**KHN's 'What the Health?'**
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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, Feb. 10, at 10 a.m. As always, news happens fast, and things might have changed by the time you hear this. So here we go. Today, we are joined via video conference by Anna Edney of Bloomberg News.

**Anna Edney:** Hi, Julie.

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

**Karlin-Smith:** Morning, everybody.

**Rovner:** And Joanne Kenen of the Johns Hopkins [Bloomberg] School of Public Health and Politico.

**Joanne Kenen:** Hi, everyone.

**Rovner:** So no interview this week, but more than enough news. So we will get right to it. I want to start this week with PDUFA first, since I know I have both of my FDA experts here. I imagine some of our listeners will know what I'm talking about, but lots of them won't. So let's start with what PDUFA is and why we should care about it. Sarah, this must be something that's going to occupy a lot of your time this year.

**Karlin-Smith:** So PDUFA, or the Prescription Drug User Fee [Act], and there's also medical device, generic drugs, biosimilars. Basically, it's a process where the various medical product industries and FDA come to an agreement where the companies pay certain fees to FDA in return for commitments for speedier reviews and so forth on their applications. PDUFA was first started right after the peak of the AIDS crisis. There was a lot of public realization of how underfunded and understaffed FDA was. And this was one solution to try and get promising drugs approved to Americans sooner.

**Rovner:** And it's done that, right?

**Karlin-Smith:** I mean, there's no question that the time for drug approvals has significantly dropped. So it sometimes used to take FDA upwards of three years to review a drug application. Now, a standard application will get a decision in under a year. Some priority applications get a decision in six months or less, or occasionally even see a speedy decision in like two months. So it's made a big difference, and it's drastically expanded the size of FDA as well.

**Rovner:** That's right. And, Anna, I guess you were the one who pointed out that it isn't just drugs anymore that we have these user fees for. Industry is now basically helping pay FDA reviewers for a lot of things.

**Edney:** Yeah, there's also one now for generic drugs. There's one for biologic drugs. There's one for medical devices. The list goes on. And they're not all as big as the Prescription Drug User Fee is. They do bring in a large chunk of money for the FDA. For the prescription drugs, it funds a huge amount —the vast majority of the drug approval reviews that the FDA does — and so it's necessary for all the staff. I saw in the agreement this year it's going to help them hire more than 350 new staff to do the drug reviews. But, yeah, every adjacent industry has seen the success of this and decided they could do their own thing, too. The one downside is it does fund some activities for once a drug is on the market, making sure the companies are doing some things that they should be or inspections and things, but not a huge amount of that. So it really

puts the emphasis at the agency on getting a drug to market, less of the emphasis on what happens once the drug is there.

**Rovner:** And basically the process works — I think I have this right. One of you will correct me. The FDA puts out a document saying what they want out of the next five-year agreement, and then they negotiate with the drug companies, and then they send the whole thing up to Congress, and Congress gets to sort of ratify it, right?

**Edney:** Yeah, I think you got it pretty right. The negotiations are … There were like a hundred meetings or something this time around. So it's not just FDA being able to say, "here's what we like," and they kind of say OK pretty quickly. It takes a couple of years. So they … and it's like an election. They start it way before it's actually going to take place. It takes a while to get all that worked out. Eventually, they send it to Congress, and hopefully that gets passed. It usually ends up — there's a lot added to it often. Congress is going to look to add anything that they can remotely relate to it because it's a must-pass bill. It's got to go so the FDA gets funded, and other things will end up getting tacked on to it. It looks like this year, some of the focus might be on what's called "real-world evidence," where they'll want to be looking at programs that can use all our patient data that's out there nowadays, through registries and insurance information, and to try to use that in getting drugs, at least new uses of drugs, approved and things like that. And I'm sure there are other priorities as well that Congress will have.

**Rovner:** Since this, as you point out, a must-pass bill, is there a chance that lawmakers are going to try to attach other things to it, too? I know that's been an issue in the past. Obviously, the drug price stuff was supposed to go on the Build Back Better bill, which is now floundering around. And here's a moving train. Is there a possibility of attaching any of the drug price legislation to this?

