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, Sept. 23, 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 videoconference by Joanne Kenen of Politico.

Joanne Kenen: Good morning, everybody.

Rovner: Sarah Karlin-Smith of the Pink Sheet.

Sarah Karlin-Smith: Hi, Julie.

Rovner: And Mary Ellen McIntire of CQ Roll Call.

Mary Ellen McIntire: Hi, everyone.

Rovner: Later in this episode, we'll play my interview with Scott Gottlieb, former commissioner of the Food and Drug Administration and author of a new book about the covid pandemic. It's called “Uncontrolled Spread: Why Covid-19 Crushed Us and How We Can Defeat the Next Pandemic.” Scott has never been one to mince words, and I think you'll be interested in what he has to say. But first, this week's news.

So, Congress is back for real this week and Democrats are in — wait for it — disarray. And it's not just President Biden's big domestic agenda that's hanging in the balance. Congress has just one more week to pass all of the spending bills or a continuing resolution to keep that spending flowing after the start of the new fiscal year, Oct. 1. Congress also needs to raise the so-called debt ceiling. They have vowed to do those things together, the debt ceiling and the spending bill, without apparently any help from Republicans. Meanwhile, House leaders have promised Democratic moderates that they would vote on the bipartisan, quote, hard infrastructure bill by next Monday. But liberals say they won't vote for that bill unless they get to vote for the big social spending bill first. Mel, the sausage-making is never pretty while it's actually happening, but this is an even bigger mess than usual, right?

McIntire: There is just so much happening it's hard to keep track of what different people are talking about and doing this week on the Hill. I just feel like there's a lot going on this week, especially government funding and the debt ceiling are sort of top priority. We've got a week before government funding runs out, trying to figure out a way to do that. And then, at the same time, what I've been really focusing on is the reconciliation package with all of the drug pricing and Medicare and Medicaid and ACA provisions that the House committees marked up
last week. And the Senate is sort of trying to figure out what could get 50 votes here, trying to balance all the different priorities. You've got Bernie Sanders really pushing an aggressive drug pricing package and Medicare expansion, and Ron Wyden is still trying to kind of thread the needle with some sort of drug pricing package. And he definitely wants to go as far as he can, but sort of seems to be, you know, holding the cards close to his chest, doesn't want to come out with anything just for it to become, as one source put it to me this week, a piñata, which I think kind of squares with what he's been doing. But, yeah, there's a lot going on. Congress is back and they are Congressing and it's kind of hard to see what the end of the road is at this point.

**Rovner:** I feel like everybody went to the White House yesterday and nobody said anything afterward, which actually can be a good sign, right?

**McIntire:** Yeah, I think it did not seem like anything became worse after the White House meeting, which is a good sign. Everyone is still at their sides, but there seems to be some sort of desire and acknowledgment that they kind of need to come up with some sort of package here. I think, you know, in the short term, the biggest questions are what happens with this infrastructure vote that is technically set in the House for early next week, on Monday. Progressives say they have the votes to take it. The thought is that they probably don't want to have this vote just to have it fail. But what sort of happens there? And then, of course, what happens with some sort of government funding bill? Can they, can Democrats get 10 Republican votes in the Senate to pass it? It is not looking likely. Sen. McConnell seems to have his members really in lockstep on that. So that's sort of the short-term question. And then in the next couple of weeks, depending on what happens there, I think you start to see more clarity on what happens with the reconciliation package and how it starts to take a little bit more shape.

**Rovner:** So, where are we with the drug pricing changes? Democrats obviously need to rein in drug prices, partly because it's something they promised to do and it's popular, but also in order to pay for the other health expansions for Medicare and Medicaid and the Affordable Care Act. But moderates in the House and the Senate don't want to go as far as liberals on either drug savings or benefit increases. Obviously, last week we talked about the fact that drug price changes couldn't even get out of the Energy and Commerce Committee. It failed on a tie vote, although they did get out of the House Ways and Means Committee. So, it does look like they're going to put them in the package, right?

**McIntire:** Yeah. So, I believe it's not clear yet to me if the Budget Committee will meet next week to sort of take the next step in the process on the House side. But that would be the next step. And yes, they have the drug pricing provisions from Ways and Means. Rules could always put them back into the Energy and Commerce Committee section, if that's something that they need to do. Negotiations are still happening here. You have the moderates, who are sort of trying to talk to the senators to see where they could be. You have, you don't really have Democrats who are saying that they don't want any negotiation at this point or any drug pricing
provision. So, I think people are trying to figure out what can some of these moderates, what are they looking for? You have the Scott Peters and Kurt Schrader bill for Part B negotiations, not expanding the Part D, is that sort of a starting point? Is that something that people can get behind? Someone like Tom Carper, who ... Delaware is a state that has a lot of pharmaceutical industries. He's saying that he does want something bigger than that, but less than the $600 billion that was in the House bill that they put out. So, there's a lot of negotiating and talking back and forth going on, and I think you also have people starting to sort of figure out what exactly their top priority is. So, Scott Peters is obviously against H.R. 3 but wants some sort of negotiation in there. Congressman [Lou] Correa, who is someone who signed on to Scott Peters’ bill, has sort of made clear this week that, yes, he signed on to that, but his top priority is immigration. So, I do think you're going to start seeing people trying to figure out in this massive bill what is most important to them and where they are really trying to put their energy. When I talked to him earlier this week, it sort of seemed that, well, if immigration isn't there, that's where I'm putting my attention right now. Not necessarily drug pricing.

