AT: Welcome to the Infinite Women Podcast. I'm your host, Allison Tyra, and today I'm joined by Dr. Kaley Butten, a research scientist with CSIRO, to talk about pharmacologist and physician Dr. Frances Oldham Kelsey. So why don't we start with what she's best known for?

KB: In 1960, Frances Oldham Kelsey was hired as a reviewer for the U.S. Food and Drug Administration. One of her first assignments was an application to approve the use of thalidomide as a tranquilizer and painkiller, specifically for pregnant women to ease morning sickness. Although it had been previously approved in more than 20 other countries, including Canada, and despite pressure from the manufacturer, Kelsey withheld approval and requested further studies. She was concerned because an English study had documented peripheral neuritis, inflammation of the nervous system, as a side effect. She also wanted evidence that the drug was not harmful to fetuses. So in July 1962, she was hailed as a hero on the front page of the Washington Post for, I quote, “preventing the birth of hundreds or indeed thousands of armless and legless children.” Birth deformities in Europe had been linked to their mothers taking thalidomide. As a result of the story coming to light, the Kefauver–Harris Amendment was passed unanimously in Congress that October, strengthening drug regulation in the U.S. Companies would now be required to demonstrate the efficacy of new drugs, report adverse reactions to the FDA, and request consent from clinical study participants. The law required stricter limits on the testing and distribution of new drugs, and for the first time, recognized that effectiveness should be required to be established prior to marketing.

AT: So it sounds like she pretty much established a precedent in the U.S. for making sure that drugs aren't harmful before approving them, which kind of seems like a big deal.

KB: She did. It's really impressive work. It's something that kind of changed regulation worldwide. Particularly from a woman at that period of time where there's so many barriers, she spoke up and challenged the social norm. More than 20 other countries had approved this, and she stood up against big companies, her peers. She would have had to be so brave.

AT: Yeah, and it's important to remember that she wasn't working in isolation, because I'm sure there are many other people, including women, who have expressed reservations about things, and if you don't have people above you who are willing to listen, it falls on deaf ears.

KB: Totally, and I think this is really heartening to hear. She credited her superiors at the FDA for backing her up, rather than pressuring her to rubber stamp thalidomide. As you said, too often, women's opinions and research are dismissed out of hand, and those consequences can really be devastating.

At: Dr Kelsey's interest in teratogens, which are drugs that cause both defects, this actually started when she was at university in Canada.

KB: Yeah, and I love this story because it's funny how she got the job. She had been encouraged by one of her professors at McGill University to write to a pharmacology department

at the University of Chicago asking for a position to do some graduate work. And the person unaware of the spelling conventions with Francis with an I versus Frances with an E, I believe accepted her request thinking that she was a man and offered her the position. So she started working in 1936, and it was during her second year there, that this person, Geiling, was asked to work for the FDA to research unusual deaths related to an antimicrobial called a sulfanilamide. And she assisted on this research project and it showed that there was 107 deaths that were caused by diethylene glycol, which is a solvent that's used in the medicine. And from that, the next year, the United States Congress passed the Federal Food Drug and Cosmetic Act of 1938. And in that same year, she finished her studies and received her PhD at the University of Chicago in pharmacology. And this kind of work that she was doing with Geiling caused her interest in teratogens or drugs that cause birth defects or congenital malformations. So she joined the University of Chicago faculty after completing her PhD. And then in 1942, like many other pharmacologists, she was looking for a cure for malaria, and learned that some drugs are able to pass through the placental barrier, which is essentially what a teratogen can do and cause a birth defect.

AT: It is worth noting that Dr. Kelsey was married in 1943. So as we're talking about how she's doing these studies and she's going to uni, she had two children. But unlike a lot of women of her era, it doesn't seem to have negatively impacted her career as a faculty member. So you mentioned first, she was at the University of Chicago, and later she was working at the University of South Dakota. So the fact that she was married with children while simultaneously building a career was, I mean, it's great, but it was very unusual.