**Karlin-Smith:** I'm a little skeptical that something as partisan as drug pricing will get onto a user fee package. I do think it could end up being a Christmas tree-type bill, but I think the things will be a bit more partisan in nature. So something like Sen. Patty Murray and Sen. Richard Burr's pandemic prep bill — if that doesn't get passed some other way beforehand — I think could catch a ride. Potentially Cures 2.0, which has a lot of FDA-centric health policy reforms that, again, appeal to people on the right and left. Maybe even [President] Joe Biden's cancer "moonshot" or Biden's plan for this advanced health research agency — again, if they can't find a way. Those are the kinds of things. I think there is some general sense of PDUFA too often trying to keep out like those really controversial things because I think Republicans are going to want to vote for this.

**Rovner:** Yeah.

**Edney:** If it's not passed like by a very specific time, by the time the fiscal year's up, FDA has to start sending out pink slips to people. It gets really complicated, so it's hard to put something on it that might in any way hold it up. It has to be bipartisan issues.

**Rovner:** Yes, and I will point out that this is PDUFA 7. I'm so old I covered the original one. So this is now the seventh time they've done this. I think maybe by now they're kind of figuring out how it all works. But I know the FDA has had to send out pink slips a couple of times because Congress has gone right up to the deadline. And I guess the deadline is the end of September, the end of this fiscal year, right? So they have until Sept. 30, right?

**Karlin-Smith:** The end of September 2022. And I've alluded to this before, but if you look at FDA's biggest center, their Center for Drug Evaluation and Research, the last numbers I saw, 70 percent of it was funded by user fees, compared to taxpayer dollars. And the last user fee cycle if they had to send out those pink

slips, I think the number was over 5,000 workers that would get that warning. So the way I have been comparing it is having any risk to the User Fee Act would be way worse for FDA than a government shutdown, a prolonged government shutdown. So I think that's how big a deal this is in terms of needing to get it done on time.

**Rovner:** So while we are discussing the FDA, Republicans on the House Ways and Means and Energy and Commerce committees — those are the two panels that oversee most health issues in the House — have written to Health and Human Services Secretary Xavier Becerra and Centers for Medicare & Medicaid Services Administrator Chiquita Brooks-LaSure challenging the CMS coverage decision for Aduhelm, the controversial Alzheimer's disease drug that may or may not work. Before we get to the Republican complaints here, Sarah, remind us what it was that CMS decided about covering this very expensive drug.

**Karlin-Smith:** So CMS is basically deciding at this point they will not provide coverage of the product unless you are enrolled in a clinical trial that's going to further elucidate the benefits of the product.

**Rovner:** Now to the complaint — the Republicans seem to be arguing that CMS is basically trying to replace the FDA by requiring more clinical trials. But CMS has the authority to do what it's doing, right? I mean, what are the Republicans trying to achieve by politicizing this? I saw you had an interesting story with some thoughts about it.

**Karlin-Smith:** I think they seem to be suggesting that CMS is overstepping their authority here and overruling FDA inappropriately, arguing that FDA has said this drug has … its safe and effective and CMS should be covering it more widely. The theme I saw in some of their remarks and comments is that Alzheimer's patients deserve hope and a chance to have this product and it's unfair for CMS to deny them that. The problem here is that you have a drug that was very controversial and that many people in the medical space and medical field feel FDA shouldn't have approved and FDA is the one that missed the bar here and approved a drug they shouldn't have approved because it's very questionable whether there is actually any efficacy signal. And this drug actually can be fairly dangerous in terms of its side effects and so forth. So while Republicans are pushing this idea that Alzheimer's patients deserve hope, there are other people who say it's unfair to suggest to people this drug provides hope when really, we know very little about that possibility and what we do know is there's certainly grave risk and you have to be transparent about that.

**Rovner:** And false hope is worse than no hope, which brings us back to the whole "right to try" thing. Joanne, you wanted to say something.

**Kenen:** Sarah's actually written extensively about right to try, and she may want to come back to that. But we've also seen this politicization of covid drugs. You've seen Republicans embracing ivermectin — not so much anymore, but earlier hydroxychloroquine. And the most recent thing was Gov. [Ron] DeSantis in Florida. There are three monoclonal antibodies to treat covid. Two of them do not work against omicron. They are great for delta. They've saved lives. They're good drugs. But not only does the FDA say these two strains don't work against omicron, the drug makers themselves said, "They don't work on omicron, so let's save them for something that works. Don't give people a drug that doesn't work." And Gov. DeSantis has challenged that and demanded that the federal government send him the ones that don't work because he says they work and that Democrats are trying to deprive Floridians of a drug that's going to save their lives. And I haven't seen a governor do the equivalent with a controversial drug, maybe Sarah or Anna remember an example, but here's something that there's no debate. There's no dispute on this. These two monoclonal antibodies do not work against this specific variant. And like everything else in covid, it's become very political.

