

Transcript: California plans to make its own insulin and sell it super-cheap. Really.

Dan: Hey there. When I started making this show, one of the absolute must-do stories on my list was the price of insulin.

It's may be THE symbol of how out of control our medical system is:

Here's a drug that was discovered a hundred years ago now, a drug the people who discovered it DID NOT WANT TO PATENT, they never wanted anybody to make a profit on it.

... and people die all the time because they can't get it, because of the price.

How that came to happen was one of the first dozen or so stories we did.

And over time, as this show started focusing more on the practical how-tos of surviving this out of control medical system, a lot of the people I've learned the most from have been... people who need insulin to live.

People who have had to shape their lives around making sure they could get insulin. People like our producer Emily Pisacreta.

Emily: I've lived with type 1 diabetes since I was 11. For me, insulin is non-negotiable. If I go without insulin, within about 6 hours, I'm throwing up. Within 24, I'm in the ICU. So basically, my entire adult life has been molded around being able to afford insulin. Priced as it is in the US, that means I need good health insurance to afford to literally live.

Dan: And Emily, pretty much the first story you pitched me when you came aboard -- more than a year ago -- was about an idea to maybe solve this problem for a lot of people.

Emily: The idea was: California could make its own insulin. And sell it really cheap.

Dan: But at the time, it was still kind of an idea. Something the state of California was studying. Now, it's at a different stage.

Emily: Yep. A stage where there's real money involved. Here's California Governor Gavin Newsom announcing the plan in July.

Gov. Gavin Newsom: California's now taking matters into our own hands, the budget, I just signed sets aside a hundred million. So we can contract to make our own insulin at a cheaper price, close to at cost, and to make it available to all

Dan: They're calling the program Cal RX. But how's it going to work? IS it going to work? California, here we come.

This is an Arm and a Leg, a show about why health care costs so freaking much, and what we can maybe do about it. I'm Dan Weissmann. I'm a reporter and I like a challenge, so my job on this show is to take one of the most enraging, terrifying, and depressing parts of American life, and bring you something entertaining, empowering, and useful.

Emily, you've really really dug in to find out how far Gavin Newsom's \$100 million is going to get him. And you're the person to tell us how all this got going.

Emily: Yeah, well...For people who need insulin, the status quo is a crisis. A vial of insulin – which for me lasts about 10 days – is about \$300. --Which is five times more than it was in 2007. That's how we've ended up in a situation where an estimated 1 in 4 people who need insulin in the U.S., ration it. Meaning they take less than they need and hope to get by. Some of those folks develop long term complications. And some people die.

And this started getting more well known around 2017 when stories about young people dying because they couldn't afford their insulin started popping up in the news. There was Alec Smith in Minnesota.

News archive: Alec was a type one diabetic. Someone who needs to take insulin every day to survive, but turning 26 meant his parents' insurance would no longer cover the cost.

Emily: And Antavia Lee Worsham from Ohio.

News archive: Antoinette Worsham's daughter, Antavia, died at just 22 years old. Her mother says it's because her daughter could not afford to pay for insulin to treat her diabetes.

Emily: And there are lots of others. Their moms spoke out, and the media started paying attention.

News archive: The mothers in anguish, protested outside a Cambridge drug company today,

Emily: They got together with activists around the country to protest in front of the headquarters of Eli Lilly, Novo Nordisk, and Sanofi, the three giant pharmaceutical companies who make and set the price for insulin.

Dan: Yeah, didn't some states start actually passing laws to cap the price of insulin?

Emily: Well, Dan, that's what politicians wanted to say they were doing.

Delivering lower healthcare costs by capping insulin prices having the price of insulin. capped the cost of insulin and fought the drug companies.

Emily: But no. They were actually promoting COPAY caps.

Dan: Yeah, remind me why copay caps are... bad?

Emily: Copay caps limit how much you pay over the counter if you HAVE insurance.

Dan: Yeah, right. There are still a bunch of people who don't have insurance.

Emily: And for most people WITH insurance, these copay caps didn't do anything. Because, as we've touched on in this show, states don't even have the power to regulate the insurance most people get from work.

Dan: Oh. That seems like a pretty useless approach then.

Emily: Well, it's useful if you want to tell voters you're doing something about insulin... without doing anything the pharmaceutical industry would object to.

Dan: Oh, right. Those guys. A whole chunk of our last episode was about how powerful they are. So, yeah.

