[Intro music by C. Ezra Lange]

David Burda:

Welcome to the 4sight Health Roundup podcast, 4sight Health's podcast series for healthcare [00:02:30] revolutionaries, outcomes matter customers count and value rules. Hello again, everyone. This is Dave Burda, news editor at 4sight Health. It is Thursday, August 31st. Good to see long prison sentences for all the people who tried to overthrow our government.

(<u>02:49</u>):

I do hope they save the longest one for their leader, a wannabe fascist dictator who was out on bail, most of which he didn't pay himself. Who pays is the topic of today's podcast. We're talking about Medicare's announcement of the 10 prescription drugs subject to price negotiations with pharmaceutical companies under a provision of the Federal Inflation Reduction Act passed last year to discuss the short and long-term policy and market. Implications of the announcement are Dave Johnson, founder and ceo of 4sight Health, and Julie Murchinson, partner at Transformation Capital. Hi Dave. Hi Julie. How are you guys doing this morning, Dave?

David Johnson: Well, I've got a heavy heart this morning. Dave, Kerry Weems, my friend and 4sight Health contributor has developed a neoblastoma brain tumor and gone from diagnosis to hospice in the last six weeks. Kerry has had a remarkable career, including serving as a CMS Administrator in the George W. Bush administration. [00:09:30] Well, lots more to say about that in the coming weeks, but at the present moment, we're just sending our thoughts and best wishes to him, his wife, Jean, their kids, and their grandkids.

David Burda (09:41):

Gosh, I'm sorry to hear that, Dave. We have same here. From all the 4sight, health family. Thank you, Julie, how are you?

Julie Murchinson (09:51):

Oh, that's terrible, Dave, that's really disappointing to hear. I'm well. I'm excited to be talking about our topic today, [00:10:00] and I caught a cold, so I'm not going to complain about

I hope you recover quickly too. Thank you. Now, before we talk about the implications of Medicare negotiating prices for these 10 drugs, let's talk about what you've been up to for the past four weeks. As you know, we went on hiatus in August and rebroadcast four updated podcasts. We talked about private equity in healthcare, [00:10:30] regulation of healthcare, ai, the market frenzy over weight loss drugs and CMSs, new primary care value-based care model.

Dave, did you think about any of those topics while you were out and what were you up to?

David W. Johnson (10:45):

Well, I spent most of the time during the hiatus on our annual beach vacation at Lake Michigan, which is my absolute favorite time of the year. We did have dinner while we were there with a friend of ours who's gone on Kovi [00:11:00] and she's lost 40 pounds and describes it as an absolutely miracle drug. So I did have that healthcare experience. I actually tried to not think too much about healthcare, which is hard for me to do. I did read the new Martin Luther King biography, which is incredible. John EEGs book, I walked away with three strong impressions. One was just how young Martin Luther King was

when he was on the national stage. He was only 25 when he started, or when he led the Montgomery Bus boycott in 39 when he died.

(<u>11:49</u>):

I can't imagine myself at that age trying to lead anything close to what he did. So just young for that level [00:12:00] of accomplishment. Also, the level of F B I harassment against him is much clearer in this book and unbelievable that our government, the extent to which our government went to disrupt him and his life. And then finally in the last couple of years of his life, as he was moving away from just fighting segregation in the South and to fighting the broader issues of poverty and injustice throughout America, [00:12:30] how much more revolutionary his thinking became. I'd recommend that book to anyone who has an interest in American history, particularly of that crucial period of time

David Burda (<u>12:43</u>):

You educated yourself. Usually I just go fishing. So good for you, Julie, how did you spend your summer vacation? Were you talking about healthcare AI around the campfire?

Julie Murchinson (12:55):

I was thinking when Dave was talking about the m I K book, I saw Barbie and my friends and I want [00:13:00] to have a Barbie party, and that just doesn't seem quite as intellectual. So my family and I took a big bike trip and I biked 36 miles with some really nice, decent elevation on my birthday, which is one way to spend another tour around the sun. And all I'm going to say is thank God for the e-bike creation.