**Edney:** And I think the FDA is a great punching bag right now. It's low-hanging fruit because it's in everyone's consciousness with the pandemic and the vaccines. And with Aduhelm, I think it's good to remember that there was an accelerated approval. So while the FDA technically said it's safe and effective, they don't have all the information yet. They're waiting on that information, and it's within Medicare's right to want to decide on lesser coverage because they don't have all that information yet, either. And if they were to cover it fully, then premiums for Medicare, certain premiums, are going to be higher and Republicans will bash Democrats for that as well once that has to kick in.

**Rovner:** Well, actually, it had kicked in. That's sort of the irony here. The Part B premiums have gone up in anticipation of having to pay for this drug that now CMS has decided Medicare mostly isn't going to pay for, which is a whole other issue.

**Edney:** Right.

**Rovner:** So, Joanne, you're right. This is probably of a piece with Republicans' politicizing other drugs. I was just a little bit surprised to see this because it is so expensive. And Republicans are … there is some bipartisan cast to the "so doing let's do something about drug prices." So this just seemed to be a reachout. But I think, Sarah, you may be right, this may be part of the "people have a right to whatever drug they want as long as it's not going to kill them" is essentially the argument here. And the fact that it costs $28,000 a year is something that we'll have to talk about down the line.

**Kenen:** But that's a mere bargain compared to the $56,000 it was going to be a few weeks ago.

**Rovner:** One more FDA issue before we leave this, our podcast colleague Shefali Luthra has a very provocative story over at The 19th this week about how the Biden administration might be able to use the FDA's authority to shore up abortion rights. The agency has already made permanent a pandemic-era policy that allows the abortion pill mifepristone to be prescribed via telemedicine. But in Shefali's story, Mary Ziegler, a law professor at Florida State who's also been on this podcast, suggests that the FDA could argue that its regulations could override the 19 state laws that still require the abortion pill to be delivered in person from doctor to patient. A second law professor Shefali interviewed suggested the FDA's approval of the abortion pill could override early state abortion bans up to 10 weeks, which is as long as the pill can be taken safely, according to the FDA. I have never seen the FDA try to say it overrides more restrictive state laws, but that's not to say it couldn't happen. Do you think that there's a possibility that the administration could try to use the FDA to preserve abortion rights?

**Karlin-Smith:** I've seen some other legal experts actually make the case. It was in one of actually the major medical journals recently — and I don't know the one, I should have found it before this podcast — but, right, that FDA policies might preempt some of the state restrictions on access to the abortion pill. It seems like that could be a reasonable possibility, but obviously the Biden administration would have to put some effort into legally challenging that. And there's some precedent, I think, in the past with things like, so if you look at certain laws around the drug supply chain and other things where basically states were going to take action on their own, particularly California, and it did end up spurring sort of national legislation that would preempt the state legislation to ensure there weren't 50 separate state systems for these things. So I think that's certainly interesting. At the end of the day, though, as you mentioned, these pills can only be used for up to a certain point. Certain women may, for various reasons, need other types of abortion procedures and so forth. So it seems like FDA might be able to provide one avenue that provides a little more access but not address the whole picture. And, of course, as we've seen with Rob Califf's nomination to be FDA commissioner being stalled or hurt significantly because of FDA's action on the abortion pill, this would be another tough political fight in the U.S., so it wouldn't be easy.

**Kenen:** But I also think that there's a difference between saying that while abortion is legal, access to telemedicine abortion should be expanded versus we don't know what the Supreme Court is going to do. And we just don't know what abortion rights are going to look like. There may not be legal abortion up to 10 weeks and the whole FDA versus the state could look different if it's a new landscape of abortion limits being sanctioned by the Supreme Court. If it's no longer a constitutional right, it's a whole different.

**Rovner:** Yeah, but that's sort of the whole argument. If it's no longer a constitutional right, then does the FDA override the state?

