

Big Law Redefined Podcast – Digital Health Miniseries – Episode 1

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Charles Dunham: Welcome to Greenberg Traurig's mini-series podcast on digital health law. Today's episode will focus on the rise in digital health technologies, including [00:00:30] artificial intelligence, machine learning enabled technologies, the changing US federal and state regulatory landscape related thereto, and the importance of internal governance and compliance for developers and deployers of AI tools.

I'm your host Charles Dunham. I'm a corporate health care attorney and shareholder in GT's Houston office. And with me today is Nick Diamond and Kieran Dwyer. Nick is a shareholder in GT's Houston office. His practice spans research, [00:01:00] commercialization, post-market compliance, marketing and promotion, and enforcement across all FDA regulatory products with a primary focus on drugs, devices, and diagnostics, including digital health products.

Kieran is a shareholder in GT's Minneapolis office. He advises cloud providers and technology companies in technology transactions and partnerships, product development, artificial intelligence, and regulatory compliance. Kieran was previously the [00:01:30] head of Global Partner and Specialist Strategy and Engagement at Amazon Web Services.

Gentlemen, welcome to the GT Podcast.

Nick Diamond: Thanks, Charles. Pleasure to be here.

Kieran Dwyer: Thanks. Looking forward to it.

Charles Dunham: All right. Well, let's level set on terminology before we jump into substance. Nick, well, if you can get us started with your definition of digital health technology and the breadth of that definition.

Nick Diamond: Well, Charles, I'll slightly dodge your question here and give you a sense of how FDA, rather than me personally, thinks [00:02:00] about a definition of digital health technology.

And bottom line upfront is FDA uses that terminology in the broadest sense possible, which I think is pretty consistent with how industry uses the terminology as well. So FDA would include things like mobile health applications, health IT, wearables, even telehealth and certain personalized medicine technologies in that definition as well.

Where the nuance comes in, which I know we'll get [00:02:30] into in a bit, is that certain digital health technologies can be considered a medical device

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based on falling under the definition of a device in federal law: essentially any technology, hardware or software that has an intended use for medical purposes. So to treat, diagnose, or prevent a disease and not otherwise a drug. There is some nuance there, but generally speaking, FDA thinks about digital health technologies in that [00:03:00] very broad way.

Charles Dunham: Yeah, and I agree. I think that's consistent with the market and especially just the term "digital health" alone, touching the advent of so many new opportunities and developments in the health care arena and how that term is being utilized, even as broad as just encountering telehealth and telemedicine. So thanks, Nick.

Kieran, for your definition of artificial intelligence, which is also a term that has different uses, and give us some examples of practical use cases in the health care industry.

Kieran Dwyer: [00:03:30] Thanks, Charles. I'm glad you said "my definition" of artificial intelligence, because there are hundreds of definitions floating out there between the legal side and the computer science side as to actually what constitutes artificial intelligence. But from a practical standpoint, if you look at how regulations define it, it breaks down into five things.

It's a computer system that can operate autonomously based on objectives and can infer from inputs how to generate an output. Now, that's a mouthful. It's a little abstract. [00:04:00] And so from a practical standpoint, AI encompasses a number of technologies that are adaptive based on the inputs. It can include the generative AI that many of us are beginning to use to help write emails and do research, to facial recognition software and things like computer security that adapts to threats that continue to evolve in the environment.

There's a lot of great examples across the industry, but in health care, there are some ones [00:04:30] that I particularly love. One great example that I think many of us have had firsthand experience with is doctors using AI to take notes during a doctor's appointment.

I love this example because the use benefits are so immediate if you think about it. That AI tool saves doctors a ton of time charting. It doesn't replace charting, but on average, studies show that it saves about two to three hours a day for doctors. Think about how much time that gives doctors back to spend time on care [00:05:00] and on recharging and being rested.

It also allows the doctors to help put patients at ease because it eliminates the need, in many cases, to have a medical scribe. They're present, which can make patients feel like they don't have the privacy that they would normally expect with a doctor.