David Burda (<u>13:24</u>):

I'm not sure

David W. Johnson (<u>13:25</u>): You can call it a bike trip. That's a motorcycle trip right there. Oh,

Julie Murchinson (<u>13:28</u>):

Stop. I [00:13:30] was at a low power. I didn't use the turbo.

David Burda (<u>13:35</u>):

That's great. Well, I'll just say happy birthday. That's great. Good for you. Thank you.

Now, when I look back at my August calendar, it reads like one long party, barbecues, picnics, festivals, concerts, birthday parties. So we have one more long weekend to go, and then it's back to cereal, milk, and a banana for breakfast instead of leftover ribs. So there you have it. Good summer. [00:14:00] There you go. Fishing and ribs,

David W. Johnson (<u>14:03</u>): Leftover of ribs for breakfast.

David Burda (<u>14:05</u>): Oh, sure, Julie Murchinson (<u>14:06</u>): Yeah. Sounds gross. But

David Burda (<u>14:08</u>):

Breakfast of champions. Yeah, you eat a cold one while you're heating up the others in the microwave. Dave kind of like pizza. So yes, that's how the other half lives. So I wonder if there's any statins on this list from Medicare? Let's see. As you know, Medicare earlier this week released the names of the first 10 drugs subject to price negotiations [00:14:30] between the Medicare Part D program and drug companies. Let's see, I see four drugs for diabetes on the list. Three drugs for heart failure, a couple of blood thinners for blood clots, and a couple for arthritis. No statins and nothing for blood pressure. That's great. Alright. Medicare selected the 10 drugs using five criteria. Most notably, the drugs have no generic or biosimilar competitors, [00:15:00] and the drugs cost the Medicare Part D program the most money using cost data from 2022 and 2023. Medicare will make an initial price offer to the drug companies by February 1st, 2024. The companies will have 30 days to accept the offer or make a counter offer if they can't agree on a price. Let the negotiations begin. Negotiations end on August 1st, 2024, and the prices take [00:15:30] effect in 2026.

Dave, what do you think of this list and how Medicare pick these 10 drugs? How do you think the negotiating process will go and from a policy perspective, is this the best way to control drug costs for consumers? Welcome back.

David W. Johnson (15:54):

Those are big questions. Let's dig in. During the 1970s, the [00:16:00] Nixon administration implemented wage and price controls in four phases to address the rampant stagflation that occurred in the wake of the Arab oil embargo. I remember an editorial cartoon that appeared after the phase four rules went into place and the country was pretty tired of wage and price controls. It showed Nixon on the sidelines as a football coach standing next to a downs marker that said phase four, the captioned underneath read [00:16:30] punt. So I'm not saying the Biden administration is punting and it certainly isn't forth down, but there is so much profiteering and market failure in the pharmaceutical industry between the manufacturers, the wholesale distributors, the PBMs, and the pharmacies, that there does appear to be the profound need for government intervention.

The IRA's approach to drug selection, as you asked Dave, makes sense to me. [00:19:00] High expenditure, single source drugs without competition. It's not hard to believe that there might be excess margin to capture here. Regarding the negotiating process, my guess is the manufacturers will come to the table and negotiate in good faith. Medicare is too big a market to ignore, and these manufacturers don't want to want the media and others to paint them as greedy monopolists. [00:19:30] No snidely whip flashes here behind the scenes. I'm sure they'll be trying to do everything they can do to water down the impact of the I R A and the new pricing mechanisms through lawsuits and regulatory adjustments. But stepping back pharma is complicated. The industry has delivered many of healthcare's highest value interventions in recent decades. Just think about it for a second, the Hep C drugs, the cardiovascular drugs that [00:20:00] have dramatically improved cardiology outcomes, the covid vaccines, the new weight loss drugs that we talked about earlier, and the list goes on at the same time. There are just so many bad actors and so many bad practices that to continue on the current path just doesn't make sense. So when you've got market failure, unfortunately the government needs to step in

As I said before, the nation needs a Goldilocks approach to regulation, and we certainly need that in managing pharmaceutical drug prices and the pharmaceutical marketplace. So not too hot, not too cold. The I R A isn't perfect, but it's a start. [00:21:00] So let's see how it goes and adjust as necessary.