Emily: Politicians in these states didn't even try to cross them. One exception is Minnesota. That's where Alec Smith was from. One of those people whose

death made early headlines. Minnesota passed the Alec Smith Insulin Affordability Act, to help low income people get an emergency stash of insulin for free. And they wanted the insulin manufacturers to help pay for it.

Dan: And then what happened?

Emily: The insulin makers sued! The case is still in court. So when some folks from California were trying to decide how they wanted to tackle insulin prices, along with other drug prices, they knew pharma -- and politicians reluctant to piss them off -- would be an obstacle. So they had to get creative.

Chris Noble: At that time, we were throwing everything at the wall and saw what stuck.

Emily: That's Chris Noble. He works at an organization called Health Access California. Like me, Chris knows first hand what it's like to need insulin. He has type 1 diabetes too. He told me about a memory he had that's stuck with him. The summer after he finished college, he worked at a camp for kids with diabetes.

Chris Noble: And at the end of every summer, all of the camp counselors would basically. Put all of the donated insulin that was left over from the summer of sessions and distribute it to the folks that didn't have health insurance.

I didn't have health insurance at the time. Yeah. And so I was filling a backpack with vis of insulin to basically hold me over until my job started in the fall. So, and some people, they didn't have a job in the fall, so they would fill up their bags. They would get more bios of insulin to hold them over until the winter session of summer camp started.

Dan: That's some motivation.

Emily: It's hard to forget something like that. In 2019, Chris's colleagues at Health Access paired up with a California state senator named Richard Pan from Sacramento--who also happens to be a doctor. And they had an idea. What if it's not about capping anything.

Chris Noble: If pharma's gonna come up in arms and say, no, you can't regulate our prices. Well, what if we have another way around? And we actually just produce a commodity at cost that's the California state owned commodity. That we decide the prices, the government decides the prices

Emily: So, Senator Richard Pan, the doctor, introduced a bill in the fall of 2019 mandating the state undertake a study on whether it could manufacture its own generic drugs, including at least one form of insulin. And it passed. Pan says he learned about the public manufacturing drugs .. a long time ago in Massachusetts, where he was a medical resident.

Richard Pan: Massachusetts was manufacturing, vaccines, and some other items as well. And of course, other countries around the world.

Emily: So what California says they're trying to do with insulin has a lot of precedent. But that doesn't mean there won't be some obstacles. And the big ones -- they're not what you might expect. That's right after this.

-

Dan: So, California wants to make its own insulin. They want to sell it at or near cost. And the state recently budgeted \$100 million dollars over the next year to get it started. Is that gonna cover it?

Emily: Yeah, let's talk this budget. So it's a \$100 million for the first year. They're putting half the money toward building a manufacturing facility. And the other half will go essentially to a contractor. An existing company to develop the drug and spearhead the regulatory process.

Dan: The regulatory process?

Emily: Yeah dude. Drug companies love to talk about this: There's the cost of all the science to get a drug that works, and then all the studies you have to run to prove to the FDA that it's safe and effective. And that is does what you say it does. And that can be expensive. Especially for a drug like insulin-- what's called a "biosimilar." A generic biologic drug.

To get a sense of whether California has put enough in the piggy bank for biosimilar insulin, I talked to someone who's looked at this.

Melissa Barber: my name is Melissa Barber. I'm a PhD candidate at the Harvard, th Chan school of public health.

And I'm a health economist.

Emily: A couple years ago, Melissa worked on a project for the World Health Organization: figuring out what it costs to develop drugs and get them to

market. The idea was to give governments better ammo -- like, solid information-- when they negotiate with drug makers.

Dan: So -- let's see. We just went through this. That's like "drug development," which is all the experiments you run to actually get a drug that works, and then that 'regulatory approval process' and I guess raw materials ?

Emily: Yep, And on top of that, Melissa's also allowing for what would be generous profit margin in the world of generic drugs. And Voila. A potentially-reasonable price.

Because-- no surprise-- at their current market prices, a whole lot of brand name drugmakers have given themselves profit margins that are notoriously outrageous.

Melissa Barber: Some of the first drugs we costed were for, for hepatitis. Which was originally brought on the market for \$84,000 for a cure. And those drugs cost about 40 bucks to make including a profit margin.

Emily: In this case, a profit margin of 10% -- that's a little more than average for generic drugs.

Dan: I mean, OK, 10% is average, but maybe I want more than average here.