Rovner: But, of course, the parliamentarian in the Senate has said that immigration can't be in there, which is part of the whole insanely difficult balancing act — or as people like to call it, it's like a huge Jenga tower.

McIntire: And there are questions on the health care stuff. And drug pricing in particular, about what will get past the [unintelligible] and the parliamentarian. That is an area that, you know, Republicans are expected to bring arguments to the parliamentarian in terms of budget rules. So that could come up again in the health care space as well.

Kenen: We have all covered a lot of huge deadlines, either the fiscal year, Oct. 1 or whatever. There's always deadlines. And we've covered big, huge, messy legislative fights. The amount of moving parts on this one, both the politics and the policy and the money and how many things are coinciding or colliding. And we're not talking weeds. You know, any one of these things could have been the subject of a huge piece of legislation in and of itself. So, it's not like weeds; it's like sequoia forests on fire. And it's, I don't know what the, I don't see what the endgame is. The idea of everything coming crashing down is unlikely but not impossible. And, I mean, do they have to do something temporary and keep fighting about this into the coming weeks? It's quite, quite possible. We've seen that happen before. It's really complicated. An enormous amount is at stake.

Rovner: Well, one thing Congress is exceptionally good at is kicking the can down the road. You can usually bet on them to kick the can down the road.

Kenen: And we expect some of it will be punted, right? But it's just pretty epic. And the amount of, you know ...

Rovner: Before we get off this, I was going to say you literally cannot turn on the TV without seeing a half a dozen ads sponsored by the drug industry warning of terrible things that will happen if Medicare is allowed to negotiate drug prices. And somebody asked on Twitter, you
know, when's the last time the drug industry actually lost one of these big fights? And I was having trouble remembering. I mean, I remember when the tobacco industry was unbeatable until it wasn't. Is the drug industry as strong as it has ever been?

**Karlin-Smith:** I think they're pretty strong right now. Covid certainly has helped them. Yesterday, at a speech at his covid summit, President Biden called the CEO of Pfizer his good friend. You know, I think some of the hits I'm thinking of that they have taken and, you know, I guess it's not so recent anymore. They paid a lot of money to kind of, they would argue it was a big hit in the ACA. To some extent they paid that money to kind of get out of more regulation. So, it's a trade-off.

**Rovner:** Yeah, they negotiated that.

**Karlin-Smith:** It seems like at this point they're going to take some hit. It's just the extent of it. So, can they keep it to sort of a more moderate revamp of Medicare Part D, which they might be more OK with, particularly if it helps seniors reduce their out-of-pocket costs and gets them off the hook? Or do they get into more tricky situations like government negotiation of drug prices in Medicare Part D or Part B? And then, of course, there's broader plans to try and even expand that to outside of the Medicare space, which I think would really hit them hard.

**Kenen:** No, I mean, I think Sarah made the same point that there's two things colliding, right? Or two separate, parallel tracks. The country, poll after poll for several years now, has really shown that Republicans, Democrats and Independents all think that drug prices have to come down. And that's been strong and consistent, across the political divisions. And yet, as Sarah said, we are in an era — I mean, covid, they have come up with fast, somewhat remarkable things. There's more to be done on therapeutics, obviously. But, you know, clearly the vaccines and some of the early drugs are saving lives, the monoclonal antibodies, and even before that, I mean, we really were sort of in an era of innovation. There's a lot of interesting new drugs that aren't just copycat me-too drugs. There's been genuine breakthroughs and new developments. So, there is this tension. But, I mean, I think the public says, “We want both.” You know, “We want the breakthroughs, but we don't have to pay quite this much.” You know, people are hit directly with drug prices when they buy them. Whereas not everybody goes to a hospital every year. But, you know, many, many people either buy a drug or have a family member buying a drug. So it's more common to have firsthand experience.

**Rovner:** It's why it's always sort of near the top when you ask people what's their biggest concern about health care costs, drug costs — not because they're necessarily the highest, but because they're the most visible to the most people.

**Karlin-Smith:** When people see those industry ads, too, saying, you know, if you attack our pricing at all, you know, you're going to lose out on innovation, you're not going to be cured of X, Y or Z disease, I always try and point out — and there was a good op-ed in The Washington Post yesterday by some Harvard professors addressing this — that, you know, not all the incentives in our current system incentivize the best innovation. Not every drug that gets
developed is probably considered worth the price. Some are incremental advances. Sometimes companies are incentivized to work on incremental advances and keep profits on a drug that will still remain on patent. And a number of years ago, a chin fat drug got approved in the U.S.

**Rovner:** Excuse me?

**Karlin-Smith:** Yeah, it's basically, you know, I guess it helps remove some of the fat under your chin. So, you know, yes, I think people will have a right to be concerned: If we hurt this industry's profits, what happens to the medicines we want or need? But it's not quite as straightforward as the industry would like you to believe in terms of the innovation that is happening now and what we would really lose if some of their profits were cut. And you also have to remember, the industry often always says, you know, like the U.S. gets all these drugs that other countries don't get, like Europe is a little bit tighter on controlling what they give their citizens based on cost-effective analyses. But, in many cases, Europeans actually live longer and better lives than Americans. So, you know, you always have to dig a little bit deeper than some of those ads initially want you to feel.

**Rovner:** But there sure are a lot of them. All right. Well, let us move on to covid, where things are still not great. This week, we officially passed a milestone where covid has killed more Americans than the 1918 flu pandemic. Guess [that’s] something we can tell our grandchildren. Sarah, I am glad you are here with us this week. Where are we on the booster question, other than really confused?