David Burda (21:03):

And I think that's our first Snidely whiplash reference on the show. So you get bonus points for that. Dave, good analysis. Thank you, Julie. Any questions for Dave?

Julie Murchinson (21:17):

Dave, I've heard a lot of people all over the industry talk about how this is the first step towards European price controls. Do you think we're really headed towards a system that works like that, or [00:21:30] do you think we'll stop short?

David W. Johnson (21:32):

Yeah, yeah. There's certainly overreaction. I really don't think so. As I said, when the marketplace is so out of whack as it currently is on some of these drug prices, then you need the government to step in. This doesn't strike me as an outrageous way to do it. It's not as though the government is [00:22:00] mandating what the prices are going to be. They're going to enter into a good faith negotiation. I believe it will be good faith, but anytime you get the government involved, there's the opportunity to misallocate resources. The question is, why don't we have level playing competition, particularly in the small molecule market? And we do sometimes, but often we don't. And [00:22:30] the policies around patents and patent protections and how we extend them and so on have worked disproportionately in favor of big pharma. They play it like a Stradivarius, the whole regulatory approval process. So I don't think it is, I think it's a rational reaction to an out of control market, and there'll be lots of hyperventilating, but trying to reign in prices for [00:23:00] drugs that have no competitors that come from a single source, that doesn't strike me as outrageous at all.

David Burda (23:06):

Got it, Dave, thank you. Julie, what do you think of the drug selection process? Do you think the selection criteria in any way changes how drug companies think about developing new drugs? And from a market innovation perspective, is this the best way to make drugs more affordable for consumers?

Okay, so in the year since the Inflation Reduction Act has passed, pharma companies and venture capitalists have massively, I mean, materially shifted their priorities and response. So I think this list of drugs is not necessarily impacting anything around the innovation process, but what's [00:24:30] coming down the pike I think is being pretty severely impacted, but in probably good and bad ways. So both VCs and pharma, big pharma are really placing less emphasis on the synthetic drugs that'll be subject to price negotiations faster than the biologics. The synthetic drugs, which are called small molecule drugs, have a nine year window and the biologics have a 13 year window. So listen to some of this. It's kind of crazy. 50% of the drugs revenues [00:25:00] come in years nine to 13. So it's pretty interesting to see the reaction by some. So I saw that a Boston base investment firm told its biotech companies to switch to large molecule versions of their small molecule drugs.

experts say it's hard to quantify the deals that aren't getting made or research that's being deferred. But there are a lot of other examples like that. Genentech, c e o said earlier this month that they are slowing down research on drugs for smaller markets because of the I R A Novartis dropped [00:26:00] early stage cancer drugs from its pipeline as a result of the risk of negotiations. Even Lilly confirmed that it's sideline three drugs so far because the I R A so tapping all over the place and potentially equally is damaging executives of drug companies with products that are already on the market say it no longer makes sense to perform studies on additional uses of their drugs or off-label uses because [00:26:30] the price may be locked by the time the evidence is available.

(<u>26:33</u>):

So I actually am a big believer in identifying other uses of drugs, and that limits a mass amount of potential, much cheaper innovation, frankly. And some companies that have really pivoted from the big blockbusters to making drugs for small patient populations are really pulling back because they're concerned that they won't see the [00:27:00] payout. So we'll know soon, I guess, because the companies will have a month to submit data to C M S for the price consideration. But it'll be interesting. I do think the one thing silver lining that could come out of this is that with the drugs that are currently listed for this year, and Dave, I think in your discussion talked about how most of it were highly rebate. So the [00:27:30] ultimate savings this year may not be as high as maybe in future years when they're negotiating costs for lower rebated drugs and 15 to 20 drugs instead of just 10. But I do think that a lot of this may really benefit the seniors who will have their share of the drugs cost based off a lower list price. So there could be some good that comes out this, that's for sure.

