that violates their ethics. OK, 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 producer, Francis Ying, who makes the weekly magic happen. 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. Joanne?

Kenen: @JoanneKenen

Rovner: Alice.

Ollstein: @AliceOllstein

Rovner: Sarah.

Karlin-Smith: @SarahKarlin

Rovner: We will be back in your feed next week. Until then, be healthy.