Sawbones 349: Clinical Trials

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[theme music plays]

Justin: Hello everybody, and welcome to Sawbones, a marital tour of misguided medicine. I'm your cohost, Justin McElroy.

Sydnee: And I'm Sydnee McElroy.

Justin: Hey, Syd.

Sydnee: Hi, Justin.

Justin: We've had an interesting, uhh, week.

Sydnee: Yes. Yes, we have.

Justin: It's always an interesting week if your eyes are open, and your heart is ready for the world around you. There's always something fascinating around every corner. But…

Sydnee: That's a good way to look at it. That is— has been a bit of a hard sell this year, that sort of… idea.

Justin: I— Syd, I think there's a beautiful mystery behind every chrysanthemum, and uh, a wonder and delight in the smile of every child. So, I really appreciate the world around me.

Sydnee: Oh, okay. Well, that's good. Um… good for you. So, for me, it was an exciting week.

Justin: Yeah.

Sydnee: Because we participated in a vaccine clinical trial.

Justin: Yeah, that's true. We, uh, led by… [laughs] Your mom.

Sydnee: Led by your mo— well, my mom is not…

Justin: Leading the trial. That's true.

Sydnee: No. She did not design, and she's not responsible for the trial. But uh, so… do we wanna— do we wanna walk through our experience? I was kind of thinking I would start with the history of clinical trials before we get into this. I don't want to dive in too far.

Justin: Yeah, good teaser. Let's get into history, and then we'll talk about how it went for us.

Sydnee: Sure. 'Cause we did— we did tweet about it, and so, I know a lot of people were asking, how did we find out? What was it like? What was your experience? And I want to talk about that whole thing. But um, there's… I think it's kind of interesting, first, to look back into like, how did we figure out how to do this? Because it's so… I think that the scientific method, parts of it seem very logical now. Not all of it. It still needs explaining.

But just the idea of like, let's test something to see if it works before we put it in our bodies… makes sense.

Justin: It's one of those in hindsight things. Well, of course it would work that way.

Sydnee: Well, obviously. But how did we get there? And so, I think it's interesting to look back. If you're looking at, like, what is regarded by a lot of people who write about these things as one of the first sort of clinical

trials, so to speak— and this isn't anything like what we would call a clinical trial today. But a lot of people make references to a story from the Bible.

Justin: Oh. Really?

Sydnee: Yes. In the book of Daniel…

Justin: Bastion of science.

Sydnee: Uh-huh. In… [laughs] In the book of Daniel, there's a story about King Nebuchadnezzar, who I remember from Veggie Tales.

Justin: Yes. I think that is a lot of people's touchstone for Nebuchadnezzar. [laughs]

Sydnee: I believe he was played by a zucchini.

Justin: Uh, yes. Well, that is actually, factually, historically accurate. Nebuchadnezzar was, of course, a zucchini.

Sydnee: So, he, I guess, liked his soldiers to only consume meat and wine.

Justin: Hmm.

Sydnee: Thought to be the healthiest diet… at the time.

Justin: Sort of a proto-Atkins. [laughs]

Sydnee: [laughs] And he uh, he had a group of soldiers who said, y'know, we don't want to eat meat. The wine is fine.

Justin: Wine, we're okay with.

Sydnee: But we don't want the meat. We would prefer lentils. And…

Justin: Those are also— y'know, that's a high density, uh, carb. Lot of nutrition packed into those legumes. Good stuff, lentils.

Sydnee: And so, this group of uh, vegetarian, or perhaps vegan, I don't know…

Justin: Maybe lentil-tarian. That's all they—

Sydnee: Soldiers… [laughing]

Justin: —all they like.

Sydnee: … stood up and said, "We don't want to eat all this meat anymore." Maybe they realized like, we don't feel so good when we gotta do our soldiering after we've eaten a bunch of meat.

Justin: Yeah.

Sydnee: So, we'd rather eat lentils. And he said, "Well, I'll tell you what. For ten days, you guys eat the lentils with your wine, and everybody else is gonna eat the meat with their wine, and we're gonna see who's healthier."

Justin: And then you have a fight. [laughs] And whoever wins…

Sydnee: I don't know. Somehow, it was judged that the lentil guys were healthier than the meat guys at the end of ten days.

Justin: Ten days should be long enough to…

Sydnee: I'm saying 'guys.' That's not— I don't know the genders of these soldiers. I'm kind of assuming from the time period that they were probably…

Justin: Yeah.

Sydnee: But either way. So, the lentil people were healthier than the meat people. And I know right now, all of our like, vegetarian and vegan listeners are goin', "Uh-huh. Yes."

Justin: But listen, nobody likes a know-it-all, so why don't you stop talking to your phone and just listen to the podcast. Okay?

Sydnee: [laughs] Uh, and I guess that could be considered a trial of sorts. Right? You had two groups.

Justin: Yeah.

Sydnee: You changed one thing about the two groups. You had one variable.

Justin: Yeah.

Sydnee: I don't feel like it was randomized, necessarily. You just had the people who wanted to eat lentils, and the people who didn't. So, it's not really random.

Justin: Or maybe they did, but they gave them up for science. We don't know. We don't know if they wanted to eat lentils.