**Karlin-Smith:** You know, you always do the caveat at the beginning of the podcast. This week I think we're really in a tricky situation because at noon a CDC advisory committee is going to start debating a decision FDA made late last night about 8 o'clock to clear Pfizer's covid vaccine for a booster in certain populations: people 65 and older, people who are considered, 18 and over, at high risk of severe covid, and then people who, because of either the situation they live in — like, are you in a prison, a long term-care facility? — or because of their occupation, like being a health care worker, they're at high risk of covid or complications from covid. They'll vote on that at 3. CDC ACIP has a lot of — Advisory Committee on Immunization Practices — has a lot of ability to kind of tailor what FDA has done, and they can rein that in a bit if they feel that is an authorization that went too far based on data and current situations, including factors FDA doesn't really take into account in their decision-making, like the global health equity situation, with lots of people in the world needing their first shots. So, based on the conversations the CDC’s committee has had so far, it seems pretty likely they'll rubber-stamp the recommendation that people 65 and older get the vaccine, or the booster shot. I'm a little bit less clear how comfortable they will be with the other populations because there's just a bit less data on the need for boosters in that population. And they seem concerned about that. And, actually, I want to step back, and I made this mistake initially yesterday, too. I think another big issue that's going to come up is right now FDA has only cleared Pfizer's shot for people who got Pfizer's initial vaccine series. And CDC’s committee seems to feel like really we need to have a booster campaign that's not tied to what initial vaccine you got. And it's not
clear if they have the flexibility to say, “If you got Moderna, or you got J&J, you can also get this Pfizer booster.” And I think that's going to have a lot of tension because they feel like that's unfair, that's confusing. And we should hopefully in the next month or so have more data on the other vaccines and products. So, is there a chance they try and punt this a few weeks or a few months? I don't think the political situation may easily let them do that. But today's meeting is certainly not going to be kind of a sure yes vote for this booster campaign to move on quickly.

Rovner: And it didn't help that the Biden administration basically targeted this week as their rollout. I mean, I get what they were trying to do, which was to say, “When this is approved, we want to be ready with the rollout plan.” But it looks like the rollout plan got ahead of the when-this-is-approved part.

Karlin-Smith: Yeah, I think putting a specific date on it really confused the public. It's one thing to say, you know, our top scientists are concerned that we may need boosters and they're working on evaluating it. We'll keep you updated. But we just kind of want to give you a little bit of forewarning so people who need to plan can plan and people can maybe get comfortable with the idea that they might need a booster shot. It's another thing to say, like, eight months after you got your vaccine series, we're going to start boosting people and it's going to start Sept. 20. In Colorado, Maryland, some state governors have kind of gone ahead of, gotten ahead of the FDA and CDC and already tried to start rolling out these campaigns. CDC has tried to pull them back. We certainly know a number of people have just been trying to go to pharmacies and get a booster. And it seems like some of them are succeeding without the recommendation. So it's certainly created logistical issues.

Rovner: Yes, it's kind of a mess. So, in the meantime, with all of this going on, there is still no sign of a nominee to head the FDA. My KHN colleague Rachana Pradhan has a great story out this week about how this is starting to, I won't say panic people in public health, but it's certainly frustrating people in public health. I mean, I feel like we talk about this every couple of weeks, but I feel like we should talk about this every couple of weeks.

Kenen: They're really lost. I mean, I think we're all hearing that they don't really have a plan, that they thought they could get Janet Woodcock through. They kept thinking they could get Janet, who's the acting head. ... She's temporarily running it and she's been there for years. They thought they could get her through, and they kept thinking they could get her through long after we all realized they couldn't. So, you hear these names floated, but none of them are real. I don't know who it will be or when it'll be. They have to do something by November. Sarah probably knows the exact date and how that works. They can have, they don't have to have somebody confirmed and in place, but they have to take the next move. I mean ...

Rovner: They have to have somebody nominated in order for her to stay on and then she can stay on as acting until the nominated person is approved.
Kenen: Which could take a long time. And, you know, we've also been all told that not a lot of people want the job. That it's difficult, you know, and it's somewhat thankless. You know, it may be somebody that we haven't heard of who's not on our radar, who is maybe an academic who works on [unintelligible] issues. You know, some of the FDA commissioners were not household names. We didn't all know who was coming. So, it could be somebody very competent who is outside the political world. Sarah, who covers this more closely than the rest of us, may know more. But it's like ... when people were saying in February, “There's no FDA commissioner!” — that's pretty normal, even in a pandemic. February, March, you know, you had a competent person there. You didn't, it wasn't like there was nobody; it wasn't like it was an empty building. But October, November, in a pandemic? Even without a pandemic, it would be crazy. But in a pandemic, this is really pretty extraordinary.

Rovner: Yeah. FDA is pretty high-profile right now not to have even a nominated commissioner. All right. So, while we were debating who to give an additional dose to, President Biden at the U.N. this week is promising to give millions more doses to countries around the world whose citizens haven't been able to get their first shot yet. But vaccinating the world is about a lot more than just providing the doses, right? There seem to be issues beyond actual just vaccine supply, right?