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Another example is AI-based drug discovery and pharmaceutical design. There are now new drugs already going through the approval process that have been designed by AI.

One final example I'll cite too is there are ballpark around [00:05:30] a thousand AI-enabled medical devices somewhere in the FDA's approval process. And about 70% of those are in radiology, where they are helping medical professionals analyze and diagnose from imaging.

As this evolves, we're going to see a lot more technology, and it's going to pervade the health care space. Because it's not only going to happen in the medical device and clinical space, it's also going to attach to everything else that happens in the health care space, from supply chain to staffing. [00:06:00] All of these will have AI applications that will start to be adopted in the industry.

Charles Dunham:

That last example, Kieran, about the frequency with which radiology and radiologists have utilized these tools and historically and the percentage of which those AI tools and the FDA approvals are so predominant. We're seeing that now in pathology is that is expanding in imaging and assisting pathologists in diagnosis.

And if you haven't heard, examples of something that can even be a personalized [00:06:30] tool to, as Nick was mentioning, oversight, which we'll get into. But even melanoma and tracking that, and being able to have personal apps that can track that and give feedback to individuals on that front. It's a fascinating arena and where it's expanding to.

Let's turn to that, Nick, on FDA regulation. Can you provide a brief historical overview of FDA's regulation of digital health technologies, specifically and including AI- and ML-enabled technologies?

Nick Diamond:

[00:07:00] I think the history here is maybe going to be surprising to some folks. And I think most people, just given the way technology has paced in the market over recent years, would be forgiven to think that FDA has really only been watching this space for, let's say, the past five or so years.

But if you go all the way back to the 1980s, FDA had actually been starting to basically, at nudging from industry, start to look at, quote unquote, [00:07:30] computer products was the terminology they use in weighing whether certain computer products might fall under FDA's regulatory purview as medical devices.

And so the first document you actually see released from FDA in the digital health space was back in 1989, and essentially said that all computer products are not medical devices, which is I think no surprise to anybody. FDA doesn't regulate the underlying platform. They regulate sometimes the functions in

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[00:08:00] the digital health space, and more on that buzzword, function, in a moment.

But over time, FDA, since that policy statement in 1989 has, in order to essentially keep up with the technology, taken a step-by-step approach rather than a comprehensive regulatory approach in the digital health space. It wasn't actually until 2013 where we saw FDA release guidance on, to use its terminology, device software functions. [00:08:30] In other words, software that's regulated as a medical device in the same way that FDA regulates hardware medical devices.

And in 2013, FDA had really released that guidance because there were activities happening within IMDRF, which is the International Medical Device Regulators Forum, essentially a convening group that brings together regulators from different markets around the world together with industry to work on really timely [00:09:00] issues, which over the years have included digital health issues and more recently, especially AI- and ML-related issues.

So after that guidance was released, not much happened for a couple of years in terms of what was shared publicly. But the 21st Century Cures Act was signed into law December 13th of 2016. And as we can talk about a little bit later, the Cures Act modified some parts of the law with respect to medical devices that [00:09:30] dealt with what we commonly would call clinical decision support tools.

And so that end of 2016 mark was really important because later in 2017, and a few years after that, in 2019, FDA released more guidance specifically to address some of these issues that were teed up by the changes under the Cures Act.

And around that same time, we also saw FDA releasing draft and then final guidance on a topic I know we'll get into in a moment, general wellness [00:10:00] products, which are somewhat related to devices, but not necessarily regulated as devices.

So just as a framing comment to round out that historical arc, I mentioned that buzzword, function, before. And FDA does not regulate digital health products in terms of their underlying platform. For example, a digital watch is not itself regulated. But the apps that might be loaded onto that digital watch [00:10:30] and used by users, if they have a medical device intended use, the app, the function, would be regulated.

And there might be multiple functions that are regulated within a single app, but FDA really looks at the function and based on the intended use of the function would determine whether it was a regulated medical device or not.