**Kenen:** I can't imagine this court allowing that.

**Rovner:** Yes, I imagine it would create another whole court battle.

**Kenen:** But if the court strikes [*Roe v.* Wade] or de facto strikes *Roe* and gives the state a green light to … We don't know what they're going to do. We don't know if it's going to be six weeks or 12 weeks or 10 weeks or 15. We just don't know. I just can't imagine that the Supreme Court, even if it's a second case, wouldn't grant the states the right to define that.

**Rovner:** Yeah, well, watch that space. All right. Well, let's turn to covid. The big news of the week seems to be the announced relaxation of mask mandates, particularly in blue states, starting with New Jersey and New York. Now granted the omicron wave is receding pretty fast and in some states the mandates won't actually expire for several weeks, but in Wednesday's White House covid briefing, [Centers for Disease Control and Prevention] Director Rochelle Walensky pushed back, reminding that the CDC is still recommending indoor masking where transmission is high, which, as she points out, is still most of the country, even if it is dropping. Is this just governors' recognizing covid fatigue and calling it quits? Or are they trying to sort of preserve their ability to maybe put mandates back if there's another variant or things get bad again?

**Edney:** It was interesting when I was reading the New York Times story yesterday when they were writing about New York lifting some of this, and it talked about voters like in the first paragraph — not just like for people, but for voters. And I think that this is really what a lot of this is for is there is pandemic fatigue. People both Republicans and Democrats who are really sick of a lot of it, and there are many who are not as well. But it feels like in Virginia, there was a governor's race lost because of some of the pandemic fatigue. That's been blamed for [Democratic candidate] Terry McAuliffe losing the governor's seat, and I think that they're trying to look ahead to the elections coming up and just making sure that that doesn't happen again.

**Rovner:** Although the first one out of the gate was New Jersey, where the governor just got reelected, barely.

**Kenen:** Barely.

**Edney:** Barely. I think it was a surprise to the governor and is trying to help out the rest of his party, right?

**Kenen:** Right. The New Jersey one doesn't take effect for almost a whole month. … I don't know the dates by heart of all the states.

**Rovner:** I think New York is pretty quick, but I noticed that several of them are, "yes, we're going to take off these mandates in a few week."

**Kenen:** But I wrote about this last week in the Nightly. I mean, we're in a different place. The pandemic is less bad than it was even six or eight weeks ago. There's still a lot of deaths, and that's going to take a while

to drop. There are people who are already sick, who have already been exposed, who are unvaccinated, who are vulnerable, and those death rates are still really high. We're still like 2,500 a day, roughly. But the caseload is really, really dropping, and the number of people, that pressure on the hospitals is beginning to decrease in many, many, but not all states. So I think, though, that the mistake public health and elected officials keep making is declaring it over, instead of declaring a lull. And we don't know what's next. And we're not educating the public to say: "Enjoy the lull, enjoy this period that's coming — it's not in all states, but it's coming. See people, do things, take off your masks if you're comfortable. Respect the people around you who need to be masked. This is good. We might have a really nice spring, but we don't know what this virus has in store. Maybe it has in store becoming milder and milder. And it'll be easy, relatively easy, to live with. But maybe it's just going to throw us one more curveball or two more curveballs or three more, that we don't know what the next variant looks like. We don't know if it's going to be better or worse. We don't know when it's coming. We don't know if it's coming. If we're lucky, we've hit the worst. How do we know that, right?" So that's what's missing. It's like, "OK, masks off." It's not "we are going to be able to take masks off, but we're going to have to realize we might have to put them back on." And that is really hard. It's hard to communicate nuance. And we have learned in the last two years that our public does not understand or listen or want to hear nuance. But it's necessary because otherwise people feel that it's whiplash, that they were lied to. That if the virus changes, it's not because some scientists lied about it, it's because the virus changed.

**Rovner:** Yes, we're still having trouble with this concept.

**Kenen:** There's also a myth that each variant will be less severe than the previous variant, and that is a myth. Viruses are not programmed to get … particularly if it bounces into an animal and out of an animal. We just don't know what it's going to do. Period.

**Rovner:** All right. Well, that's a good segue to the next question, which is one way to deter the next variant would be to get the rest of the world vaccinated so we'll be less of a reservoir for the virus to manipulate itself. But it seems that Johnson & Johnson, which makes the one vaccine that's pretty easy to move around the world and store and get out to people, quietly stopped producing its covid shot at the one facility where it was being produced in Europe so that it could make something more profitable. It's apparently going back to making covid vaccines, according to The New York Times. But in the meantime, hundreds of millions of doses have been delayed. Is this why so many governments wanted to license manufacturing of these vaccines to the underdeveloped nations themselves so that they were not at the mercy of companies basically whose job it is to produce profits for their shareholders? As I read this, the wheels started to go around in my head and I'm like, "Oh, maybe that would have been a good idea."