Karlin-Smith: There are issues in the Biden administration, I think also made a commitment yesterday to help in this regard, just in terms of actually getting shots to where they need, having the infrastructure and people to administer them. But it still seems like the biggest obstacle right now is just the amount of supply that's going to the world. Even ... so, the U.S. has now basically committed to donate a bit over 1 billion vaccines. I think they've only given a very small fraction of that right now, about maybe 150 million at the most. And so that conversation has really started to intersect with the booster conversation. And basically at the beginning of this process, there is this initiative created called Covax, that the idea was to try and get both wealthy and less wealthy countries to kind of participate together, pool resources and kind of help make sure the entire world could get vaccinated. Essentially, what happened is a lot of wealthy countries aren't participating or they sort of cut these side deals that have basically made it impossible for Covax to get the deals they need with companies or get the deals fast enough. There was an interesting article in Roll Call, I think this morning, that talked about how Biden made his grand announcement yesterday. Then they turn the cameras off and there is a lot of discord among the other international leaders there about what's actually going on with vaccinating the entire world, because I think it's about 1 to 2% have gone to really the lowest-income countries. And most of the vaccines have still gone to wealthy nations. And at this point, I've seen these horrible predictions that if the pace kind of keeps up, you know, huge portions of the world won't get vaccinated for years on end at this point. So, I think the Biden administration certainly likes to say the U.S. has donated the most shots of any country and pledged to do that. But at this point I think the global community feels like we need to move beyond donations, particularly given the pace that these donations are rolling out, and figure out how we can kind of transfer some of the technology from some of the vaccine companies
and allow more production of vaccines and access to the recipes to make these vaccines in different parts of the world.

Kenen: And remember, it's both the moral imperative of helping poorer countries [and] it's also totally in our self-interest because more variants will arise, and they will arise in unvaccinated populations — delta being the worst one we've seen, and the entire world is not coping with it, but enduring it. You know, to the best of our knowledge, it emerged in India, where there were like a billion unvaccinated people, and that will happen again and again. And some of them will be less dangerous and some of them could be nightmares. So, it's not just “We need to help them because it's the right thing to do.” We need to help them because we have no choice.

Rovner: And it's the right thing to do for us. Meanwhile, for people who don't get vaccinated, as well as people who do and get covid anyway, they are now, at least here, at much higher risk for big bills, thanks to the expiration of most insurers’ policies to absorb all of the costs of treating covid. Could this impact vaccine behavior, or will it become just another piece of bad news in this whole pandemic?

Kenen: It adds to the confusion. You know, it just ... if you keep hearing about breakthroughs in people who already [have been vaccinated], why should I get it? I'm still going to get sick, etc. People don't understand that most breakthroughs are, in fact, mild. I don't want to get a breakthrough. I mean, you know, “mild” in how a doctor describes “mild” means, you know, your organs haven't failed, but some people still feel really, really sick. And then, you know, we don't really know what the risk of long covid is in breakthrough cases where, you know, it's possible. We think it's less likely or less severe. But there's a lot of unknown about that. It's just another layer of “Huh?”

Karlin-Smith: To me, this decision seems to reflect more on our broader health care system challenges in the U.S. than the covid crisis in particular, just because it brings up this sense of why did some people get, you know, relieved of that burden and not others? And it's not just a covid-specific situation. We know that depending on what disease or ailment you have in the U.S., you may be subject to huge long-term medical bills for your entire life. If you have medical debt and other people end up more fortunate based on maybe the price of the products they need or the price of the surgery. And I think that's kind of what it highlights is, why [is] some of this arbitrariness baked into it and why do we sometimes put so much burden on people who are sick?

Kenen: Yeah, I mean, you could go into a hospital last year when the health plans were paying for it with two people, same socioeconomic, same symptoms, same everything. Both 64 years old on the same commercial health plan. And they both had respiratory failure. And one of them turns out to be covid and their bills got paid. And the other one turns out to have plain old old-fashioned pre-covid pneumonia and their bills aren't paid. So, it's just more craziness.

McIntire: The average person also probably isn't aware if their health insurance plan stopped paying at some point covering certain covid things. Like, it wasn't like there was, like, “OK, on
this date, this all ended” that was widely covered. It kind of seemed more sporadic in how it went. So, I'm just not sure anything like that is going to convince people. But I mean, to Joanne's point about how mild breakthrough cases [tend to be], my colleague wrote a piece this week. She had a breakthrough case, like, two weeks ago, and she was basically like, “‘Mild’ means you don't need oxygen and you didn't go to the hospital. Like, it does not mean ... because I run very long distances and I could not get off the couch without feeling like I had just run a marathon.”

**Kenen:** Right. But if people begin to feel afraid of cost ... [unintelligible] like, I really actually don't know what my health plan is doing right now. But I know that I basically have decent insurance and if I got really sick, I would go to a doctor. There are people who can't afford their copays or can't risk those big bills. And again, you know, with these breakthroughs and what's serious and who has what and, I mean, rapid treatment is important with covid. If you're ... at risk, you know, if you have to lie on the couch and feel crummy, but you can breathe and you don't need emergency care. But for people who are at risk, some of these drugs only work or work best if administered very, very early. So, seeking care and not being afraid because of the cost, because the cost only gets worse if you end up in an ICU, and, of course, the risk to your health only gets worse. So, the word we used to use before we got serious with a pandemic was “crazypants.” And I think in this conversation we can restore it — with due respect to [Michigan health law professor] Nick Bagley, who introduced it to us.

**Rovner:** Yes, more evidence of dysfunction in the U.S. health care system. All right. Well, speaking of dysfunction, let’s talk about abortion. The fallout continues from that Texas law that depends on individuals to sue to enforce it. We have our first lawsuits thanks to a San Antonio OB-GYN who advertised that he had performed an abortion in defiance of the law by writing an op-ed in The Washington Post. And sure enough, there are now at least two people suing him. But this isn't exactly what anti-abortion forces in Texas were hoping for, right?