KB: Yeah, I find this really interesting as well, particularly because there were a lot of anti-nepotism rules at American universities, which prevented spouses being employed at the same university, even if they were in different departments, which is kind of ridiculous. And, you know, typically it would be women that lost their job or were prevented from being hired. The same thing happened, you know, in Australia, up until November 1966, the Australian Public Service required married women to resign and lose their work. And there's a very notable CSIRO radio physicist Ruby Payne Scott. She actually hid her marriage so that she could continue on working, which I both love and hate, you know - fancy having to choose between the love of your life and recognizing a partnership and then, you know, your passion and your work.

AT: Well, it's especially funny because she led everyone to believe that she was living in sin with the guy. And that's, you know, with the stigma that that would have had in, you know, mid-20th century, Western culture. And I think this went on for something like seven years. And the fact that she would rather deal with whatever social stigma there was, because then when it did come out, she did actually, like, you know, like you were saying, she lost all of these benefits and everything.

KB: So it is maddening that it happened. But it's that sort of story that says that, you know, Dr. Kelsey must have had really good supports in place. She must have had a successful personal

partnership to have this successful professional career, which is really lovely to think about.

AT: Yeah. And it is nice to acknowledge the supportive men in these women's lives, like, you know, Mr. Payne Scott, which I'm pretty sure was not his actual name, went along with the, sure, we'll just hide the fact that we're married from everyone for years.
Dr. Kelsey also had quite a long career. So she worked for the FDA for 45 years. And she was actually 90 years old when she retired in 2005, which is impressive by any standard.

KB: She contributed a lot up until the age of 90. It wasn't just consultation. She was, you know, actively working. She was recognized in 2010 - the FDA presented her with the first drug safety excellence award and named the annual award after her. And I'm so pleased that she got the recognition. I really don't think many people know about her, though. And what she did and the implications for health care globally, you know, it's not just the United States that benefited. It was, you know, our health care regulations and the frameworks that we have and the standards that we have. She stood up and made change.

AT: I believe there's also a connection between, you know, the groundwork that she laid and the work that you are doing today.

KB: Yeah, there is. And I should say, one of the reasons I'm so proud is because she is Canadian. She's from my hometown on Vancouver Island in Canada. But also, I suppose, I work for the Australian eHealth Research Center. And we are exploring, you know, innovation and technology in health care. And I suppose we reference a lot of kind of the work and standards that she fought for in terms of, you know, making sure that health care is safe for everyone, particularly vulnerable populations. And I think that's something that's important to note, you know, there's pregnant women and women in general can be vulnerable in health care. And so her putting her hand up and standing up for women and pregnant women was super powerful. Within the eHealth Research Center, we are very passionate about regulations and standards and making sure that we've done our due diligence when we're exploring whether technology is fit for a health care environment and creating technology interventions, you know, whether it be something for monitoring or whether it be an active intervention, whether it's for screening or diagnostics, using these regulatory frameworks to ensure that people's privacy is protected, to ensure that it's not going to actively harm anyone. You know, it's fine for something to be effective, but is it safe? So certainly I think thalidomide was effective in reducing morning sickness, but it wasn't safe. And, you know, it seems an obvious thing. And I think in technology, you know, innovation can be so exciting and we think it could be a panacea for everything. But that's not necessarily the case. And these regulatory frameworks keep us safe and keep healthcare accessible. People have confidence to adopt something if they know that we've crossed our T's and dotted our eyes and gone through all the rigorous checks to make sure that that technology is going to be useful and safe for them. Even though I'm not on pharmacology, you see the connection across the board, just in science in general, this kind of adherence to standards and the importance. And particularly now as, you know, artificial intelligence is blowing up, we're very mindful at the eHealth Research Center that we need to ensure that all of

this new, exciting stuff is meeting the standards.

