Health Care Beat: Episode 52 - AI & Health Care: Innovation, Regulation, and Reality – Part 1: Understanding the Present and Preparing for the Future

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Amanda Genovese
Welcome to Health Care Beat, a health law podcast brought to you by Seyfarth Shaw's cross disciplinary Health Care group.

Chris DeMeo
Each Health Care Beat episode focuses on key industry trends and legal developments while identifying practical takeaways for those dealing with these issues every day.

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I'm Amanda Genovese, a Seyfarth attorney in New York.

Chris DeMeo
I'm Chris DeMeo, a Seyfarth attorney in Houston. Let's get started.

Amanda Genovese
On this episode of Health Care Beat. We'll kick off a multi-part series exploring the intersection of artificial intelligence, health care, and the evolving legal landscape that organizations must navigate to stay compliant and adaptable. We're joined today by Rachel See, senior counsel in Seyfarth's Washington, DC office. Rachel, welcome to Health Care Beat.

Rachel See
Hi Amanda, glad to be here.

Amanda Genovese
Well, Rachel, you have an incredible background, and we would love for you to provide an overview for our listeners. Get into the nitty gritty, please.

Rachel See
Oh gosh, I got to talk about myself so. So So before returning to Seyfarth in 2023 I worked for over a decade in the federal government. I was at both the EEOC, the US Equal Employment Opportunity Commission and the National Labor Relations Board, working on technology. So I worked for Commissioner Keith saunderling As a senior counsel for AI and algorithmic bias, and also held management positions such as Acting Executive Officer, Special Assistant to the EEOC chair, and I

was also on the litigation side as the EEOC Assistant General Counsel for technology, essentially helping the commission sort out technology, including artificial intelligence, and what it meant for The Commission's mission to help prevent and remedy unlawful discrimination.

Chris DeMeo
Thanks, Rachel. What I'm curious about, and what I think some of our listeners are going to be curious about, is, obviously, we've heard a lot about AI in health care, and it's easy to get lost in the forest and not see the trees. Can you start with an overview of your understanding of AI and health care, why it's important and why we need to be talking about it today.

Rachel See
Thanks, Chris. So first, my disclaimer primarily an employment lawyer. I've been working in the law and technology sphere for almost all my career, and you know, I think there are some really exciting and useful parallels between the industry, the AI industry, and the tools that we're seeing in the employment sphere and the way that folks are looking at AI in the health care sphere. And so one of, one of the ways to think about it is, where are we not seeing AI in these industries? And the answer is, you know, I think there's an AI application, or people want to use AI across all the life cycle, whether we're talking employment or health care or, you know, there's a tool out there. These are multi billion dollar industries, and so, you know, in health care, whether we're talking about things that directly affect patient care, that affect the business of health care, that affect insurance, that affect, you know, just just making health care providers lives easier and helping to automate or augment processes. Those are all there, just like we're seeing in the employment sphere, where we have some decision making applications as well as things that help the humans be better. And yeah, there are people that are asking chatgpt whether or not they should do things, and that comes with different risks too.

Chris DeMeo
Thanks for that overview, Rachel. And you know my understanding, and I think a lot of people think about AI as organizing or finding data and without getting bogged down into predictive analytics versus large language models, et cetera. The definitions, how is AI being used in health care in that context?

Rachel See
So one of the ways to think about AI and machine learning and these models, these mathematical models, is that, fundamentally, what they're doing is they're taking a bunch of data, lots of data, they're analyzing it, and they're seeking the models. Are seeking to make mathematical predictions about what might happen, what result is going to happen if you feed different data in it, or to make predictions about is this similar. So for instance, we have, we have image recognition technology, basic image recognition technology, that that's whether it's facial recognition or, you know, is, is it? Is it a cat or a dog? What kind of dog is it that that's basic AI machine learning image recognition technology? And, of course, there's an application to that, to reading X rays or MRIs. And do these machine learning models understand the concepts of you know, there's these different applications. Well, no, they're seeking to find things that are similar. That's the fundamental way that the technology works, making predictions based on data. Now, a lot of folks are hopefully familiar by now with chatgpt and large language models. Large language models fundamentally pretty. Predict what word comes next. We took our developers, took a bunch of data, a bunch of words, whether it's the internet or books or medical

journals or medical articles, peer reviewed articles or not, and mashing them into a model and trying to predict what word comes next. And that that can be very powerful, but also have totally different applications than an image recognition program, an image recognition model that's helping a radiologist interpret an X-ray.