**Kenen:** One of the people suing him actually described himself as what, a disgraced lawyer who's in jail? I can't remember all the details.

**Rovner:** He's on home confinement.

**Kenen:** Home confinement after I think it was a 15-year prison term — you know, described himself that way, as like “I'm a bad guy, but I'm going to get this $10,000.” And it's about, you know, the critics of the law say it's a bounty system, bounty hunters. Some polls have shown it's very unpopular, but right now it's still difficult legally to fight. So this is round one in the fight and we'll see how it plays out.

**Rovner:** Apparently, both people who've sued, though, are suing to try to invalidate the law. They're not so much anti-abortion forces trying to get this doctor. In both cases, they are people who want to get, who want to create a lawsuit so that the court can strike it down, except that there was actually a Bloomberg story suggesting that if they're not on the other side, then this may not be, you know, clean enough lawsuits to have the law, you know, fully
discussed by a court. So, this will continue to go on for a little while longer. Meanwhile, the Supreme Court has scheduled oral arguments in that Mississippi case that we all thought could be the end of *Roe v. Wade* before this Texas case happened and still could mark the official end of *Roe*. The arguments will be held on Dec. 1. So mark your calendars. And in anticipation of that, the House is scheduled to vote on a bill that would write abortion rights into federal law. This is something Congress tried to do the last time it seemed that *Roe v. Wade* was on the precipice of being struck down. But the House didn't have the votes. Do they have the votes now? And, Mel, I mean, you know, we were talking about all of the insane things that Congress needs to do in the next week. Did they really need to do this, too?

**McIntire:** This was something that Speaker [Nancy] Pelosi said they were going to bring up, sort of in response to the Texas law taking effect. Trying to show that the politics of abortion — you know, they have changed, particularly among Democrats. The House, it does seem, will have the votes to pass this. That is not necessarily the case in the Senate, as we have discussed so many times on so many different issues in the last several months. But, yeah, I think …

**Rovner:** I think it's safe to say it's certainly not the case with the Senate, 'cause they would need 60 votes, even if they had all the Democrats, which they probably don’t.

**McIntire:** Yeah, I think it is interesting. You have seen more House Democrats come out and say, you know, “I may be personally opposed to abortion, but I'm, you know, in the case of this Texas law, this is changing how I think about things.” So, it does appear that the House will be able to pass this bill when it comes up potentially tomorrow. I know it’s supposed to be this week. ... It won't really go anywhere, though. It's not expected to come up in the Senate. I think Senate Democrats are trying to figure out, you know, what maybe they can do in this space, but it's not something that's expected to go anywhere. But I think you are going to see more of these types of votes coming up, especially as Democrats are trying to make abortion more of an issue for the midterms.

**Rovner:** Yeah, I mean, it's clearly a signaling bill. I'm fascinated because the last time the Democrats tried this, which was back in 1992, they didn't realize, I don't think, until very near when they brought it to the floor, that they didn't have the votes — that there were a lot of Democrats who thought, you know, even though they call this a bill that will write the protections of *Roe v. Wade* into law, it could actually go much further and strike down a lot of abortion restrictions that the Supreme Court has allowed to stand since *Roe* was decided in 1973. And we've already seen Susan Collins, who, you know, calls herself, you know, a pro-abortion rights Republican, saying she wouldn't vote for this bill because it goes too far. I wouldn't be surprised to see other Democrats say that, too. And I think that the people on the other side of the abortion debate are also going to see this vote as possible campaign fodder. I just wonder which way it's going to cut, if ... even if it just passes the House.

**McIntire:** Yeah, I think time will tell, particularly with a bill kind of as broad as this one.
Rovner: Yeah — that didn't go through committee in this case. We will watch that space. All right. That is the news for this week. Now we will play my interview with Scott Gottlieb and then we will come back and do our extra credits.

Rovner: We are pleased to welcome back to the podcast Dr. Scott Gottlieb, who I believe is our first three-time guest. When we last spoke, Scott was about to step down as commissioner of the FDA. And if you weren’t familiar with him then, you probably are now, as he’s been one of the most accurate interpreters of the pandemic for the past year and a half. Scott has a new book out just this week called “Uncontrolled Spread: Why Covid-19 Crushed Us and How We Can Defeat the Next Pandemic.” And clearly, he has thought about this a lot. Scott, thank you for joining us again.

Scott Gottlieb: Thanks for having me.

Rovner: So, you’re not lacking for public outlets for your opinions and advice. You’re regularly on TV, radio and in print. What made you want to put all this in a book?

Gottlieb: Well, I think a book provides a better format for trying to put it all together. You know, clearly, there were a lot of political mistakes made in terms of how we organized our early response. But I think there were also some systemic shortcomings and systemic woes with respect to the structure of our response, with respect to what we had enabled government agencies to do, where they were under-resourced, didn’t have the right capacities. And I wanted to focus on that. You know, some of the more systemic woes that contributed to what happened and made us excessively vulnerable to covid’s spread.

Rovner: So, it’s not like the federal government didn’t know a pandemic was likely in the next several years. We had close calls with SARS and with MERS and several different influenzas. I personally spent hundreds of hours covering congressional hearings and tracking legislation aimed at making the U.S. more ready for a possible pandemic. How are we still so unprepared?