Sydnee: [laughs] But uh, in 1025 CE, Avicenna was really the one who kind of laid out… he's sort of thought of as like, the father of clinical trials. The one who wrote down basic ideas that we still use today when we're designing a clinical trial. So like, um, we need two different groups to compare, if we're gonna decide if something is working or not. Um, we need to think about confounders, which are… confounders are other things that you can't control in an experiment that might affect the results.

Justin: Mess it up.

Sydnee: Yeah, that might confound, or mess up the results, and lead you to believe something that isn't necessarily true. So, you have to look out for those kinds of things when you're designing a study.

And uh, and reproducibility. This is something that I think we often forget – just because a study leads to some sort of conclusion, doesn't mean, like, that's it. We did it forever. We're done. You have to be able to like, reproduce that result. If you get one answer one time, and then the opposite answer 30 times…

Justin: Well, then, maybe you were wrong. Maybe the science is bad.

Sydnee: Uh, there were also, um, the uh… [laughs] The Babylonians used to actually just have somebody who was, like, sick kind of stand in a public place, and like, have different people come up and offer advice.

Justin: Okay…

Sydnee: And like… like, I'm gonna display my sick person, and different people can offer advice, and we can compare advices.

Justin: Just come on by and let— let the sick person know kind of where you're at.

Sydnee: Yeah. Mm-hmm. That's a way you could do it. We also had, um, kind of an example of an experiment, so to speak, from Samuel Pepys, who wrote about an experiment with a subject. A local college had hired what was described as a "poor and debauched man" to have some sheep blood let into his body.

Justin: Mm! Delightful!

Sydnee: As an experiment. So, I guess those were sort of…

Justin: I mean, I guess that's an experiment…

Sydnee: … trials. [laughs]

Justin: Although, if that counts as an experiment, I've done a lot of things in my life that you could count as "an experiment."

Sydnee: I really just— [laughs]

Justin: I wouldn't call myself a scientist because I dumped a bunch of Spider Man vitamins into my milk to see if it gave me superpowers.

Sydnee: I like to mention Samuel Pepys, because he's been misquoted widely on the internet these days. Everybody thinks that he said some really, uh, like, in hindsight, some really intelligent things about the plague that were applicable to the coronavirus today. And when you see those memes circulating on Facebook and Twitter, those are actually not— he didn't really write that.

Justin: Mm.

Sydnee: It'd be really cool if he did, don't get me wrong. If he was saying like, "I'm not going in the bars, 'cause you're gonna get the plague there!" And we were all like, "See?"

Justin: See? Even back then, we knew!

Sydnee: We knew in the 1600s! But he didn't write that.

Justin: Oh, okay.

Sydnee: Yeah. I just thought that that was worth mentioning.

Justin: Okay. Is there any other bubbles you'd like to burst before we move on, or…?

Sydnee: No, I'm just saying.

Justin: Okay.

Sydnee: Um, we've talked about Paré a lot on this show, um, because he did— he revolutionized a lot of, when we think about, like, surgical care, in

like, good ways. And likewise he sort of inadvertently did one of the first early trials. In 1537, he was treating wounded soldiers, and at the time, the customary treatment would be to take boiling oil and just cauterize a wound.

Justin: Woof. I mean, it's still rough.

Sydnee: Right. It is.

Justin: It's rough.

Sydnee: And— but the problem was, there were so many wounded soldiers, he knew he didn't have enough oil. There was no way he was gonna be able to, y'know, cauterize all these wounds. So instead, once he ran out, he started applying a mixture of egg yolk, turpentine, and rose oil.

Justin: Just a guess. I have to imagine it was just a wild guess.

Sydnee: Here's the weird thing. So, the next day, he went to check on all of his patients.

Justin: Mm-hmm.

Sydnee: And the ones that got the mixture of egg yolk, turpentine, and rose oil actually were doing better.

Justin: Now, is that attributed to the, uh, efficacy of that blend? Or is it attributed to just how bad it is to dump scorching hot oil onto wounds? [laughs]

Sydnee: Bingo.

Justin: [laughs]

Sydnee: Yes.

Justin: It's not that this is good, it's just, the other one is so bad!

Sydnee: But this actually— it was important, because it changed his practice, and he talked about that. He wrote about that. Like, "I saw it head to head. It wasn't better." Now, it probably led a lot of people to think that…

Justin: It was a good mixture. [laughs]

Sydnee: Rose oil, turpentine, and… [laughs] And uh, egg yolk was a good mixture, but…

Uh, we've talked at length about scurvy and James Lind. We did a whole episode on it, so I don't want to rehash that whole experiment. But it has to be mentioned, if we're gonna talk about the history of like, the development of clinical trials, because what James Lind did with scurvy really is one of the earliest examples of like, intended… like, I am trying to do a study. This is intentional. I am trying to set up control groups and different variables. I'm trying to figure out what works best.

And in 1747, he had— he took 12 sailors who had scurvy, divided them up into six groups of two, and gave each of the six groups a different treatment. So, two sailors per group got either vinegar, this elixir that was like, popular at the time, some sea water, some nutmeg, some cider, or oranges and lemons.

Justin: Mm-hmm.

Sydnee: And then, of course, the citrus fruits…

Justin: That did it.

Sydnee: … won out.

Justin: That did it. Even I, a layman, know that.

Sydnee: And that immediately fixed scurvy. No, it didn't. Actually, it was 50 years before… [laughs] that recommendation would be adopted, and

sailors would be issued lemon juice. And then, later, lime juice, because it was cheaper.

