The Good Bot: Artificial Intelligence, Health Care, and the Law —
AI and Pharmacovigilance Under the FDA's New Emerging Drug Safety Technology Program
Host: Brett Mason
Guests: Judy O'Grady and Kyle Dolinsky
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Brett Mason:

Welcome to *The Good Bot*, a podcast focusing on the intersection of artificial intelligence, healthcare, and the law. I'm Brett Mason, your host. As a trial lawyer at Troutman Pepper, my primary focus is on litigating and trying cases for life sciences and healthcare companies. However, as a self-proclaimed tech enthusiast, I am also deeply fascinated by the role of technology in advancing the healthcare industry.

Our mission with this podcast is to equip you with a comprehensive understanding of artificial intelligence technology, its current, and potential future applications in healthcare, and the legal implications of integrating this technology into the healthcare sector. If you need a basic understanding of what artificial intelligence technology is, and how it's being integrated into healthcare, I recommend starting with our first podcast episode. There, we lay the groundwork for understanding the technology that is the basis of all of our discussions.

I am excited today to welcome back to the podcast two of my colleagues, Judy O'Grady and Kyle Dolinsky. Judy is a partner in Troutman Pepper's Washington, DC office, and she leads the firm's FDA regulatory team focusing primarily on drugs, biologics, and medical devices. Kyle is an associate for now, although about to be partner in our Troutman Pepper office in Philadelphia. His practice consists of FDA regulatory counseling in the food, drug, biologics, and medical devices space. Kyle also does fraud and abuse counseling and some litigations in the life sciences space. So, Kyle, Judy, welcome back to the podcast.

Kyle Dolinsky:

Thanks. How's it going, Brett?

Brett Mason:

We're good. We're good. Congratulations to you, Kyle.

Kyle Dolinsky:

Thanks. Not sure when this is going to air, but the public announcement comes in October, so it's time –

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Brett Mason:

We'll be good. Now, since we're welcoming you back to the podcast, Kyle, could you just remind us and highlight some of the topics we covered in the last episode that you and Judy participated in?

Kyle Dolinsky:

Sure, Brett. Last time, we delved into how AI is being integrated into medical devices and drug development, highlighting the FDA's proactive stance in addressing AI through their regulatory framework. We also discussed the FDA's evolving strategies, including their focus on a lifecycle-based approach to regulate artificial intelligence and machine learning driven devices.

Brett Mason:

Judy, do you also want to chime in to some of the things we discussed during our last episode?

Judy O'Grady:

Of course. So, we also talked about how the FDA had stressed the importance of post marketing surveillance in their proposed regulatory framework. They specifically discussed AI being a potential benefit in the context of adverse event evaluation for approved products. So, they have now moved forward with that, and they believe that the AI or machine learning can help detect and address any issues that arise after a product is being marketed.

Brett Mason:

It was a great episode. So, listeners, if you missed it, I would recommend you go back and give it a listen. Kyle and Judy are wealth of knowledge, and I really enjoyed talking with them about that. Which also leads us nicely in today's discussion, which is examining the FDA recently announced emerging drug safety technology program. So, let's start there, Judy. What is this new program that's been announced by the FDA this summer.

Judy O'Grady:

Sure. So, this is the FDA new program called the emerging drug safety technology program. They of course have an acronym for it, EDSTP, yet to be seen if that will be actually said phonetically or will just refer to it as the EDSTP. But as part of the new program, the FDA also announced emerging drug safety technology program meetings. So, the programs and meetings were announced in the Federal Register on June 6th of this year. I don't think it was a surprise that FDA went in this direction shortly after the discussion papers, or the most recent discussion paper that we last talked about. Because safety and ensuring that marketed products are and remain safe is one of the cornerstones of the FDA's mission.

Brett Mason:

So, Kyle, can you just talk about the substance of the program before we get into the details?

Kyle Dolinsky:

Sure, Brett. I'm happy to. This is a new initiative aimed at identifying, evaluating, and implementing cutting-edge technologies to enhance drug safety. It's designed to leverage integrative technologies such as artificial intelligence, machine learning, and advanced data analytics to improve the detection, assessment, and prevention of adverse drug events. Traditionally, this has been done, and this new program is going to be administered by the Center for Drug Evaluation and Research, or CDER, which is responsible for ensuring that drugs marketed in the US are safe and effective. CDER evaluates new drugs before they can be sold, monitors drugs that are already on the market, and ensures that drug information is accurate and informative. Essentially, CDER plays a critical role in protecting public health by overseeing the safety and efficacy of pharmaceuticals.

Brett Mason:

Thanks for that background, Kyle. I think what you're talking about there is related to a term that is being used when we're talking about this new program, pharmacovigilance. That's a bit of a mouthful, but Judy, could you explain to our audience what pharmacovigilance is and what that means in the context?