So just want to make that point that I think sometimes gets missed in these discussions that FDA, for example, is not regulating an entire generative AI

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platform. But [00:11:00] it might regulate particular functions that that gen AI platform performs.

And the second thing also, because this has come up increasingly as the historical arc in the past couple of years has bent towards these AI and ML issues, FDA does not necessarily regulate based on a software function leveraging artificial intelligence or machine learning. FDA is looking at software broadly. And if that software happens to be AI- and ML-enabled, [00:11:30] and also if that function otherwise performs a medical device intended use, then it would be regulated.

But essentially from FDA's perspective, whether it's a device or not a device, AI and ML doesn't really bend things in one direction or another. It really comes back to that intended use.

Charles Dunham: Excellent. And we know when the FDA and their positions, enforcement discretions and guidance that comes out, it can vary from administration to administration. And so I want to stay on [00:12:00] this topic of FDA and how they're otherwise addressing those issues that you've just raised with general wellness and clinical decision support.

Now there's been a lot of buzz recently around how the FDA under the current Trump administration is approaching the use of digital health technologies and general wellness and clinical decision support. Nick, can you summarize the FDA's recent announcements and guidance, and provide us with your insights on the potential impact of these developments?

Nick Diamond: [00:12:30] Well, if we zoom out a little bit to start, in the current administration from FDA, we've generally heard a more and more favorable position on digital health products from the FDA. And that to some degree started in the prior administration. And I think as in most people, I think watched this space would agree, has accelerated quite a bit in the current administration. And by "favorable," I mean that in two [00:13:00] ways.

The first is FDA increasingly looking in very targeted ways, such as the final guidance documents I'll talk about here in a moment, to clarify ambiguities in prior guidance, which industry has wrestled with in recent years, and often has to go to FDA to ask for clarification when they're trying to make business decisions.

And then second, clarification itself has increasingly bent in the direction of more [00:13:30] and more digital health technologies not being regulated as medical devices. And that's not a wholesale-type position. It's still, in the way FDA has always done it, taken it on a product-by-product basis.

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But increasingly, those clarifications have essentially widened the space for non-device digital health products, which for most of industry, staying outside of FDA's regulatory purview is generally a business goal.

So two examples of that recently, [00:14:00] and this has only been in the past few weeks, FDA released two final guidance documents, the first one on what they call general wellness products, and the second one on what they call clinical decision support.

This would be an exceedingly long podcast if we went through all of the nuances in both of these final guidance documents. So I'll just give you the highlights. Again, this feeds back into that general directional trend that I was referring to a moment ago.

So for general wellness products, FDA thinks of general [00:14:30] wellness products just conceptually as having an intended use that relates to maintaining a healthy lifestyle or reducing the risk or impact of certain diseases or conditions, and that also present a low risk to safety for users.

So general wellness products essentially do not have that medical device intended use. They're not intended to diagnose, treat, or prevent a disease or condition. So the impetus [00:15:00] for the general wellness guidance, which was first released, I believe back in 2019, was to clarify for industry if you're releasing a digital health product and you think it might have a general wellness intended use, here's how to think about whether it's going to be a device or not a device.

The recent update to that final guidance got into some issues that industry had been essentially asking FDA about for several years, particularly around wearables. And this was something [00:15:30] we saw the FDA commissioner comment on quite publicly around the time this final guidance update was released.

And so there is some commentary about wearables essentially to say that if it's a non-invasive sensing function that's intended to estimate, infer certain outputs like physiological parameters, blood pressure, blood glucose, heart rate variability, as long as it doesn't have a medical device intended use, in other words, not diagnostic, not [00:16:00] for treatment, then it might be a general wellness product. Again, outside of the definition of "device," pretty favorable for industry.