Justin: Mm. And more delicious.

Sydnee: ‘Cause it was really expensive! That’s why! Did you know that?

Justin: Really?

Sydnee: It was just cost prohibitive. James Lind figured it out, and the British Navy was like—

Justin: “What do you want, a bunch of lemons? What are we, made of lemons?”

Sydnee: That’s basically what they said. Like, we don’t have— we can't— what— there’s no point. We can't do this.

Justin: “There’s like, eight lemons right now. ‘Cause look at the calendar right now. There’s like, eight lemons.”

Sydnee: Because of this, May 20th is international clinical trials day. I didn’t know that. Because of this. Uh, what I enjoyed is that, as I was preparing this episode, I was reading about James Lind’s trial, and Charlie came and asked me what I was reading about, and I explained it to her, and her reply was, “Can we act that out with our toys?”

Justin: So, you recreated this with who? I guess Peppa Pig families?

Sydnee: Mm-hmm. Peppa Pig was in there. Minnie Mouse was in there. SpongeBob, Squidward… two dinosaur toys that I think we got from a fast food restaurant.

Justin: Okay.

Sydnee: Um, all of her favorite characters were in the group that got oranges and lemons. [laughs]

Justin: Oh, that's nice. Yeah. We want that.

Sydnee: And then, the ones she didn't like as much didn't get the good stuff.

Justin: RIP, generic dinosaurs. Sorry you couldn't— you guys got scurvy.

Sydnee: Uh, Josh from Blue's Clues was James Lind in this.

Justin: Oh! He was solving a mystery.

Sydnee: He was.

Justin: Piecing together the puzzle. I love it. It works.

Sydnee: Yeah. It was a weird thing for her to want to act out, but I'm not gonna lie, I was proud.

Justin: Yeah.

Sydnee: Uh, so, um… in the late 1700s and early 1800s, the next big thing that was like, a step forward for the idea of a trial, of a regimented way of testing a therapeutic, was placebo.

Justin: Mm-hmm.

Sydnee: Placebo was originally something that you would give a patient, not necessarily to make them better, but just to make them… happy.

Justin: That's nice.

Sydnee: About it. Um, initially, these weren't necessarily inert. Y'know, a lot of the times, we think about a placebo now as a like, a sugar pill, right? Something that has absolutely zero effect. Back then, a lot of the times, a placebo would be some sort of like, maybe herbal, or folk remedy, that

doctors didn’t really think worked, but they knew patients liked, and it pleased them. And so, they would just say, “Well, just use that. That’s fine.”

Justin: Well, in those days, if a pill didn’t give you diarrhea, you knew that it was not real. Like, “This can't be medicine, it didn’t get me high or give me diarrhea.” [laughs]

Sydnee: Which makes sense, because eventually, when that would be replaced with like, sugar pills and bread pills and things like that…

Justin: Tell me about bread pills.

Sydnee: I mean, I'm assuming they're just pills made out of bread.

Justin: That’s so cool.

Sydnee: Just tiny little pills made out of bread. But uh, once they were replaced with those kinds of things, then you would know it wasn’t doing anything. Or at least, you would know it didn’t have any very clearly demonstrable effects on your body.

Justin: Yeah.

Sydnee: The way that some of those early patent medicines probably did, even though they weren't necessarily treating or curing anything.

Justin: Absolutely.

Sydnee: Uh, but these— again, these weren't necessarily for trials at first. These were more just for patient satisfaction. In 1863, a doctor, Austin Flint, kind of did a study using one of these herbal treatments as a placebo for rheumatism, and then, used an established, like, what he believed to be the real treatment in hospitalized patients.

And this was the first time when people went, “Ooh, hey. Well, we could… we could do this in studies. That’s where this placebo stuff—that’s where this

business could be really helpful, other than just like, patient satisfaction scores. We could do it to learn something."

Justin: Was the idea with placebos… not using, like, fake placebos – was it the idea of like, "Well, we want to do *something* for them, even if it's not the medicine." Like, it was less scientific, and more—well, I guess it's still scientific, but it's like… well, we want to help them in some way, maybe.

Sydnee: Before they were used in trials, placebos were very much, um… it was not a bad thing for a doctor to be giving you something that they didn't know would work. Because our idea of what we knew would work was so different. I mean, what you're really talking about is this idea that, if the patient seems pleased with the treatment they've received, you've done a good job.

Justin: Customer-focused medical care.

Sydnee: Well, and that's a very different goal than, "I want something that I know works for the condition that this patient has." And so, if you gave somebody a placebo, and then, they… y'know, a week later, told you that they felt great, and they told other friends about it, and they're back to work or whatever, then… good!

Justin: Yeah. Great.

Sydnee: Then, you did it. Y'know? So… it wasn't so necessarily tied to like, is it real?

Is it real, though, honey? Is it real?

Justin: I don't know.

Sydnee: I mean, if your patient… is it real?

Justin: Yeah. The mind body link. You and I don't see eye to eye on this, but…

Sydnee: No. Well, I'm an empiricist. This is— this is the conversation.

Justin: I believe that the mind has incredible power to heal the body. So, if your mind believes something is real, then you still are getting a practical benefit. It's just a difference of opinion.

Sydnee: I think that… okay. Before we delve into this, um, sort of philosophical argument any further… why don't we head to the billing department?