**Karlin-Smith:** Yeah, I think this is certainly one of the reasons why other why certain countries wanted more local control to make the vaccines. One thing in reading The New York Times' coverage of this, it made it really clear to me and reminded me, part of it is not just that J&J switched what they were doing at this one facility, but they've also had troubles at other manufacturing facilities that have impacted their supply and so forth. Very, very early on in the pandemic, where people were making these wild predictions about how fast we could get vaccines, one of the things that was often discussed with me as something that might stop it from happening faster was how complicated vaccine manufacturing is and how few places we have set up to do it. And it's not easy to set up new stuff. And I think this piece really emphasizes that that just the U.S. as a nation and on the globe, there's not a lot of spare capacity to make complicated medical products just sitting around empty for a pandemic. And, unfortunately, the developing world and places in Africa and so forth have paid the biggest price because they don't have some of the economic leverage that countries like the U.S. have had.

**Rovner:** I feel like this is a victim of the "just in time" manufacturing that has given us so much trouble with the rest of the supply chain and is giving us trouble with medical supplies as well.

**Karlin-Smith:** Right. And it was pretty interesting that the vaccine that J&J was pivoting to producing in this facility was an RSV [respiratory syncytial virus] vaccine for adults, which … The story talks about how outside of wealthier countries, very few adults really get tested or screened for RSV and are unlikely to get vaccinated for it and how far away that vaccine is. So it doesn't create a good public relations picture for J&J in terms of their decision-making.

**Rovner:** Yes, definitely.

**Kenen:** I mean, you really need a diversity of manufacturers because like what happened in India, where there is the Serum Institute, I think it's called. What are they making? AstraZeneca?

**Rovner:** I think so.

**Kenen:** When India had that big, horrific surge a year ago, the prime minister, [Narendra] Modi, said that all the generic vaccine had to be kept in India, so you can see his motivation. But that was supposed to be part of the global solution, and that got a stop put in that.

**Rovner:** Sidetracked.

**Kenen:** I don't know if that export ban has been lifted by now. I'm not sure of the current rule, but at a point when the globe needed those vaccines, they were cut off. Global vaccination is partly a matter of wealthier countries donating and assisting. They also have some of their own logistical problems and distribution given their roads and transportation, etc. And they have vaccine hesitancy. They have their own versions of it, and it's quite severe in some countries. So is it rich countries have to donate more? Yes, but that's not the end of the story.

**Rovner:** All right. Well, meanwhile, even though this latest crisis seems to be abating somewhat, our health care providers are still not OK. While many of us have resumed somewhat more normal lives, the people who held the hand of the people who died on ventilators are still suffering. And I worry that premature burnout might end a lot of health care/caring careers early. Is there anything anyone is suggesting that we can do to help these people, who we desperately need as a society? I really feel like this is still sort of being ignored. It's like, "Oh, they'll be OK now that they don't have patients stacked up in the emergency rooms anymore." And I feel like from everything I can tell, that is not the case.

**Kenen:** I mean, there are some hospitals … I only know about this anecdotally, through a friend. I haven't reported on it. There are some hospitals that are creating support groups and therapy groups for traumatized health care workers, which is also leading to trauma of the therapists because there's been so much trauma and so much death. I don't know how common that is. Those are the kind of … There are many tools. Staffing issues, when things are in a lull, do we have the capacity to let people take mini-sabbaticals and recuperate? Are there therapeutic tools and peer support? And then what are the workforce issues going forward? Because some people have left, and if they've left permanently, that creates a larger burden, particularly on the primary care and nursing workforces and ICU workforces. That means that even when the virus abates, if there are fewer people, they're overworked, and strain will continue until we … There are a lot of issues. Julie's written more about this, I think, than any of the four of us, on medical workforce and nursing workforce, and who's [being] trained for what kind of positions, and what are the incentives to change that, and where are they, and underserved rural areas and underserved urban areas, etc. So all those problems existed before the pandemic, and the pandemic made them

approximately 1.97 zillion times worse, rounded number. And we're just going to think really hard about this.