Emily: Well Melissa says you could get a huge margin, without ending up with the kinds of prices we have now.

Melissa Barber: So a government could be like, fine, we're gonna give you like, you know, 300% profit margin, a thousand price have profit margin and still, it would be less than what is being charged.

Emily: And for the insulin that most people use today --what Melissa's team found was that it could be produced for between \$78 and \$133 bucks per patient per year.

Dan: So I could charge double that-- hundred percent profit margin-- and it'd be less for a whole year than a single vial of insulin is now.

Emily: Yeah, and the cost Melissa is quoting here includes an allowance so you can recoup the costs of starting this whole operation. California is just putting in this hundred million bucks upfront, without planning to get it back later.

Dan: So, those are Melissa's numbers. Has anybody else priced this out?

Emily: Yeah-- she says she's looked at estimates from folks who are in this industry to make money, and their numbers look like hers. So, Melissa thinks California's budget seems like a reasonable place to start.

Dan: So, a hundred million covers putting together a drug that works, getting it approved by regulators, and... building a factory?

Emily: Uh-huh. Melissa points to what the big for-profit insulin makers have reportedly spent building their factories in recent years.

Melissa Barber: 50 million is a reasonable ballpark figure for the kind of money you'd expect to need to build such a facility, especially if they're just repurposing existing facilities or co-investing with a contract manufacturer.

Emily: Melissa says a lot is likely to depend on the terms of this contract, this private company California's partnering with. But the upshot is that, the budget doesn't seem totally off base here. And they're also not the only people attempting to make biosimilar insulin right now.

Dan: Yep! There's a non-profit called Civica Rx. And their insulin project is funded by a big partnership among health insurance companies, plus some diabetes nonprofits and foundations.

Emily: And Dan, your theory is that Civica Rx might well end up being Cal Rx's contractor.

Dan: And that maybe... who knows... California may not have been willing to bet on biosimilar insulin without Civica Rx.

Emily: I mean, that's your hunch and you're welcome to it. But you're not alone in speculating that they might end up being the partner. They did confirm to me that they applied, and that they share many of the same goals as Cal Rx.

Which means they'll probably face some of the same challenges.

For instance, pharmaceutical companies are notoriously litigious about their patents. And maybe it's not a patent on the insulin itself – with the ones Cal Rx is looking at – those are all long expired. But maybe it's something small, like a component part on an insulin pen.

Dan: I've told you before. You mess with that shit, you're going to court.

Emily: Totally. Sanofi took Merck to court when they tried to bring a biosimilar insulin. And Merck ended up pulling it. Not worth the hassle I guess.

Dan: So that's how this gets derailed? The pharma companies sue California?

Emily: We can't predict for sure. The folks I spoke with at Cal Rx admit that's always gonna be a risk. But I talked to James Love, an expert in drug patent law. And he told me that California might have a huge leg up on this front. Thanks to a big Supreme Court case in the 90's, states are actually immune from patent challenges.

Dan: Hmm! Lawsuit-proof. I'm starting to think this could actually work out.

Emily: Not so fast. There's a different hurdle that Cal Rx could face. This is something I hadn't even thought of until a consultant from Cal RX brought it up. Getting their insulin covered by insurance. This is David Toppelberg:

David Toppelberg: do you know how the pharmacy benefits managers work? The PBMs?

Emily: Unfortunately, I have some idea. Yes.

Dan: Aw, man. PBMs! We did a whole episode on these guys. They're middleman companies that basically decide which drugs your insurance plan will cover. They're super-powerful, partly because there's only three big PBMs.

In theory, they're negotiating with pharma companies to get discounts.

In reality, they're skimming a ton for themselves. So, higher a drug's list price is, the more there is for the PBM to skim.

Emily: Yep. Expensive insulin means PBMs make more money.

Dan: It's wild.. Emily, after you brought up David's concern, I talked with Karen Van Nuys-- she's an economist at the University of Southern California who published a study last year about who makes how much on expensive insulin.

And I asked her: Come on, if California makes super-cheap insulin, PBMs are gonna cover it, right?

Karen Van Nuys: optimistic to be, but I will say that the incentives are not, um, are not conducive to, uh, PBMs, happily making that agreement,

Dan: that just seems bananas to me though, right? I mean,

Karen Van Nuys: right? Yeah. Well, the drug pricing. Yeah. yeah.