Justin: Let's go!

[ad break]

Sydnee: So, what we really think of—

Justin: Wait, you didn't want to delve anymore into the… the philosophical discussion of the mind body link?

Sydnee: No, I was trying to distract you with ads.

Justin: And it worked!

Sydnee: You're always distracted by ads.

Justin: Fair enough.

Sydnee: It's true. So, in the uh, in the 1900s is really when we see like… the… at the same time that governments were figuring out how to regular medicines and drugs and all that kind of stuff, we were figuring out how to test them more rigorously. Right?

Justin: Right. Not much sense in regulating them if you can't actually tell if they're working or not. [laughing]

Sydnee: Well, and I mean, initially, there were just like, councils set up by like, the American Medical Association, where like, a bunch of experts just went, "We think this works! But that doesn't."

Justin: "So… anyway."

Sydnee: "There it is."

Justin: "We're going to lunch."

Sydnee: [laughs] But in 1943, the medical research council of the UK did an actual double-blind, randomized controlled trial with a drug called Patulin that was used for colds. And they enrolled over a thousand British people in it. They gave them either placebo, or Patulin. It didn't show that the drug worked, but it was a really good design.

Justin: I'm sure that was cold comfort to Patulin.

Sydnee: And in 1947, that was built upon with Streptomycin. So, there was a huge study that was designed in 1947 to see if Streptomycin would be a useful medication for tuberculosis. And what's really interesting about this trial is that, at— in this one… so, the way they used to randomize patients, like, if we're gonna test Streptomycin, then you would just give it to every other patient. Like, if you come in, you get Streptomycin. The next person who comes through the door doesn't. The next person who comes through the door does, and so on, and so forth.

What it— can you foresee what the problem with that is? Like, why would that not work? Why is that not an okay way to randomize patients?

Justin: Uh, I don't know.

Sydnee: So, let's say that the next— first of all, imagine doing that in a small town like ours.

Justin: Mm-hmm.

Sydnee: What are the chances that I'm gonna know one of the people who walk through the door?

Justin: Very good.

Sydnee: And what if they walk through the door, and they're a friend of mine…

Justin: And you wanna give them the good stuff.

Sydnee: And I wanna give them the good stuff, 'cause I really think it works.

Justin: Or, flipside, you don't want this stuff. It's basically rat poison that we put orange flavor into. Do not. You cannot. I'm gonna give you the fake stuff.

Sydnee: So, there's part of it. The other part of it is, like, you might be tempted to… if somebody came in who was really, really sick, and you thought, "Well, it's kind of too late. No matter how much I believe in this, I don't think that this is gonna work." Maybe you don't want to include them in your study.

Justin: Yeah.

Sydnee: I'm not saying that this was happening, but—

Justin: There's all kinds of human— dumb, human stuff.

Sydnee: Yes.

Justin: I mean, maybe you're like, a huge racist. [laughs] I mean, it just— it could be anything.

Sydnee: There's so many ways that this could go wrong. So, the idea was that, can we really, um… let's randomize people in a way that where even the person who is bringing them back, putting them to bed, and giving them

medicine doesn’t know who is who. Take the control. And that’s the whole idea of, like, a double-blind trial. Right? So like, the doctors don’t know who’s getting the real thing. The nurses don’t know who’s getting the real thing. And the patients, the subjects, don’t know who’s getting the real thing.

Justin: Triple blind.

Sydnee: Yeah. Well…

Justin: Well, no.

Sydnee: No, it’s still—

Justin: Doctors and nurses count as one blind.

Sydnee: They're one group, yes.

Justin: Okay, got it.

Sydnee: And so, this was— this was a big revolution. Now, we can do studies where we can really get good data. This study was like, inspiring to many. We can get good data back to show us, y'know, exactly what works and what doesn’t. It, by the way, did show that Streptomycin was helpful.

Justin: Oh, good! See, a win. A win for science. They're both a win for science.

Sydnee: Y'know what’s interesting? Now, I will say, do you know what the alternative was at the time?

Justin: Mm, nope.

Sydnee: Bed rest. [laughs]

Justin: Okay, well…

Sydnee: So…

Justin: You could do that, too, if you want.

Sydnee: [laughs] So, and I should say, um… A. Bradford Hill, Austin Bradford Hill, was the one who designed this study. He was a statistician, and he was famous for this. He is known as one of the early, y'know, like, scientists, statisticians who really got this stuff, and was able to like, put it all together.

Justin: Congratulations, Stan.

Sydnee: And uh, throughout the 1900s, you start to see like, the protocols… okay, so now we know how to do it, but like, how should we regulate this stuff? You can kind of imagine what sort of events drove… tighter controls. First, uh, after World War II and the Holocaust, there were a lot more regulations put in place as to like… you have to tell people they're in trials, and they have to agree to be in them.

Justin: Yeah.

Sydnee: And you can't just…

Justin: You have to let them out if they don't want to be in the trial. [laughs]

Sydnee: And also, you can't just experiment with anything on anybody for any reason. Like, you have to have reasons. Why do you think this works for this, and that kind of thing. 'Cause otherwise, you just harm people, right? Uh, Tuskegee is another good example.

Justin: Of course, yeah.

Sydnee: Of, after that came to light, that it is— it's unethical to have a treatment for something and not give it to people, just so you can observe the natural history of a disease.