FDA also had some commentary on wearables in the recent updates that said that if a wearable is displaying values, ranges, trends, summaries over time, it could still be a general wellness product if it's contextualized in relation to something like sleep or stress or recovery, the types of things we just intuitively [00:16:30] think of as relating to general wellness rather than medical treatment

per se, and if those values and ranges, et cetera, have otherwise been validated by the manufacturer.

So this is where it gets a little bit squishy, and it's not 100% clear what FDA would expect in terms of sufficient validation by a manufacturer. The guidance references testing by the manufacturer refers to peer-reviewed clinical literature. But the specifics there are still a [00:17:00] little vague.

FDA also said with respect to wearables that they can still be general wellness products if a wearable is notifying the user that they should go essentially ask their doctor for more help. And this is something that those of us that have played around with the different wearable products out there in the marketplace pretty regularly see.

And so what FDA was essentially saying here is, "We want to provide a little bit more clarity on the guardrails for those types of notifications [00:17:30] to help the manufacturers determine is their wearable not a device? Or is it actually performing a diagnostic or treatment function?" So that's in a nutshell the updates to the general wellness guidance. Again, all directionally pretty favorable for industry.

With respect to the clinical decision support guidance, this goes back to that mention I made earlier of the changes under the 21st Century Cures Act. I won't go through all of those changes in [00:18:00] detail because again, that's a much longer discussion. But the updates to the clinical decision support guidance recently were intended to basically, number one, clarify a few questions that industry typically has on some of the ...

There are four criteria under the Cures Act that essentially you have to check all four boxes in order for your CDS function to not be a medical device. And so FDA provided some clarifications [00:18:30] on discrete criterion based on what industry essentially had been asking them for quite some time.

But importantly, FDA, with respect to one of the criterion, introduced this new enforcement discretion policy where it said that it would not enforce against software functions that provide one clinically appropriate recommendation to the user, but otherwise satisfy the other three criteria under the CURES Act.

[00:19:00] So just to situate things there, the CDS, in FDA's view, is intended to be a HCP-facing tool. So this is not something that you or I as a general consumer would be interacting with in the same way that I was talking about those wearables under the general wellness guidance.

This is really a situation where you have a software function, oftentimes AI- and ML-enabled increasingly so, that is looking at a bunch of different data inputs and making [00:19:30] one or more recommendations to the HCP on next steps.

So the prior guidance had some language that essentially pushed software developers to provide a suite of recommendations in these instances rather than one single recommendation. And what FDA is saying here is, "We're not changing our position necessarily with respect to one versus multiple recommendations. But if the software function happens to only [00:20:00] offer one clinically appropriate recommendation based on the data, for example, that it was analyzing, we'll exercise enforcement discretion."

And Charles, as you alluded to before, enforcement discretion really is just FDA saying, "We're not going to send you an angry letter," for example. It's not FDA really changing the regs. So sometimes you'll see one administration have a particular perspective on enforcement discretion, and then the next administration have a different perspective [00:20:30] on that. So for folks listening that developing digital health tools, just keep that in mind that enforcement discretion is not written in stone, so to speak. It might change when the administrations change over.

And then finally, just briefly, FDA had provided some clarity in the CDS guidance updates on the fourth and final criterion under the Cures Act. And very specifically, FDA was trying to clarify how and what [00:21:00] level of information about an underlying algorithm should be presented to an HCP in order to enable them to independently review, for example, a recommendation that the software function is making.

In the previous version of the guidance, FDA had put by industry's perspective, a relatively onerous set of guardrails in place about the level of detail that an HCP user should be provided about [00:21:30] how the software function essentially churned out the output.

And some folks had questioned, "Is that level of detail about the underlying algorithm really going to be relevant and practical for an HCP trying to make an important clinical decision?" And so FDA essentially walked back some of those expectations here. Again, pretty favorable for industry in particular, because this puts software developers in a place where they don't have to [00:22:00] disclose necessarily the same amount of information on the underlying algorithm.

And look, if you have a proprietary algorithm, you probably don't want to disclose a certain amount of the underlying details about that algorithm as part of the function. It would be better generally from a risk mitigation standpoint to simply tell the HCP users only what they needed to know in practical terms. So that's more or less the impetus behind that change.