David Burda (27:56):

It's fascinating. It really sounds like business behaviors [00:28:00] and strategic planning are changing because of this. Thanks, Julie. Dave, any questions for Julie? Big picture just strikes me that big pharma is shifting from one set of incentives to another set of incentives, and I'm not sure which one is better, but the push that we've had for orphan drugs that don't have competition and can have astronomical [00:28:30] prices and really benefit only a small portion of society, I've questioned that for a long time, and I've always found it strange that big pharma advocates for free market principles when it derives its primary benefit from patent protection that comes without cost benefit analysis or limits on market prices for approved drugs. So I guess I'd ask, and it's maybe even too [00:29:00] soon to get a full answer on this. I guess I'd ask if the current behavior is really a function of how the government approves and pays for drugs through the F D A, and then we've got this whole basket of ways that the industry exploits the incentives that I was talking about. If they've traded that set of incentives for a new set of incentives, [00:29:30] do you think one is, or the new set of incentives is necessarily worse than the old set of incentives? I don't have a clear read on that myself.

Julie Murchinson (29:42):

I don't think we know, but I do think, let's say that this investment firm that's pushing their biologics or pushing their portfolio company to move towards biologics, biologics by definition are more expensive. I shouldn't say that that way, but [00:30:00] on the whole, they have been a more expensive way to deliver drugs, and that's where we're getting a lot of the high cost drug war. So it's going to create a whole different commercial battle that I think could actually, maybe it could really accelerate everything that we're dealing with because it will just drive costs higher and higher. I don't know. This is a real game changer for the drug market. I think everyone's business model is up for grabs. It's like you want a generic competitor if only to get off this list and charge whatever you want, or maybe spin off a generic competitor of your own, or do you double the price you charge to commercial payers, and then what do PBMs do? I would agree. I think it's going to get nuts in the short term. Thanks, Dave. Thanks Julie. Great discussion. Now let's [00:31:00] briefly talk about other news that happened this week. It wasn't all bad, was it Julie, anything else we should know about?

Julie Murchinson (31:09):

Well, on this note, one of the companies in the space, true Hill, had one of those amazing rockets to the moon and just agreed last week to cut some of its shares that were valued in 2021 by 90% [00:31:30] to get its valuation back down to where it needs to be. So we're seeing a lot of the drug innovators who came out of the gate to solve this problem having a bit of a rocky time.

Something to watch. Dave, what else is worth a mention?

David W. Johnson (31:47):

Well, this is definitely good news and good news that Julie will particularly enjoy. The Guardian reported on two major studies that found that female surgeons had fewer complications [00:32:00] and less follow-up care than their male surgeons for similar operations. And it's attributed to better technique and working more slowly, making fewer errors as they're performing the surgery. So let's bring more female surgeons into the industry.

Julie Murchinson (32:21):

Dr. Barbie.

David W. Johnson (<u>32:23</u>): There you go.

David Burda (32:26):

I think you could say the same thing about cooking, at least in my house. So [00:32:30] yeah, I'll need to read that. That's great. Thanks Dave, and thanks, Julie. Welcome back. That is all the time we have for today

If you'd like to learn more about the topics we discussed on today's show, please visit our website at 4sighthealth.com. And don't forget to tell a friend about the 4sight Health Roundup podcast. [00:02:00] Subscribe now and don't miss another segment of the best 20 minutes in healthcare, although I think we went a little long today. Thanks for listening. I'm Dave Burda for 4sight Health.

[Music by C. Ezra Lange]