Justin: What happens. Yeah.

Sydnee: Yes, that is… and so, uh, things like that evolved into the concept of informed consent. Do you know that— I use that term because I use it all the time. Do you know what that means, informed consent?

Justin: I mean, I got the idea, but maybe…

Sydnee: That is a… for a layperson, it makes sense. In the medical world, that concept of informed consent is incredibly important. And I think it… it is more than just its words. Obviously, before I do a procedure or give you a medicine or whatever, you give me consent. I ask, do you want it or not? And you say yes or no.

The informed part is hugely powerful, because I have to inform— I have to make sure that I feel confident that you understood why I think it's a good idea for you, why someone else might not think it's a good idea. What are the risks? What are the benefits?

Justin: That I'm okaying it, but also, you know that I know exactly what that means. What my acquiescence means.

Sydnee: And that— it can sound very simplistic, but it really is… I mean, you can spend— if you're good at your job, this will take you a long time sometimes. I mean, sometimes it's really easy, right? You have strep throat, here's the antibiotic for it. If you don't take it, here's what happens. If you do take it, you'll get better. [laughs] Y'know. Sometimes, it's really straightforward.

But informed consent sometimes is not that straightforward, and takes a lot more time to really make sure that you and the patient are on the same page. So that concept took a long time to evolve, alongside, um, the idea of it.

In the US, as I mentioned, initially, evidence-based medicine was guided by like, the American Medical Association, the AMA, and the FDA. They kind of

moved from like… at first, how would you decide if a medicine worked? Well, a doctor just said it did. To like, these pooled observational kind of studies, where like, let's get different doctors from all over, and all of their opinions, and come up with a consensus.

Justin: Mm-hmm.

Sydnee: And expert consensus opinion is still used to guide practice to this day in areas where we have an absence of data. But that was replaced, especially with the use of the FDA, by actual rigorous studies and trials. This was driven forward by a couple incidents. In 1938, there was an antibiotic, sulfanilamide, that was released, which was good and did work, except…

Justin: It sounds bad.

Sydnee: Well, it's a— it's one of the early sulfa drugs.

Justin: The name, I'm saying, just sounds bad. It sounds concerning.

Sydnee: [laughs] The drug is not bad. The problem is that it was, uh, when it was prepared, it was put in a solvent of diethylene glycol, which you probably know by the name *antifreeze.*

Justin: Oh no!

Sydnee: Yes. And so—

Justin: That's not solvin' anything!

Sydnee: Exactly. A hundred people died, because they were given an antibiotic that would have worked, had it not been…

Justin: For the antifreeze.

Sydnee: … mixed with antifreeze.

Justin: Jeeze-o-Pete. That's ghoulish.

Sydnee: Uh, and there were a ton of new regulations put in place after that incident. Because they didn't test the final compound. They tested the sulfanilamide, but they didn't test the final thing they were about to put in human bodies, right?

Justin: Right. Yeah.

Sydnee: So, that changed things. Um, and then, thalidomide in 1961 would lead to a lot more oversight and regulation. I won't belabor that, 'cause I think that's a whole episode in and of itself.

And over time, the other big change that has been made slowly is, initially, when you would do these studies, uh, you might focus on like… well, one, there was an idea of, you needed a population that could handle it. And two, who you had access to and that kind of thing. And so, there are… y'know, there were definitely, and we've talked about on the show, times when, um, populations who did not have control over, y'know, like a population that was imprisoned, would be used for these trials.

But also, sometimes, it would just be— you would do a whole trial of young, healthy, cis, straight white men. And like, eventually, they had to say, well, I mean, maybe these trials should not only have men in them. And maybe we also need to check on the elderly, because they can respond to things differently.

And maybe also kids. We need to know what works for them and what doesn't work for them, 'cause their… y'know, their bodies can react differently. And beyond ethnicity. There were a lot of things that had to change. To get truly diverse sample populations to check a drug in, to see, does it really work or not.

Justin: Which isn't just about inclusivity. It's safer for everybody.

Sydnee: Yeah, it's safer for everybody. And it makes sure that the pill that I'm recommending to you would work for you, and not just for a group of

people who are completely unlike you. You know. That helps us for a lot of reasons.

So, I want to talk a little bit about our experience now.

Justin: Yes!

Sydnee: Because we… so, how did we find out about it first? That's one big question.

Justin: Your— uh, so, your mom mentioned it to us, but I actually… y'know, it's not hard. You can Google, like, COVID-19 trials in your area.

Sydnee: Vaccine trials.

Justin: Vaccine trials in your area, and if one is going on. Or I think there's some services that like, match you with a trial in your region. I kind of thought it would be like jury duty, where they'd have to like, call you if they wanted to. But no, you just apply to do it.

Sydnee: Yeah, it was actually really easy. So, my mom was very proactively looking for one, and found this one. Um, and immediately enrolled both her and my dad. And then, after asking our permission, enrolled… she enrolled us. [laughs]

Justin: Yeah.

Sydnee: Enrolled both of us, and my sister, Rileigh, as well. And then, also passed that information on to like, 30 other people in our area.

Justin: Yeah. Which, I've been doing the same thing. Like, "Hey, this trial— " I've been surprised at how many people have been like, "Ehh, I'm just gonna wait until it's done, before I, uh, participate in any sort of trials."