Gottlieb: Well, I think first of all we prepared for the wrong pandemic. We always prepared for a flu. Back in 2005, when the pandemic planning really began in earnest, we were worried about H5N1. I think we allowed some of those preparations — frankly, a lot of those preparations — to atrophy. But we also prepared wrong. I didn't think, we didn't have enough foresight to see what would happen in the setting of a global pandemic — that, for example, every country would be tugging on the same supply chains at the same time. So, supply chains that we relied on wouldn’t be open to us, because every country would be husbanding their supplies, their resources. This should have been apparent to us. For example, in 2009, with H5N1, we saw countries nationalize production of vaccine facilities that were producing vaccine that was supposed to be destined for the U.S. We did the same thing to the United Kingdom, where vaccine that they were producing in North Carolina, we held on to it. Took a call from the British prime minister to President Bush at the time to get us to unlock those supplies. We also didn’t have the capacities that we thought we would have. We didn't have the ability to scale the production of diagnostic testing and the production of monoclonal antibodies, which were
always going to be the first line of defense against a new viral target. We didn’t have the
capacity to collect information and offer data in sort of a real-time fashion and real-time
analysis. We relied on the CDC to do this. And CDC is a very retrospective agency. It's a high-
science organization. They're accustomed to taking four months, five months to carefully vet
data and do careful analyses and publish them in exquisite morbidity, mortality, weekly reports,
not actual real-time information that you need in a setting of a fast-moving pandemic. We
needed the equivalent of the Joint Special Operations Command for public health. And what we
had was a high-science organization that moved like a school of public health.

Rovner: You’re pretty tough in particular on the CDC in the book. Is there a way to fix what's
wrong, or do we need a different agency to lead in public health emergencies like this?

Gottlieb: Yeah, I think it would be a mistake to think that we need to create a new agency or
new department or we need to consolidate existing agencies like we did after 9/11 with the
Department of Homeland Security. I think CDC is the right organization with the wrong
resources, the wrong culture, the wrong capacity. That doesn't mean the current CDC is a bad
organization. It’s very good at what it does. It’s just not properly equipped to be operationally
focused, be able to move with the speed that was required to be able to translate data into sort
of public guidance and have a process for vetting that and carefully evaluating it and
transmitting it in a way where it could be taken up by people who had to make decisions about
their daily lives. It’s just not what the organization did. And I think that there was an
unreasonable expectation of what CDC was going to be capable of doing. The idea that they
were going to be able to develop a diagnostic test and scale testing across the country in a time
frame that was needed to keep up with a fast-moving epidemic — they were never going to be
able to do that. And so the political class that was relying on CDC to do this should have
recognized early on that the organization really wasn’t equipped to do it. Now, CDC could have
raised their hand and said, “Hey, guys, we don't have this. This isn’t what we do.” They didn’t
do that. It's hard for an organization to self-organize in the setting of a crisis to take on a new
mission. But we need that kind of capacity. We need an organization that has more of an
operational focus, has a FEMA-like focus. We need an organization that's able to do a handoff
to commercial manufacturers and scale production. Ultimately, there was a recognition of what
was lacking in the creation of Operation Warp Speed, because Operation Warp Speed really
was a marriage between the high science of NIH and the regulatory capacity of FDA with the
DOD, with the Department of Defense, that had the capacity to scale up manufacturing and
distribution. So, we recognized that we needed to marry this sort of high-science component
with the operational component. We just realized it too late, and we realized it only narrowly in
the context of vaccines.

Rovner: So, are you saying going forward we should beef up CDC operational capacity?

Gottlieb: I think it’s going to be probably a new component within CDC. I think you need to
think of, you know, how do we create a more operational crisis-oriented component within CDC
that has a national security mindset? And so it will be attributes of CDC pulled into a new
function. You know, CDC also is very siloed. There's expertise in CDC that's relevant to responding to a pandemic that exists within these discrete silos. And the organization doesn't talk well amongst itself. And so you're going to need some new structure that becomes a center of gravity for crisis response. And we're going to need to be willing to resource it and keep it operational, even in a peacetime setting, just like we do with the military. I mean, we fund a military that we hope we never have to use. We're going to have to fund a capacity that on a routine basis might not be fully operational. But we're going to need to continue to fund it in perpetuity because we need to look at public health preparedness through the lens of national security now. This crisis was so grave, not just in terms of the cost in lives, but how it crowded out all our other national priorities. It changed the course of history. It changed geopolitical equilibrium. We can't allow this to happen again. And so we're going to need to fund a capacity in perpetuity that is a safeguard against this happening again. And the goal needs to be not to make the next pandemic less bad; it has to be to prevent the next pandemic. And so that's also going to include an overseas capability that's different. We can't just rely on, you know, multilateral arrangements and capacity-building in hot spots and everyone coming together as part of the WHO and agreeing to share information to keep us safe. We're going to have to have the capacity to actively gather it. That also means getting our tools of national security more engaged in the public health function overseas to do information-gathering. Historically, we haven't wanted our spy agencies anywhere near this mission. That's also going to have to change.

**Rovner:** It's going to be a real national security effort, not just a cooperative U.N. sort of … “Let's all hold hands and be good to each other.”