Amanda Genovese
So Rachel, let's kind of shift gears a bit and talk about the legal landscape. You know, AI, compliance, regulatory challenges. Who are the regulators primarily for health care when we're thinking about the application of AI?

Rachel See
Absolutely. Thanks, Amanda. So I think that in the employment sphere, we talk about what the EEOC has said and what our existing laws are, and I think the health care environment is much the same way that that we we don't have a lot of laws that specifically say for AI. If you do this with AI, here's the steps you have to follow. Rather, we have existing laws and regulations that apply to the use of AI or machine learning. So, if you did it with a spreadsheet, if you did it with a human being, what are the requirements? And if you say, oh, but I'm using AI Now, are there different requirements? Well, sometimes there are, sometimes, sometimes not. But our starting point is that is that our existing laws apply. So in the context of health care, someone you know, one of the fundamental questions is, is the use of AI here? Is it a medical device? And so we have the FDA regulating medical devices and approving medical devices. And so if we have an AI system that fits into that definition that were that the intended use of that AI system qualifies as a medical device under the FDA act, then we're into that regulatory umbrella. Likewise, you have, you have these broader concepts of truthful advertising and privacy regulations, and HHS is broader regulations on health care, and that all makes these agencies interested stakeholders in all of these tools and in the way that people are using all of these tools.

Amanda Genovese
And how about data privacy concerns thinking of HIPAA state level regulations. What are we looking at there as it relates to legal landscape and AI compliance?

Rachel See
Oh yeah, that's definitely something to be to be aware about. So I guess it's the flip side of my other answer. There's no, but I'm doing it with AI. I don't have to comply. There's, there's no exception like that. So all of these existing regulations about privacy and HIPAA and HIPAA high tech, and the things that you need to do to protect PII or spii, if you're sending it through AI, if you're sending it through an AI system for analysis, or, you know, if you're if you're training a machine learning model on it, do these regulations apply? Well, well, they might. It depends on what consents you have. It depends on what you're doing with it. If you're pasting patient data into chat gpts web interface, I suspect you might have a problem. Perhaps you should talk to your lawyers at Seifert or elsewhere before you paste in patient data into chat GPT and so, you know, I think the regulators you what you know at the state level, whether we're talking California or elsewhere, I think they're extremely sensitive to, you know, understanding that automated decision making tools ADM tease in the word in the language of the California Privacy Protection Agency, you know that that's an area of regulatory concern, and they're

passing new regulations that specifically target that. But again, our starting point is the existing regulations, the existing laws apply to AI.

Amanda Genovese
And you have, you noticed any specific challenges in AI related litigation and liability?

Rachel See
Sure. Well, first, AI litigation, you know, on, you know, what's it involved lately? You know, I think there's a lot of things that that folks are worried about the existing litigation. You know, we've seen people go after open AI on copyright infringement, but the lawsuits or the regulatory action targeting vendors or, you know, AI developers or deployers for the way they're using the application, we've seen not a lot of that. You know, certainly in the employment sphere there's there's one well known class action that's pending. And in the health care sphere there, there's people that have taken exception to models being used in various ways, but that kind of litigation isn't being filed every day now. Certainly there's things over the. Horizon that folks are worried about, and I think risk management needs to take that into account. So, you know, just because folks aren't filing the lawsuits today doesn't mean that there isn't risk. And you know, part of you know, the fundamental question that I think folks need to be asking across all of these domains is, what's the benefit that you're seeking to attain, that you're seeking to achieve, from using this AI application, from throwing AI at this problem, and what's the risk? And part of thinking about AI risk is, what happens if the model is wrong. So, you know, again, going back to medical devices, I think you know, one of, one of the fundamental questions is, is this application a medical device? And if it is a medical device, what happens if it's wrong? Now, if we're talking about other applications that aren't medical devices, if we're talking about things that are helping, say, a primary care provider transcribe some notes, helping out with dictation, helping out with insurance coding, where is this in a gray zone, and where is it not and the risk of that algorithm, the risk of that model being wrong, can be different, and the way we react or we manage lower risk applications should be different than the way we manage higher risk applications.

Chris DeMeo
And just to pick up on that concept. So what if the AI gets it wrong, and there's an incident with with a patient, is that, you know, from a litigation perspective, do you see the doctor? Do you see the AI company? Do you get somebody that says you didn't build your AI model appropriately? Or can you go straight to products liability, if it's a device, and say, bad outcome, strict liability.