Sydnee: So, I want to tackle that right away, because I think that bleeds into the next point I wanted to make, which is, people have asked why. Why did we get involved?

Justin: Hmm. Okay.

Sydnee: In this trial.

Justin: Twofold. For me, personally. One is… y'know, there's a decent chance that we're gonna— I mean, there's a decent chance we'll get the vaccine. Also a decent chance we'll get the placebo. Uh…

Sydnee: It is a better chance that— this study design, which, by the way, was the AstraZeneca slash Oxford vaccine is the one that we have either gotten or gotten placebo of. The first dose at this point.

Justin: Yeah.

Sydnee: There are two doses, uh, 28 days apart. We have received the first one, and… um, it isn't— if you're interested, you can read about it. It's supposed to be an adenovirus vector vaccine. They use this harmless, non-replicating virus…

Justin: Let's not get bogged down in a lot of technobabble. I mean…

Sydnee: The… anyway.

Justin: So, I like the idea of… one, I like the idea of, whether or not I get the vaccine, I'm helping. Y'know, we're kind of putting our money where our mouth is. Or our bodies where are mouths are, which is part of our bodies, now that I think… y'know what I mean. Uh, we've talked about vaccines a lot on this show, and I like the idea of being able to help a little bit with a vaccine. That's cool. That makes me feel good.

Uh, also, be chill to be vaccinated against COVID. Sydnee is a healthcare worker, and I'm less worried about myself.

Sydnee: And you live with me. That's why you're worried. [laughs]

Justin: I do live with Sydnee. So yeah, I don't… and y'know, her parents are— and my dad and step-mom are, y'know, in their twilight years.

Sydnee: Well, I wouldn't say that about them. They might listen.

Justin: [laughs]

Sydnee: And not like that.

Justin: I would say that to my dad's face. But the point is, we want to try to protect them, too. So, I don't know. That's what we…

Sydnee: I— those are— I mean, those are pretty much my reasons. That's what I would say. I would couple to that, um… first of all, I was not worried, because even though a lot of people have used the word 'rushed' in regard to these vaccines, I do not— I do not see them as rushed, because the thing that usually hangs up vaccine or drug development is not that it takes that much time. I mean, it's not that you need, necessarily, more hours in a lab to figure out how to do these things, or to make sure that they work, or to make sure that they're safe. It's not really that.

It's usually an issue of funding. And also, competition. So, if you're gonna put a ton of money into a new vaccine or therapeutic, you are gonna want to make sure that the thing you come out with, you're gonna be able to make money off of. Make that money back, and then… let's be honest…

Justin: Make a profit.

Sydnee: Profit, yes. And so, a lot of that time is in making sure, before you throw more money into it, taking it very slow. Um, sometimes, it's getting the funding for it. And then, sometimes, a lot of drugs will make it to phase two, and people will just decide not to go any further, because other drugs are outcompeting them already, y'know? And might make it to market first and get the big share of the money, and so on and so forth.

So, for all those reasons, that's why it usually takes so much longer. Those barriers weren't in place this time.

Justin: Mm-hmm.

Sydnee: They have— these vaccine companies have had tons of access to funding to drive this as fast as it can go.

Justin: Making it at warp speed. That's what I say, Sydnee. [blows raspberry]

Sydnee: I would not use that word. This is how fast drugs *can* be made when all of our scientific and societal will is pushing in the same direction.

Justin: This is the same energy that got human beings up on the moon.

Sydnee: [laughs] This is what we can accomplish when we all have a common goal. The thing is, that's not always the case.

Justin: We're getting bogged down. Let's just talk about our experience, because I think that there is going to be at least one episode just talking about why getting the vaccine is a great idea. So, why don't we talk about our personal experience?

Sydnee: Okay. So, when we… first of all, we went to the center, which is about 45 minutes from where we live. It was in a doctor's office. I think a lot of doctors can apply to have these trials at their facility, and so, this was in like, an outpatient office. We went to the waiting room, which was nicely laid out and socially distanced, with like, chairs and signs.

Justin: Appreciate that.

Sydnee: Signed in. We had to fill out, um… we had to read a very extensive, um, informed consent form.

Justin: Which was actually very well-written. It was very, um, plainly written. Not a lot of like— you would expect more legalese, and it wasn't really that. It was more sort of a clear, understandable, "Here's what you're getting into when you sign up for this." So, it felt less like the um… y'know,

the stuff you click through when you're trying to install something on your phone.

Sydnee: Yes.

Justin: Y'know, it was not that.

Sydnee: It was— I thought it was very well done, and it asked the questions exactly, "Why would I do this? Why would I not do this? What are the risks to it? What are the risks of…" I mean, of the procedures that are around it. Because like, they do have to draw your blood first. Um, they do store your blood somewhere. All those different things were very explicitly explained, and you had to check that you understood every single page before you could move on.

Justin: It even had a thing where if you hit to go to the next one too quickly, it'd be like, "You didn't really take your time with that. Do you want to take another look and see?"

Sydnee: It recorded how long you spent on each page.

Justin: Yeah.

Sydnee: Yeah. Uh, so, once you read all of that, if you were in agreement, you signed it. You turned all that in. And then, uh, we were called back… first, for basically an H&P, a history and physical. So, a doctor came in and asked a ton of questions about my health history, my current symptoms… wanted to establish that I was at risk for getting coronavirus.

Justin: Yeah.