**Rovner:** All right. Well, speaking of people, of career paths, I want to talk about a couple of politicians. Health and Human Services Secretary Becerra seems to be getting a boost from his boss, President Biden, after a spate of stories about how Becerra has been somewhat missing in action, which we discussed at some length last week. Now there seems to be word that Becerra is going to be given a higher profile. He's appearing with the president today in Virginia to talk about drug prices. I guess the question remains basically whether his being pushed to the background was his idea or the White House's idea. I'm sort of curious for them to be saying now … It's like, "No, really, he's still here. He's doing a good job."

**Edney:** I thought about this when the Biden administration came on. It just felt to me like a continuation of [former President Donald] Trump and how he was dealing with HHS secretary as well — set up a White House task force for dealing with covid. And that seemed to be to me what Biden was doing as well and was kind of surprising that … why not bring the health secretary in? But they didn't, and they kind of kept it in the same status. And so, to me, it didn't seem exactly like something detrimental, that it meant they didn't support Becerra, but rather that they were just continuing the same thing. And it makes sense that people started wanting to see more of him, especially Latino groups that were wondering why he was being still pushed to the side.

**Rovner:** But the timing was that the administration came in and hit the ground running with covid long before Becerra got approved.

**Edney:** That's true, too.

**Rovner:** Before he was even really nominated. He was one of the later Cabinet approvals.

**Karlin-Smith:** He wasn't their first choice. So that again has raised questions about whether they maybe did purposely, to some extent, not want him on this big task. Although again, I think the other thing for me that I think a little bit about is the timing of all the criticism of Becerra and the covid response. It seems a bit to me like potentially a play by the administration to distract from some of their failings on the covid response and make Becerra a fall person for that, rather than think more broadly about their misses and so forth. So it's hard to really know whether he's being fairly criticized or maybe …

**Rovner:** Scapegoated!

**Karlin-Smith:** Yeah, made a scapegoat.

**Kenen:** There's two thoughts. I mean, some of it is a little bit self-inflicted because there are areas that he could have been more visible in, even if he was deferring to the White House, he could have stuck his head out more than he did. I mean, we really didn't see him very much.

**Rovner:** He was pretty front and center on the Affordable Care Act.

**Kenen:** One or two focal [points] but not super visible. The Trump analogy that Anna just spoke of, the White House under Trump, their task force was actually headed by Azar at the very beginning — the then-Secretary Alex Azar — that lasted about three weeks. And then they put, they kicked Alex off, Alex Azar off, and they put [Vice President Mike] Pence in charge, and they let Azar sort of say hi once in a while, but he was pretty sidelined. But if you go back to the ACA and [President Barack] Obama, Kathleen Sebelius was not the first choice, either. She was pretty invisible during the passage of the ACA. It was really run by the White House and Nancy-Ann DeParle and Sebelius then was charged with implementation, which was a

mess. So, I mean, healthcare.gov and all that. So there's precedence, all of which are not great for the HHS secretary. Do I think he can survive? Yes, I do. I don't think they really want the optics of firing him. I don't think they want the optics of the hassle of trying to get someone else confirmed. I think they'd like to keep him, but they're going to have to help him look like he's running the department and he's going to have to also look like he's running the department. You know, he knows more. I mean, Julie and I have covered him for a long time on the Hill. I mean, he does understand the health care system because he was on Ways and Means, not just Ways and Means, he was on the Ways and Means Health Subcommittee. He is not a doctor, he is not an infectious disease specialist. He is not a pandemic expert. But frankly, half the pandemic experts don't seem to be very expert on pandemics. He does understand the health care system. He understands Medicare, Medicaid, ACA insurance, he knows that. He understands antitrust because he was really a leader in that when he was attorney general of California. So I don't think that he's a health care no-nothing, by any means. I think he actually has a fair amount of expertise on the health system, the health care system. On the pandemic, no, it's not his skill set, but he also hasn't been able — either through his own choices and his advisers' choices or the White House structure — he hasn't been able to look like he's even in that loop.