So Charles, that was [00:22:30] a lot of information, but just wanted to give a sense of sort of two sides of the equation, the general wellness and then the device software function side.

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Charles Dunham: Excellent information, Nick. Thank you for the summary of a complex area and the insights and your perspective on that.

I know at the time that those guidances were released, the FDA Commissioner Makary was making a presentation, and in that presentation alluded to the desire for the agency to be more proactive [00:23:00] or forward-thinking in its regulation of AI- and ML-enabled medical devices and technology, specifically so that the market and developers would have a better roadmap and understand what the FDA was looking for.

So I assume that we're going to be waiting for more guidance and directives from the FDA, which we'll be digesting and maybe even talking about later on down the road. So thanks again for all those insights.

And Kieran, [00:23:30] I want to turn to you because of the explosion of all of the AI- and ML-enabled medical devices and technology, and being deployed more commonly in the health care market these days. How are the federal and state governments starting to regulate this arena beyond just the FDA?

Kieran Dwyer: Charles, it's a patchwork right now. And before I dig deeper into that patchwork, I want to really underscore what Nick said here and highlight the challenge that industry players are seeing in health care.

AI [00:24:00] as a highly adaptable technology is driving transformation end-to-end across the business in health care. What that means is not only are companies having to grapple with AI-specific regulation, they're having to take a step back and go revisit what all of these regulations that have already applied to their business mean for the use of AI. Because as Nick said, they don't specifically regulate software separately as a different medical device. It's all within [00:24:30] that medical device analysis.

And so this is a real challenge for companies as they have to navigate not only the burgeoning regulation of AI specifically, but the impacts that AI has on their existing regulated activities.

So as we dig into AI-specific regulation, 2025 saw so many different regulatory approaches arise at the state level. We today don't have federal action on AI. President Trump has discussed an AI [00:25:00] state law ban, but that has not been implemented to date. As a result, there were over 1,000 AI-focused bills introduced in 2025. Some 38 states adopted or enacted approximately 100 measures. And within that, 34 states introduced 250 health care-related AI bills, with about two dozen of those actually being implemented.

And here's part of the challenge, Charles, [00:25:30] is that these bills are not a one-to-one reflection of another. There is no uniform code on how to regulate AI, which means that every state is taking a slightly different approach, making it a huge challenge for companies that operate across multiple states.

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What we are seeing, though, are some trends. We're seeing trends around transparency, human review requirements, analysis of discriminatory impact, and certain prohibited uses. [00:26:00] On transparency, we're seeing disclosure requirements in some cases like California and Texas. In others, we're seeing consent requirements. For example, Illinois is requiring consent before AI can be used in connection with mental health care.

And with respect to discrimination, we're seeing also different approaches in how the laws is trying to address this problem. Because AI can have biases in how it's applied, [00:26:30] and this can have discriminatory impact, and it's something that regulators are really focused on addressing that risk. But what we're seeing is a different standard of care. Some states like Texas are focusing on making sure there's no discriminatory intent. Other states are looking at the effect and whether there is a discriminatory effect.

Also, I have to note this here, just because the state law addresses discriminatory impact of AI does not mean that separately there won't be an issue under other [00:27:00] laws regarding discrimination or common law. Because we're seeing a lot of cases being filed around discriminatory impact under common-law theories or other statutory theories.

Then, we're seeing certain requirements around human review. For example, California is prohibiting use of AI to make insurance decisions without human review. This is an area where we're going to see a lot more focus, because it's one of the key areas where we are seeing there be a need for AI controls is to [00:27:30] have a human in the loop. And so that's one that I expect that we will continue to see regulation on.

Finally, we are also seeing areas where legislators are prohibiting AI for certain specific uses: for example, holding out health care chatbots as licensed AI professionals. So it's going to continue to be a patchwork. Companies are going to have to continue to struggle with their existing regulatory frameworks, the new AI frameworks, as well as existing common-law and other [00:28:00] theories of liability that might exist with respect to use of this technology.