Rachel See
Oh, gosh, I wouldn't want to opine on litigation outcomes here, or litigation risk in the in that way. You know, I think, you know, in the employment sphere, we say, well, the AI Deployer, the employer often owns, the risk. And you know, where, where we have patient, you know, diagnoses and outcomes here, you know, where is the human in the loop? Is the bot autonomously making a diagnosis and making a decision? You know, is there? Is there a human who is reviewing the decision? You know, if the human reviews the decision, where does that, you know, come in? Where does liability attach? I think, as you know, we've seen in multiple types of litigation, everyone who touches it is liable to be tagged if something goes wrong. And where, you know, where I think we have automation bias. And you know, automation bias is, is really a thing to be aware of. The bot made me do it. The bot made me

discriminate or cause me to make this, this, this misdiagnosis. I don't know that that's an effective affirmative defense for a professional or for a human being who's ultimately responsible for a decision. And you know, as I said, our our existing laws apply. So if we're if we're talking about malpractice and malpractice liability, or products liability and uses or intended use, we have human beings who are ultimately owning this process, are ultimately responsible for this process. And if you're building something, if you're building an AI system where human beings are not responsible, where there is no human in the loop, then that comes with greater risk. That comes with even higher risk. And you know, certainly there are tools out there where the point is automation. The point is to have humans less in the loop. But ultimately, the human, you know, there is someone who says, We're gonna this is what we're doing. And, you know, the bot made me do it isn't an effective affirmative defense, because that's where I think we are today.

Chris DeMeo
The old, learned intermediary defense gets them every time.

Rachel See
Indeed, indeed.

Chris DeMeo
Pivoting a bit and looking ahead, where do you see you based on your experience in the employment field and your understanding of the use of AI and the health care field, what are some predictions or some thoughts you have about the next five to 10 years? And can we look back on the past five years of AI and make any decisions based on that? Or is the technology so out of control that it's going to be exponentially more complex in the future?

Rachel See
Oh gosh, Chris, five to 10 years, that's a tough one. I think if you asked us in 2000 what AI and machine learning would be in five years, I think most people would be wrong. Most people would be wrong for different reasons. What I can predict with confidence is that in the short term, we will continue to see FOMO Fear Of Missing Out in the industry and an increasingly maturing AI vendor space and deployer space that that people are getting more experience in buying, deploying, developing. These applications, folks are less likely to be the first charging in to these new systems, and I think that increases FOMO, and that increases Fear Of Missing Out, and the fear that if we don't adopt AI, our competitors are going to overtake us. I think that is one of one of the themes that we see on the geopolitical stage, and what we see in the AI regulatory policy of the Trump administration saying that that we are in an AI arms race of sorts with our global competitors, and seeing AI regulation as something that harms competition. And so the general approach of the current administration has been articulating a very hands off approach on AI, regulation and enforcement, and we have executive orders that talk about disparate impact, and I don't want to get too much in the weeds, but but essentially saying that statistical disparities across race, gender and protected classes are not evidence of intent to discriminate according under the federal government, and they're going to de prioritize those kinds of investigations and enforcement activities across all these domains. Now, how that dovetails in with the FDA activities on regulating medical devices that may use AI is a machine learning model that has disparate impact across sex and race. You know is that a safe and effective medical device? Well,

let's see what the FDA has to say on that. The devil is going to be in the details. There other trends to be aware of that whatever the federal government does, we have all of these existing state laws and state regulators, including state insurance regulators, and how that interacts with what the federal government is doing. That's very complicated. And I think in the absence of federal regulation on AI, I think state legislators and regulators are, especially in blue states, are feeling both compelled and perhaps empowered to act, and that makes us a very complicated environment.

Chris DeMeo
Rachel, that's fantastic. Unfortunately, that is all the time we have for today. But I will just, you know, let a look behind the curtain to our listeners. We've been trying to set this up for a long time, and it was worth it. That was one of the better discussions of AI and health care, I've heard talking about it as a challenge to learn rather than scaring the hell out of me. So I want to jump out of a window, so I appreciate that very much. And on behalf of Amanda and the health care beat podcast team, we'd like to thank you for joining us and sharing your insights with our listeners.

Rachel See
Thanks, Chris. Thanks, Amanda.

Chris DeMeo
And thank you for joining us for another edition of Seyfarth's Health Care Beat podcast, bringing you the latest developments and pressing issues in health law so you'll never miss an episode. Be sure to visit Seyfarth.com or follow us on SoundCloud or Apple podcasts. If you enjoyed this episode, please share it with your friends and colleagues. We look forward to having you with us again soon.