**Gottlieb:** We've tried that before and it didn't work. And if anything, covid conditioned countries to be even less forthcoming, because when B117 emerged in the U.K., what's the first thing that the French did? They closed the [English] Channel. We've now normalized trade and travel restrictions as a way to isolate countries that have an outbreak. At one time that was taboo. We wouldn't have done that. We would have said it would be destabilizing and it would potentiate spread of a new pathogen. Now we've normalized it. And so if you're Thailand, you're Indonesia, you're another country and you have an outbreak of an emerging pathogen, are you going to be more likely to share that information now or less likely? I think you're probably going to be less likely. And we need to go into this [with] eyes wide open. And that means we're going to have to have capacities for monitoring for these things. The old presumption was that if we had our spy agencies and our national security agencies engaged in this mission, everyone who had a white coat would be perceived to be a spy and it would erode the public health mission. But we're going to have to find a way to have these two functions coexist, and we're going to have to allow diplomatic efforts to be informed by intelligence-gathering. We do this in other realms. We do this in arms control. We're going to have to find a way to do it here. Every other country is doing it. And so the U.S. is going to have to as well.
Rovner: I have to admit I was kind of surprised by how politicized basic public health became in 2020 and by the idea that basic mitigation efforts would make people quite so angry. But it wasn't just here in the U.S. that that happened. It seems to have been the reaction from people around the world, including countries that don't have as much of an individually independent streak, as many Americans. And as you point out in the book, this is far from the first time Americans haven't wanted to follow public health guidance. How can health professionals do a better job communicating with people about the need to not put themselves and their neighbors at risk in a public health emergency?

Gottlieb: I think people are accustomed to thinking about matters of health as something that's deeply personal and involves an individual choice. And we're not accustomed to thinking about issues of health through the lens that it's a collective decision. That our decisions about our health really are a collective decision, are affecting the community. That's cultural. I think that's ingrained in our thinking because health care is something so personal. I think the more that we could allow decisions about the interventions to be made at a local level, the more that we can get that collective engagement. Because you're comfortable saying, you know, “I need to make a decision about myself to protect the people in my workplace. I need to make a decision about my own health to protect people in my school.” So, when you're making a decision within the confines of how you think about your community, I think it's easier to make that leap from “This is my choice, my body” to “This is a choice that I'm going to make for the collective good.” Then, if it's being done, it's sort of a national level. And I don't think that we pushed the decision-making down to as local a level as we should have. And now you've seen it get nationalized more. And, you know, you've seen governors prevent the local decisions while the federal government is sort of trying to enforce the local decisions. And I think both extremes actually pull in the wrong directions. It's hard, and it argues for strengthening local public health infrastructure, which we haven't done in this country, so that local public health agencies can be the tip of the spear in trying to drive this collective action. And the final point I'll make is, one of the things I worry about going forward is, there's a sense coming out of covid that the public health guidance sometimes was arbitrary, sometimes it was poorly informed, it shifted a lot, it seemed confusing. And I think that there is a body of people — and it doesn't just break down along political lines; I think that's bigger than that — that feel that the public health establishment, you know, shouldn't be as empowered as they were in this crisis. That's going to be very difficult going forward. If we're going to be prepared for the next pandemic, we need to empower public health. We need to allow people to feel confident in public health institutions. And so we're going to have to earn that back. This worries me a lot. And I don't think it's just a Republican-Democrat, conservative-liberal divide, although it's some of that. I think it's broader than that. I think that there's people who don't necessarily look at this through a political prism who still feel that the public health guidance was arbitrary. And so how do we earn back that trust? The public health community needs to be aware of that. And I think any future pandemic planning, even around, like, a beefed-up CDC, it needs to start with earning back that trust, because people aren't going to want to imbue a new operational component, CDC, with a lot of
authority if they don't think it's going to operate differently and operate in a way that people can trust what it's saying and what it's doing.

Rovner: But we've already had the opposite happen. We've had in, I think, almost half the states, states have taken back authority that public health officials used to have, giving public health officials less of an ability to do their jobs. How serious is that going to be when the next pandemic happens?

Gottlieb: This is very serious, and this is what I'm driving at. This is the direction things are heading. And so we're going to need to claim it back. I think we're going to make a mistake if we look at this, though, just through a political prism, and that's where I see some of the dialogue going. And even in the public health community, this is seen as something being sort of propagated in red states by Republican governors. I think it's deeper than that. I think that there is consumers who aren't overtly political who still feel confused, dismayed by the way the guidance was issued and their ability to incorporate it into their lives. And so we need to make a recognition of that and do things to actively earn back that trust and push back on exactly what you're talking about, which is this movement to try to take authority away from public health officials. That's going to be the first thing that needs to happen, because we're not going to have a consensus among Congress about how to properly create a new entity within CDC that has the proper authority unless we get over this first threshold, because you're not going to get the political consensus you need.

Rovner: Is there one big takeaway from all of this that you feel like people really need to know?

Gottlieb: Well, I mean, from the book, in terms of how I thought about it, I think just the issue of building out, you know, the capacities that we need and keeping it hot, not warm. We can't just build stuff and mothball it, build capacities and mothball it. In terms of the discussion around, you know, public health guidance and earning back the trust, I think we need to think about how we issue guidance in a way that we explain very clearly the basis for it, how much scientific certainty we have around it, and have a process for readjudicating it that's very objective and transparent. You know, the 6 feet of distance is a perfect example. CDC never really explained where that came from. People guessed. They didn't readjudicate it in a timely fashion. When they finally did, it seemed sort of arbitrary — 6 feet to 3 feet. It was based on science. The 3 foot was based on science, had been available for months. So that whole process feels very arbitrary. I think it needs to look more like, you know, like an FDA process, where you have a clear process, it's explained, and when it's issued you have a public advisory committee, meaning there's a clear process for readjudicating it. You need that sort of transparent, rigorous process around this. And that's not typically what CDC did. CDC's virtue is that they can put out guidance very quickly. The downside of that is that they put it out very quickly and they don't have a clear process for reassessing it and readjudicating it [in] a sort of regular fashion. So, we need to change that. We need to change how we gather information, analyze it and ultimately issue guidance to consumers in the setting of a public health crisis, because this isn't going to be the first time that we don't know enough to really have the right answer. But we
need to have a process that sort of iterates in the right direction. And, you know, that's much more of a national security mindset. If you look at intelligence agencies, when they make an assessment, they tell you the basis for the assessment and how certain they are. CDC doesn't do that. CDC is sort of, they don't tell you the basis for the assessment and they don't tell you how certain they are. And that's where I think the marriage between sort of how we do intelligence-gathering and how we look at public health through a national security lens can start to marry out.