AT: Yeah, as you've been talking about this, the word that keeps coming into my mind is trust. And I think we especially saw that with, you know, the COVID-19 pandemic and people, you know, refusing to follow safety guidelines and misinformation. But I think CSIRO has a really high degree of trust, rightfully so. And it seems like regulations like this help maintain and build that trust that in turn, you know, is really needed. Because if people don't trust you, they're not going to listen to you. And that can have really awful repercussions both for individuals and societies, as we saw.

KB: As scientists at CSIRO, we know that our work, it's the federal science agency for Australia. So we know that our work is meant to be for the Australian people. It's meant to be for the benefit of the Australian people. So that is often our guiding light, you know, that we're doing stuff to help Australians. It's never just for the sake or for the curiosity. It's really to explore how we can better support Australians to live healthy and happy lives. So that trust needs to be there. So our focus is always on that.

AT: And you're also carrying on Dr. Kelsey's legacy in a different way, helping people with the Mother app. So can you tell us a bit about that?

KB: Yeah. So I am a research scientist at the Australian eHealth Research Center. And my work is primarily looking at mobile health platforms to support the management of chronic disease. So my big project is in gestational diabetes. Usually, women with gestational diabetes or diabetes in pregnancy would have to record their blood sugar levels, their blood glucose levels in a paper-based diary. And they'd have to do that about four times a day and then go see their clinician at the hospital. They see multiple clinicians as well, it's multidisciplinary, once a week or once a fortnight. So it's a huge burden on the mom and then also on the health system because there's so many touch points. And so what we've developed here in collaboration with some of the Australian hospitals is a platform to support that management of gestational diabetes. So rather than using a paper diary, Mom can take her sugar levels with a Bluetooth-enabled glucometer. And the glucometer can talk to the app on her phone. And then the app talks to a web-based platform. And the clinician can remotely view those sugars. So Mom doesn't have to come into hospital all the time. She's not having to carry this ratty paper diary with her everywhere. Most people these days have a mobile phone. So she can just plug in her sugars into the app. And then it just talks to the clinician dashboard. And the clinician can log on at a time that suits them and check the sugars. We've been doing this study for a few years now and anecdotally, the feedback is very positive. And we've done a feasibility study. And then we've done an implementation study. And I think what's important to me is that it's acceptable to women. So women, busy moms really appreciate this technology. It fits in with their life, allows them some flexibility. So that's really important, you know, rather than something that's going to cause an extra burden. Being pregnant is challenging. Being diagnosed with diabetes is extra challenging during your pregnancy. So anything that can kind of alleviate some of that stress is a really good thing.

AT: Yeah, especially as someone who lives in a regional area with limited doctors. That's, I think, a problem for most regional areas, not just mine, but I know, you know, just getting an appointment with your GP here can take two weeks. And that's if you have a GP, because a lot of them won't even accept new patients because they're just full. So I can see how having to travel less to see specialists potentially and, you know, not having to try and fit appointments in when resources are already limited is beneficial, not just to those people, but also to the whole community.

KB: Definitely, that's something that really excites us is the potential for regional and remote areas. But even within, you know, urban settings, just having that close oversight and allowing for earlier interventions and that feeling that, “oh, someone's going to be able to catch this potentially. I'm not waiting around to get feedback.” Something that women have told us is that they really appreciate the text messages that they get from their care providers saying, “hey, you're doing a great job, you know, no change needed.” It's that little bit of communication, that bridge between a patient and their provider, which is really lovely, and, I think, improves well-being. I know from my own experience as a mother, you feel like you're adrift at sea sometimes and you just want someone to say, “hey, you're doing a good job,” or “don't worry about this. It's lovely that technology can, you know, give that little bit of extra support.

AT: It sounds like it's really the combination of technology and humanity.

KB: Yeah, totally. Technology is not a panacea, it can't fix everything. You need that human element for it to be safe and for it to work as it should, I suppose, and to get the most out of it. It's people interacting with the technology, which is the exciting bit and using it as an extension rather than a solution. We still need doctors, we still need our hospitals, but if we can just use it as a support, then that's awesome.

AT: Join us next time on the Infinite Women podcast and remember, well-behaved women rarely make history.