Charles Dunham: Thanks, Kieran. What I think is really interesting in what you highlighted is the application across all spectrums of the health care industry. One, you touched upon the human involvement in two aspects.

One being making actual ultimate diagnoses, and then making sure that a licensed professional does review and is involved in that diagnostic determination and treatment decisions in those [00:28:30] state laws that are mandating that. Texas being one of them, and California, the other example where you're talking where, well, now it's involved in payer insurance decisions of what is medical necessity and coverage determinations and mandating that human involvement in that ultimate decision.

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It's interesting, this is all designed to otherwise create efficiencies. But these laws are now mandating human review and involvement, perhaps likely because some of the areas where there needs [00:29:00] to be some critical thinking and evaluation of the outputs of this technology that these state governments are involved in. Fascinating issues and things that will continue to evolve for sure.

As health care providers and suppliers are deploying these technologies more and more from hospitals and health systems to specialty and ancillary providers like we've discussed during this podcast, Kieran, can you describe what an effective AI governance looks like and why it's so important?

Kieran Dwyer:

[00:29:30] Yeah. Charles, so first off, governance is not going to be optional. States, including Colorado and Texas are either mandating or incentivizing companies to have AI governance programs to cover risk identification, establish management policies, conduct regular assessments.

And the good news is that the National Institute of Standards and Technology AI Risk Management Framework is emerging as a [00:30:00] benchmark or safe harbor for these governance programs. I will say, however, NIST, while it's the NIST AI RMF, as it's called, framework is a fantastic deep dive into how to manage AI within a company, it is complex. There are over 70 different subcategories that a company has to pay attention to when implementing a governance program.

And so any company starting to think about how they approach governance, [00:30:30] NIST is the destination. It is not the starting point of how to think about the problem. And so let me break down how I think about the problem and how to approach it.

First off is governance has to be a shared responsibility at the leadership level. And it needs to include both leaders from the business or clinical side. It needs to include leaders from the legal and compliance teams. And [00:31:00] it needs to include leaders from the technology and security teams.

And they really have to come together and work together to understand this technology, which is the second point. Governance has to be curious about what's going on here. There is so much happening with AI, both in a clinical setting, but also in an operational setting.

I mentioned supply chain. There will be impacts to a business around adopting AI supply chain technologies. It's going to reduce costs. [00:31:30] It's going to increase efficiencies. But it's also going to introduce risks on the supply chain side as well if it's not appropriately managed. So it has to look across AI adoption for the whole business.

You also have to start listening to your stakeholders and your employees, because they're going to start using AI tools whether you like it or not. AI is

available on our phones. Everybody has access to it now. And the existing tools and software tools that people are already using in their day- [00:32:00] to-day work, those providers are adding AI features into those tools that become immediately available to your workforce. AI is proliferating everywhere, and it's really important as an initial step for that leadership team to begin to understand how the organization is using it.

And from there, once you begin to understand those use cases, create an assessment of the fundamental risks associated with this [00:32:30] technology: including security, privacy, regulatory compliance, risk management, and then all of the unique risks that will apply to the specific business. Because each company, each operator is going to have a different set of risks and unfortunate outcomes that could result if these technologies are not appropriately managed.

The second element is building out that landscape and understanding what is happening [00:33:00] with AI, and then building out that governed structure of how you want to think about risk as a company. Then you need to approach this from a cultural change standpoint, because that risk management structure is going to create new requirements on your operations.

It's going to create new requirements on your employees. And it's going to create new interactions with your patients, your customers, your stakeholders. And all of that is going to require [00:33:30] training and communication. That is so critical in this, and I think one of the easiest things that companies miss when they start thinking about AI governance.

Finally, at a high level, when approaching your governance structure for AI, you have to keep it agile. You have to understand that your governance program is going to have to continue to adapt, because we are in a period of both of rapid technology innovation where new use cases, new impacts [00:34:00] are going to be discovered, adopted, deployed.