Rovner: Anything I haven't asked you feel like people need to know?

Gottlieb: You know, I'm perplexed by why we aren't engaging in the discussion about how do we prepare better for the future. I wrote this book with the goal of trying to stimulate that debate or be part of that debate. The only thing I could fall back on is maybe it's too early, maybe since we're still in the throes of this pandemic, we can't really think about how do we prevent the next pandemic. But we should be starting to have that discussion soon, because you don't want to lose the moment to galvanize the public action that's going to be required.

Rovner: I'm sure we will have you to ask about it again. Scott Gottlieb, thank you so much.

Gottlieb: Thanks a lot.

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 list on the podcast page at khn.org. Sarah, why don't you go first this week?

Karlin-Smith: Sure. So, I took a look at a piece, “The World's Tallest Populace Is Shrinking and Scientists Want to Know Why,” by Rachel Pannett in The Washington Post. Needed something lighter this week to talk about, I think. But the Netherlands has had the world's tallest population. But now it seems like their average height is shrinking, and scientists are really interested in figuring out why. They say this actually has sort of serious implications, you know, including things like they say taller people live longer. They perhaps are sort of more intelligent or do better in life. As a shorter person, I take issue with some of this. I think some of it may be ...

Rovner: They can reach more things. I'm also a shorter person.

Karlin-Smith: I think some of this, some of the implications may be sort of societal, I guess, of how you get treated as a short person. But it is interesting, like some of the factors they're looking at is what may be causing this, including nutrition, changing diets, even some economic circumstances. So, I think it'll be interesting to see what they find or maybe, perhaps, you know, we've just peaked in our height attention. But, you know, like I said, as a short person reading some of the things we're talking about — taller people being smarter and living longer — it does kind of make you wonder whether there's, like, a true sort of biological reason for this or just a little bit about how you get treated in the world as somebody who's a little bit smaller.
**Rovner:** Well, I had no idea that the Dutch were the tallest, and [a] hat tip to Joanne, who tipped me off to this story in the first place. Joanne, why don't you do yours?

**Kenen:** This is a piece in The New Yorker by Dhruv Khullar. It's called “The Struggle to Define Long Covid.” And it has several layers. It has the layer of the patients who want fast answers and the scientists who need time to figure this very complicated thing out. It has the layer of people who had covid who then attribute absolutely everything that happens to them to long covid. And it may not, but it’s not denying the existence of long covid, but not everybody who has anything wrong with them in the subsequent months necessarily. I mean, if you were diagnosed with diabetes, you might have already had diabetes and haven't been to the doctor to even discover it yet. Most people do believe there are lingering effects, and we don't have a common definition and we certainly don't have an understanding, and it's becoming politicized. And that's what he, that I found that the most interesting thing, the way it’s becoming another political constituency, not all driven by evidence yet and not always — you know, it's another source of skepticism of science and developing a political life of its own. Not every person with long covid, but there is this phenomenon.

**Rovner:** Mel.

**McIntire:** My extra credit this week is a piece by your KHN colleague Victoria [Knight], looking at doctors who are spreading covid-19 misinformation and sort of the penalties associated with that. Obviously, that's been a huge challenge in the effort to get people vaccinated, misinformation broadly. And then you look at medical professionals who are trusted and people look to them for serious advice. And if they are out there giving and spreading misinformation, how do you handle that? You have state medical boards who are sort of in charge of overseeing that. And she sort of looked at the question of how and will these people ever be penalized for this? You know, obviously people are listening to their doctor and what they're telling them about the vaccination. So, I thought it was interesting. You know, they looked at a report that had, you know, the 12 greatest sources of vaccine misinformation around the covid vaccines and I think three of the people on that list were medical professionals, which is crazy to think about with the amount of misinformation out there on this. But an important question for sure.

**Rovner:** Yeah, absolutely. All right. Mine is from The New York Times, by our friend and frequent extra credit writer Sarah Kliff, who we hope to have back on the podcast at some point. It's called “Their Baby Died in the Hospital. Then Came the $257,000 Bill.” And it's a very sad twist on the surprise bills story that won't be fixed by the surprise-billing legislation that Congress passed last year. This particular bill was the result of a dispute between the hospital and health insurance company. The health insurance company mistakenly paid a bill that should have been paid by another insurance company because the patient was in the process of changing jobs. And the first insurance company thought that the best way to get the hospital to refund the money that it had paid mistakenly was to send the bill to the patient. It's exactly the kind of story that makes people in countries with more rational health care systems shake
their heads at us in disbelief and makes us shake our heads at us in disbelief. But these things keep happening.

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, who still manages to make us all sound good. Sorry about the dog rolling her ball around underneath my feet. Also, as always, you can email us your comments or questions. We’re at whatthehealth, all one word, at kff.org, or you can tweet me. I’m @jrovner. Joanne.

Kenen: @JoanneKenen.

Rovner: Mel.

McIntire: @MelMcIntire.

Rovner: Sarah.

Karlin: I’m @SarahKarlin.

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