Sydnee: What were my risk factors for actually, y'know, getting the disease? Which, as a healthcare worker, that was pretty much it. But because, if you never leave the house, and you'll never be exposed, we won't know if the vaccine really worked, or if you just… never encountered it. You know.

Justin: Yeah, right.

Sydnee: Which is always a possibility, but you want at least some risk, y'know, for your subjects. Um, they had me take a pregnancy test to ensure that I was not pregnant. Anyone of childbearing age was expected to do so. And uh, then they drew blood.

Justin: Not— not— not the most pleasant, but it was fine.

Sydnee: It was fine. I… it did not bother me.

Justin: I didn't look and I was a big, tough guy. So…

Sydnee: Part of it was for, like, a genetic study that they were doing in conjunction with this, and then, I believe part of it is to check for antibodies ahead of time. But they don't look— they don't like, condition what you get on that, 'cause they can't get the results that fast. It's all in one visit.

And then, once they had done all that, um… oh, and a very brief physical exam.

Justin: Yeah. Not much of anything to write home about.

Sydnee: Yes, very, very minimal. And after that, they came in, and I rolled up my sleeve, and they administered something.

Justin: Something.

Sydnee: Either a saline injection, or the vaccine itself.

Justin: So, let's talk about the reactions that we've had in our— in our cloister of people.

Sydnee: So, immediately, I had a little bit of redness, and a little bit of swelling and warmth at the injection site. Nothing painful. I didn't feel anything. But you could see it on examination. You… I think I was the only

one who had an injection site reaction on that first day. Nothing else. I felt fine.

Justin: Yeah. The next day, I had some, uh, some swelling and some soreness at the injection site.

Sydnee: Uh, as did Rileigh, and a little bit of a red circle at the injection site. My arm was sore the following day. Again, about what I would expect with other vaccines I've received. Things like the flu shot, or a TDAP, or something like that.

I had some symptoms. I did have a headache. I had some body aches. And I— I never had a fever that I recorded, but I felt like, some subjective, like, chills and sweats and that kind of thing.

Justin: Your mom had a similar reaction.

Sydnee: My mom had a similar reaction. Rileigh had a similar reaction.

Justin: Mm-hmm. Um, so maybe it's genetic. Who knows?

Sydnee: I don't know. You did not— you just felt a little tired.

Justin: Little run down. Not too bad. Of course, that could be, honestly… it's the worst symptom to try to distinguish between, uh, psychosomatic and not. Because it could very well have just been that I was just tired. [laughs] Like, that is entirely possible.

Sydnee: A little bit of nausea, too. We all had a little bit of nausea. My dad felt nothing. Nothing. Not a single of any of the things that I've mentioned, did my dad feel. Now, as to who got it and who didn't, we don't know.

Justin: Yeah, no clue.

Sydnee: What we do is, we go back in 28 days, we get our second whatever. Placebo or vaccine. And then, my understanding is, after at least

two weeks after that, there is some period of time after that, we will be made aware of what we got.

Justin: Yeah.

Sydnee: And at that point… the other thing that they did say, and also, they will be drawing antibodies periodically as we move forward. To look to see if we're creating antibodies.

Justin: We're also gonna have to keep going for the next, uh, two years or so. They're gonna keep checking up on us, and we're gonna continue to be participating in this study. So, it's not just a quick and easy way to get a… [laughs] Get a vaccine.

Sydnee: [laughs]

Justin: It's going to be frequent drives up to Charleston for quite some time.

Sydnee: Uh, it's not that frequent. It's not that bad, and we may have gotten the vaccine, so it's worth it. And we're furthering science.

Justin: That's the real exciting part.

Sydnee: That's the— that's a big thing. Of course, they'll be looking to see if any of us get coronavirus. We're supposed to report immediately if we have any symptoms so that they can find out. And they also, in addition to continuing to measure our, um, antibodies, they are following up on like, symptoms and side effects and that kind of thing. That's the other thing they are checking for. So they'll be calling us, y'know, a week from when we got it. So, in a few days, to find out how we're doing.

Justin: Yeah, there's been like a… I've gotten some emails. I don't know if you've been getting emails, about like, asking me to log my symptoms, that kind of thing.

Sydnee: Yeah. There's like, an app to check things on. And I should mention, all the symptoms we had were gone within, like, two days.

Justin: Yeah. We're fine.

Sydnee: I would call them mild, and I would say that I would do it again if that means I got the real deal. I would happily go forward again.

Justin: Absolutely.

Sydnee: It was no worse than what I've ever seen from any other common vaccine. Um, one thing that I think is important to know… they made it clear that, if at any point, a vaccine became available to us, was approved and available other than this vaccine, then they would, uh, tell us which one we got. To allow us the possibility to get that vaccine.

Justin: So, we are in the AstraZeneca trial. If, at some point, we had the opportunity to get the Moderna vaccine…

Sydnee: Or the Pfizer vaccine.

Justin: Or the Pfizer vaccine, we could ask the people of our trial, like, "Hey, do we have the real thing? 'Cause if not, I'm gonna go get at this."

Sydnee: Yes, and ethically, they have to tell us at that point. They've made that very clear.

Justin: Which I'm assuming would bump you out of the trial, right?

Sydnee: It would. Yeah.

Justin: You wouldn't be part of the study anymore.