**Rovner:** Well, the person who has been front and center in all of this and who actually technically answers to the HHS secretary is Tony Fauci from NHS, who is, I believe, the president's official medical adviser. And at the moment, Fauci appears to be taking [House Speaker] Nancy Pelosi's place as the top punching bag for Republicans, in addition to Republicans like Rand Paul taking him on in person in hearings, now congressional candidates are using him as the covid boogeyman. This seems a little bit more obvious, maybe, than what was going on with Becerra. Fauci represents everything Republicans hate about bureaucracy and science and government. But I'm wondering if this could eventually backfire by alienating non-base Republicans, if there are any left. Republicans can certainly all unite around hating Nancy Pelosi. Can Republicans really unite about hating Tony Fauci?

**Kenen:** They're doing a pretty good job so far. I mean, the irony is that Tony Fauci — who is either 80 or 81 and who has been around for every public health crisis, basically, and for decades, going back to at least AIDS and maybe further back than that — has this ability to communicate very clearly and in plain English, he can talk science and translate it. And he was considered a hero by Republican presidents. I think it was President George …

**Rovner:** It was H.W. Bush.

**Kenen:** Right, who gave him the Congressional Medal of [Freedom] for public service. I mean, he has had a lot of Republican allies, and early in the pandemic, he gave my colleague Sarah Owermohle a great quote about working with presidents. And he said, "You never want to go to war with your president." But what happened is his president went to war with him. That was Trump. And that has changed the entire trajectory. I mean, had Tony Fauci been in his traditional disease-whisperer kind of role, you know, anthrax, — he explained it to the whole country and the whole country listened and was basically grateful. HIV, other dangerous flus that didn't turn out to be quite as dangerous as they might have been. He's been out there for every public health crisis since at least the '80s. He's been at NIH since the '60s.

**Rovner:** He heads the NIH Institute [of Allergy and Infectious Diseases]. It's his job!

**Kenen:** But he was a young scientist before he even ran it. I mean, he's been there his entire adult life, and it really comes down to a dynamic that Trump set up.

**Karlin-Smith:** I was just going to say, this continued dynamic of the politicization of expertise in science that's so unusual and seems really difficult to counter because, again, topics and people that you would

never think of as being political, that would be seen as more fact-based, nonpartisan have suddenly been pushed into this political role. And how do you counter that when Fauci is just trying to say, I'm not, you know, presenting you a Democratic or Republican message or a liberal or conservative message, I'm just presenting you the health information and Republicans are saying something totally different.

**Kenen:** Right. And if you actually did fire Tony Fauci or if you just hounded him into retirement, the virus would still be there. You can't … it's not like, OK, we got rid of Fauci, everything's over now. You know, it's like shooting the messenger. And unfortunately, the death threats are real. I mean, that's what some people want to do. The fact that he hasn't made the virus go away at a press conference is because the virus doesn't watch press conferences.

**Rovner:** Yes, and the virus is not a Democrat or Republican, either. Well, speaking of people who are definitely not getting a boost from their boss, science adviser Eric Lander handed in his resignation this week after an investigation found he mistreated employees. He did not get, as President Biden had initially promised, fired on the spot for disrespecting underlings. But I'm wondering how his still relatively sudden departure will affect the president's science portfolio. I know this is a little bit off-topic for most of us, but he was working on that ARPA-H [Advanced Research Projects Agency for Health] issue. Right, Sarah?

**Karlin-Smith:** Yeah. And I think there are people that are worried a little bit about maybe what impact the "Cancer Moonshot" or other scientific projects that were pet projects of Biden may be impacted by this, although I think there are other people that were working under Lander that have been reported to being close to Biden and so forth. The other thing I think that just came up at a hearing earlier this week about ARPA-H is even if people want to focus on the more policy aspect of it, sometimes just dealing with the fallout of his resignation and why he resigned just creates a distraction that just takes time and wind out of the sails and just creates some delay.

**Rovner:** And we should mention what ARPA-H is before we before we leave this topic.

**Karlin-Smith:** Right. So it's like a new health agency the Biden administration wants to create that would be less basic-research-focused than NIH. The idea is to take big risks for big rewards and maybe put money into areas that are seen as even too risky for certain parts of the industry to really try and make big gains in devastating diseases like cancer, Alzheimer's and so forth.

**Rovner:** It's something we will have a longer discussion of in another podcast. That's as much time as we have for the news this week. Now it is 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. Joanne, why don't you go first this week?