Dan: Now, Karen had just told me: Insurance companies DO get to tell PBMs what they want. I asked her, can't they just tell the PBMs they want the super-cheap insulin? Can't they just insist?

Karen Van Nuys: Yeah, they certainly can insist, but it's basically giving up a very profitable chunk of business for the PBM and what are they gonna pay in return?

Dan: I mean, I don't know whether I'm more pissed off at the drug companies or the PBMs at this point.

Emily: Now imagine having Type 1 diabetes. Imagine this is about a drug you need literally to survive from one day to the next.

Dan: (sputters some more) And THIS is maybe the biggest obstacle to California's cheap-insulin plan? Actually making it AVAILABLE to people on their insurance?

Emily: Yep. David Toppleberg from CalRx says they do have a plan. It involves trying to bypass the PBMs, negotiating directly with insurance companies. And selling directly to patients. People can pay cash. Something people without insurance have to do anyway.

David and his boss Vishaal Pegany told me they expect Cal Rx insulin to be available at major retailers--and maybe eventually available for people out-of-state, too. In fact, whole states have expressed interest in buying it in bulk, like Washington.

But David told me the goal for Cal Rx isn't to sell a ton of insulin.. It's to get insulin prices a lot lower. Even if the state loses money on it.

David Toppelberg: let's say that we bring our insulin product to market and all of our competitors lower their prices to what we have. And we don't sell a single viable insulin because they've all lowered their prices. That would be a success for us.

Dan: Meanwhile, Emily-- from another part of your conversation with David, it sounds like one part is definitely starting to fall into place.

Emily: What kind of design are the vials gonna have? Is there gonna be like a California style logo?

David Toppelberg: There actually is, yeah.

Emily: Yeah?

David Toppelberg: We have a logo that we've designed that's in line with, uh, the California ethos.

Dan: What do you think the California ethos is?

Emily: I don't know, but it sounds pretty good to me.

Dan: Is it gonna be like raisins? Are we talking surfboards? Was California an early legal weed state? Like what's it gonna be? Snoop Dog? Beach boys?

Emily: Maybe just a golden bear.

Dan: A golden bear? What the hell is a golden bear?

Emily: Have you ever seen the flag for the republic of California? It's a flag that like a lot people have in their dorm rooms.

Dan: One of the University of California campuses has the banana slug for their mascot.

Emily: Banana slug insulin. I'm here for it.

Dan: I guess we'll find out. Meanwhile, we'll catch you in three weeks. Til then, take care of yourself.

This episode of An Arm and a Leg was produced by Emily Pisacreta, with help from me, Dan Weissmann, and edited by Marian Wang. Thanks to our operations manager, Sarah Ballema, for production help.

Daisy Rosario is our consulting managing producer.

Adam Raymonda is our audio wizard. Our music is by Dave Winer and Blue Dot Sessions.

Gabrielle Healy is our managing editor for audience. She edits the First Aid Kit Newsletter.

Bea Bosco is our consulting director of operations.

This season of an arm and a leg is a co production with Kaiser health news. That's a nonprofit news service about healthcare in America, an editorially-independent program of the Kaiser family foundation.

KHN is not affiliated with Kaiser Permanente, the big healthcare outfit. They share an ancestor. The 20th century industrialist Henry J Kaiser.

When he died, he left half his money to the foundation that later created Kaiser health news. You can learn more about him and Kaiser health news at [arm and a leg show dot com slash Kaiser](http://armandalegshow.com/slash/Kaiser).

Diane Webber is national editor for broadcast at Kaiser health news. She is editorial liaison to this show.

Also: Our pals at KHN make other podcasts you might like! For instance, if you want The Latest on the politics of health care, you may already follow "What the Health," hosted by KHN's chief Washington Correspondent, Julie Rovner. Every week she brings together reporters from top outlets to break down the latest news, including the Supreme Court's recent bombshell abortion decision. That's at [K H N dot org, slash podcasts](http://KHN.org/slash/podcasts).

Thanks to Public Narrative -- a Chicago-based group that helps journalists and non-profits tell better stories-- for serving as our fiscal sponsor, allowing us to accept tax-exempt donations. You can learn more about Public Narrative at [www dot public narrative dot org](http://www.dotpublicnarrative.org).

And those donations support this show. If you're not a donor yet, we'd love to have you. Come on by to [www dot arm and a leg show dot com slash support](http://www.armandalegshow.com/support).

Thank you!