Sydnee: Yeah. You'd be removed from the study. Um, and that— you can leave the study at any point. They make that very clear. And I just want to— one quick note. One a lot of people asked, why are there placebos in vaccine trials? Do you remember, Justin?

Justin: Well, it's so… because you have to compare how many of those people who got the placebo also got COVID, so you know how effective your vaccine is.

Sydnee: Right. Because you accept that most vaccines aren't 100%. So somebody's gonna get COVID. And if you didn't have a control group, y'know, what do you compare those numbers to?

Um, the other thing is, I do want to make a note – a lot of times, when we talk about the hesitancy of trying a new drug, or therapeutic, or vaccine, um… a lot of people point this out, that's a very valid concern.

Populations in this country that are marginalized, or have been abused or taken advantage of in our society, have been unfairly targeted for these types of things in the past. And there is still a lot of hesitancy when it comes to trying an unproven, y'know, drug or vaccine or whatever, among maybe members of the black community, or people of color, and uh, indigenous people.

And I think all of that is understandable and valid, and deserves the time and attention to, how do we overcome that together? How do we work together to make sure that people feel very comfortable, that the thing they're receiving is not… we're not using it experimentally on you because you're in a marginalized population.

I always want to give voice to that, because sometimes we're so easy to dismiss like, "Why would you be worried? Why would you be concerned?"

Justin: Makes perfect sense.

Sydnee: And we've talked about things like Tuskegee on this show before. Well, why do you think people would be concerned?

Justin: Yeah, there is not a great track record there, to put it mildly.

Sydnee: Yeah, especially when it comes to the United States government, and especially… with the current administration. I can understand why people have hesitancies or fears. But I am going to tell you that Donald Trump has nothing to do with the production of any of these vaccines. He's not in the lab.

Justin: No matter what he may claim in the coming weeks.

Sydnee: [laughs] He's not working with test tubes or beakers or pipettes or petri dishes. He wouldn't know how. The scientists who are making these vaccines know what they're doing. The science is solid. The numbers are good. I'm not worried about the stuff I've seen so far, about the AstraZeneca vaccine. It didn't give me pause.

Justin: Put it right in our veins, baby.

Sydnee: The fact that it is shelf stable— or, the fact that it is refrigerated, as opposed to having to be kept in a deep freeze, will be a big plus for like, rural communities like ours, for sure. And other parts of the world where a deep freeze vaccine would be very difficult, logistically.

All these vaccines are needed. And let me just say, I would've gotten any of them.

Justin: Yeah, sure.

Sydnee: Whatever trial I could've enrolled in, I would've. I'm not gonna enroll in multiple. That would be bad. [laughs]

Justin: Except for the Mountain Dew one. I'm not even sure that's a vaccine at this point. Um, I mean, it's made by Mountain Dew. What do they know about vaccines?

Sydnee: I don't think they're making a vaccine.

Justin: I assumed they would be.

Sydnee: Uh-huh.

Justin: But actually, I might've misread that headline, now that I think about it.

Sydnee: The Mountain Dew COVID Red…

Justin: [laughs]

Sydnee: No. But um, I would— if it is something you're interested in, look in your area. There might be a trial near you.

Justin: Might be a little late at this point, but hey, go for it.

Sydnee: They're still doing phase three trials.

Justin: Who knows? We just got ours on Sunday, so…

Sydnee: And there are other vaccines coming. These ones we've mentioned are the ones that they've talked about, 'cause they're furthest along. There are other vaccines still being trialed, and they're working on. It's gonna take a lot of vaccines to protect everybody, and it's gonna take a lot of time to convince everybody that we need these vaccines, you should get them, they are safe, they are effective…

Justin: And not to be a, um… y'know, all doom and gloom, but it is not easy to tell when you will be able to easily get a vaccine of your own. So, uh… y'know, if you are open to this, it might be worth exploring.

Sydnee: Mm-hmm. And you're doing your part for science. If you can do it, if you feel comfortable, and if you are, um, of a health that you can do so… this would, uh… this may be a good thing for you.

Justin: Thank you so much for listening to our program. We hope you've learned a little something. Hope you enjoyed yourself. Uh, I want to ask you right now… if you would be so kind, head on over to bit.ly/SawbonesPaperback. That's right – the Sawbones Book is back, and it

is in beautiful paper. I mean, it's always been paper, but this is really great paper.

December 29th, this new edition will be released. And yes, it has new content. We did some stuff about quarantines and the like.

Sydnee: Relevant to today's world.

Justin: Relevant to today. New illustrations by Sydnee's sibling, Teylor Smirl. And uh, it's just… it's great. And I really— it would mean a lot to us if you would be so kind as to go preorder that. Bit.ly/SawbonesPaperback. And y'know, it'll be out December 29th, so maybe you leave a little picture under the tree that's like, "I got you this book. It'll be here soon." It's a beautiful gift. And y'know, New Year's is just around the corner, so what better way to start… anyway, you get the idea. Bit.ly/SawbonesPaperback.

Thank you so much to The Taxpayers for the use of their song, "Medicines" as the intro and outro of our program. And uh, thanks to you, Syd, for uh…

Sydnee: Thank you.

Justin: … for listening. That is gonna do it for us for this week. So, until next time, my name is Justin McElroy.

Sydnee: I'm Sydnee McElroy.

Justin: And as always, don't drill a hole in your head!

[theme music plays]

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