**Kenen:** This is from The New Yorker by Jessica Winter: "What Happened After the Chicken-Pox Vaccine? In the COVID era, the success of the varicella vaccine in the Nineties is staggering to contemplate." I mean, that was a brand-new vaccine. Chicken pox is usually very, very, very mild for kids. Seventy children a year were dying at that point. And the vaccine, the uptake was strong. It always, historically, there have been some [people who were] vaccine-hesitant and some anti-vax, yes, but it was not a big thing. This was prior to the autism scare that came a few years later, and it's certainly obviously prior to what we're seeing with covid. But, you know, 70 kids a year, we still vaccinated every kid, versus covid — the first two years there were about 660 deaths of children and many, many more who went through the trauma of severe illness, ICU hospitalization, oxygen, all that. Thankfully, it has not been as hard on kids as it has been on adults, but it's not nothing.

**Rovner:** That's right. And obviously, to the extent you can get rid of chickenpox, you can get rid of shingles in adults, which is *not* mild.

**Kenen:** Right, right. So anyway, it's just an incredible difference in societal response to a childhood disease that had been taken for granted. The article notes that the risk factors for chickenpox, basically, before the vaccine was being born, being a child — you know, almost everybody got it. My little sister got it when she was 6 weeks old, and that was scary, for really, really little kids. Well, we all got it when she was 6 weeks old, but she was the only one who was 6 weeks old. But for the older kids, it wasn't a big deal. It was a little bit scarier for an infant. And she was fine. But we still all got it. … The next one got vaccinated. The one who was born after that got vaccinated.

**Rovner:** Yes, the world was a different place for vaccine hesitancy. Anna.

**Edney:** This is a special report from Reuters: "Inside J&J's Secret Plan to Cap Litigation Payouts to Cancer Victims," by Mike Spector and Dan Levine. It looks at this issue with asbestos-tainted talc and baby powder that people … there are a lot of lawsuits out there and some are being won and some are being lost against [Johnson & Johnson]. A lot of them are women who have ovarian cancer because they used the baby powder, over many years. And it's this tactic that Reuters has done a great job of bringing to light over a few articles that is similar to something Purdue has done with the OxyContin lawsuits as well, and that J&J created this other arm of its company and is dumping all the lawsuits into that company. And then it … they'll declare bankruptcy, and they will only have to pay out [to] the victim a very small amount. And the article goes into detail about this and about the project that J&J instituted to work on this, which is really fascinating. They told, I think it was a dozen people or so, you can't even tell your spouse about this, you can't tell anybody about this. And they know how bad it looks. And there is legislation being talked about to try and get at these tactics because it's happening more and more. And more and more the courts are the only place that people can go to get some sort of compensation and decision on whether these things are actually harmful. We're not seeing it from the regulatory agencies; they're not getting any help there. And so I think it's a space that's important to watch.

**Rovner:** It is. Sarah.

**Karlin-Smith:** I looked at a piece by Nicholas Florko at Stat News: "Despite Biden's Big Promises and a Far Better Understanding of the Virus, Covid-19 Is Still Raging Through the Nation's Prisons." And it basically goes through a number of ways where Biden has sort of promised to help work with the Federal Bureau of Prisons and change covid protocols to protect those people who are incarcerated and how that really hasn't panned out. There's still a lot of problems with adequate testing in prisons, adequate isolation and quarantine policies, that people are positive. They haven't done the best job in many cases of getting people vaccine and booster shots. And it seems if people have been offered the shot and initially said no, there hasn't been a lot of effort to really work with them and try and help understand why they're hesitant and so forth. And this is a population that because of the communal nature of living and so forth, has been disproportionately impacted by covid, particularly if you look at younger ages and so forth. So just a good piece kind of fact-checking how well, again, the Biden folks have followed through with that commitment.

**Rovner:** Yeah, really, really important piece on a really ignored subset, but important, of the population. My story this week is from my KHN colleague Jenny Gold, and it's called "Ready for Another Pandemic Malady? It's Called 'Decision Fatigue.'" It's an interview with the psychologist who wrote the book about how too many choices are just as bad or worse than too few choices. And he points out that the pandemic has forced us to make sometimes life-or-death choices on a regular basis that has us all exhausted. I actually felt a little bit better after I read this. I hope that you will, too.

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. Joanne.

**Kenen:** @JoanneKenen

**Rovner:** Anna?

**Edney:** @annaedney

**Rovner:** Sarah.

**Karlin-Smith:** @SarahKarlin

**Rovner:** We will be back in your feed next week. Happy Valentine's Day. Until then, be healthy.