We're also going to see a lot more continued regulation in this space. And so you have to build your governance program around the idea that it is going to continue to evolve.

And from there, from those first principles, build out to a full structure of risk management and governance that looks like the NIST AI Risk Management Framework. But starting from those high-level principles will drive [00:34:30] a significantly better result for the company.

Charles Dunham: I highlight what you said in the beginning there about the mandates that some state regulators are imposing upon both the developers and deployers with respects to AI technologies. That will not only be something that steers how you adopt the governance, but otherwise your policies and procedures and protocols that are in place. So keeping an eye on that and as it develops,

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Colorado and Texas being great examples [00:35:00] of those states and really diving into those laws and understanding them from that standpoint for sure.

Last question for both of you as we round out this podcast. Simple one, toss it out there: your top recommendations for developers and deployers of AI- and ML-enabled medical devices and technology to take away and key highlights. Nick, you want to start with you?

Nick Diamond:

Well, from my perspective, you really have to watch closely what FDA continues to do in the digital health space. And if [00:35:30] you asked me that same question a few years ago, I would say the same thing. But I think there's much more of a premium now on really closely watching what FDA does over the next couple of years with respect to digital health products.

And it's important to just remember that as we saw with the recent updates to the two final guidance documents, FDA tends to act through the guidance process, which those of us in the health care space that [00:36:00] maybe work more so on the CMS side of things are used to a pretty defined cadence of Notice-and-Comment Rulemaking, which generally is not how FDA works. And so guidance can be issued as we saw somewhat on short notice, somewhat of a surprise to industry.

And industry's ability to comment on guidance as it's developed or as it's changed looks different, because guidance is not subject to the same Notice-and-Comment [00:36:30] Rulemaking procedures that we have under the Administrative Procedures Act. So industry just needs to be a little more attentive and in my view, look for other opportunities to engage with FDA on priority issues.

I would also just finally say that we've been talking about these issues in a somewhat narrow way, certainly the commentary I've provided on the FDA issues. But you need to also, in my view, be mindful of how some of these issues [00:37:00] could potentially spill over into other risk areas for your business.

One that comes to mind in particular is on the product litigation and risk side of things, where even if your product isn't a medical device, let's say you've got one of those CDS non-device software functions that spits out one particular recommendation, based on underlying algorithm that an HCP uses to make clinical decisions.

Even though that might not be a device [00:37:30] under the recent guidance changes, if HCPs are making decisions based on recommendations that your software is providing, that might create if harm results, litigation risks that otherwise maybe isn't there. So that's just one example off the cuff.

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But bottom line is I would just think of these regulatory issues within the broader risk mitigation framework that your company deploys when it develops products like this.

Charles Dunham: Excellent point, Nick. And I think probably a topic [00:38:00] for our product liability colleagues in a subsequent podcast here and the digital outflow. Kieran, how about you?

Kieran Dwyer: I think the biggest thing to keep in mind is that AI is here to stay, and it is accelerating. It's going to be present in everything that companies do. And this is not a "Wait and see what happens, and then we'll get ready for it." Companies have to start dealing with this now.

The other thing is Nick highlighted the risk around these products and the potential product liability that you have to manage. [00:38:30] I would also say there's a flip side to that coin, which is AI is an immensely powerful technology. And it has the power to not only increase access to health care for our country, it also has the capability to deliver better health outcomes.

And companies should be looking at, "How do we do better with AI? How can AI allow us to achieve new levels of what our health care mission is?" It's such an exciting time, and [00:39:00] it's so easy to get lost in the risk that, especially as lawyers. But you have to keep in mind that these technologies here are immensely powerful, and the impacts are real.

Charles Dunham: Well, gentlemen, both of you, thank you for excellent content, and thank you to our listeners for tuning in. Please be on the lookout for our next podcast on digital health. Have a good one.