Judy O'Grady:

Of course, happy to. So, pharmacovigilance is the term used to describe the science and activities relating to the detection, assessment, understanding, and hopefully prevention of adverse events, or any other problems with a drug, biologic, or device in the post marketing environment. So, this isn't where we're evaluating adverse events in preclinical or clinical trials. It's really, once the product is approved. So, in other words, it's the process that occurs after the drug is approved to ensure that any adverse events reported are appropriately evaluated and considered both by the manufacturers of the products and the FDA. This is what continues to make products on the market safe.

Brett Mason:

Now, we know pharmacovigilance and this process that you just talked about, Judy, has been ongoing for years. So Kyle, can you tell us why this announcement is significant, and what prompted CDER to launch this new program now?

Kyle Dolinsky:

The announcement is significant because it represents a proactive approach to drug safety, leveraging the latest technological advancements to more efficiently, and effectively evaluate large data sets that are constantly changing. CDER launched the EDSTP in response to the growing complexity of drug safety monitoring and the increasing ability of advanced technologies that can provide better solutions than those traditionally used. By bracing these technologies, CDER aims to better stay ahead of safety issues and ensure the medications remain safe for the public use.

Brett Mason:

So, knowing that this announcement is focused on improving pharmacovigilance and improving the methods by which drug safety monitoring occurs. How is this new program going to utilize artificial intelligence to reach that goal, Judy?

Judy O'Grady:

Sure. So, as Kyle mentioned, the FDA is bound to ensure that medicines sold in the US are safe, and pharmacovigilance is the big part of how they do that. In addition, in the post-marketing setting, companies in the regulated industries are obliged pursuant to FDA regs to review all adverse drug experience information that they receive, and then submit those to the FDA. One of the problems that a lot of companies and regulatory authorities faces timely and efficient collection, processing, and evaluation of single and aggregate patient safety data.

This is compounded by the ever increasing case volumes. So, this announcement encourages companies to use AI to improve efficient collection processing and evaluation of single and aggregate patient safety data. The use of these technologies will also help reduce costs associated with pharmacovigilance in the future. The announcement acknowledges that some companies are involved in PV activities using AI already, which we'll discuss a bit more shortly.

Brett Mason:

I love hearing about this program, because one of the themes that I've seen in the podcast episodes that we've done is that there can be a budding of heads between regulatory agencies and those who want to use technological advancements like artificial intelligence. So, Kyle, does this announcement go beyond just introducing the idea of using AI in pharmacovigilance, or is it also encouraging the use of AI for pharmacovigilance?

Kyle Dolinsky:

It goes beyond the idea of just introducing the idea. Specifically, the program has three main objectives. The first is identification of emerging technologies. So, that's where the aim is to proactively seek out these new technologies that can potentially, dramatically improve drug safety. But there's more to it than just that. The second objective is the evaluation and validation of the technologies. So, it's one thing to be able to use these technologies, but given their importance with respect to drug safety, the technology needs to undergo rigorous evaluation and validation to ensure that they're effective and reliable.

Then, the third objective is implementation and integration. So, once validated, the technologies need to be integrated into the FDA's existing drug safety monitoring systems.

Brett Mason:

Well, that sounds like a comprehensive approach. Did the FDA explain how it planned to achieve those objectives?

Judy O'Grady:

I can take this one. Yes. So, you had also asked if FDA is encouraging entities to use these technologies as part of this program. I think it absolutely is. So, one of the things that is important to the program is collaboration. FDA made clear in its initial discussion papers on AI that collaboration was going to be the cornerstone of use of AI in FDA regulated product development and post-marketing.

So, the FDA again here plans to work closely with industry stakeholders, academic institutions, and other regulatory bodies to foster innovation and share knowledge. This collaborative approach aims to accelerate the development and adoption of new technologies, which will in turn benefit the entire pharmaceutical ecosystem. The FDA does note in its announcement that eligible participants can meet with CDER to share information about their current use of AI. The goal of these meetings is to facilitate mutual learning and discussion about the opportunities and challenges with using such technologies in pharmacovigilance.

Brett Mason:

Well, that's fascinating to me, Judy, that the FDA is inviting companies to come to meetings where they can talk about the learning and discussion and what technologies they're using. Kyle, how will the FDA decide who's going to be involved in these meetings and who they're going to meet with?

Kyle Dolinsky:

FDA's laid out a process that allows those interested in being part of the discussion to submit a request. Requests can be sent by applicants with at least one approved application regulated by CDER, including new drug applications, or NDAs, or abbreviated new drug applications, ANDAs. Applicants with approved biologics license applications or BLAs, which are approved and regulated by different centers. CBER may also submit a request, as can other relevant parties, supporting industries, pharmacovigilance activities. For example, academia, contract research organizations, or pharmacovigilance vendors, software developers, et cetera. These people who develop leverage, or tend to leverage AI or other emerging technologies that can be used to satisfy post marketing reporting requirements.

Brett Mason:

Kyle, you just mentioned a couple different terms there, the NDA, the ANDA, the BLA. Judy, can you just briefly explain what those are for those in our audience who are maybe not as familiar with those as you two are?

Judy O'Grady:

Of course. So, all of those acronyms are types of application that drug and biologic manufacturers submit to the FDA in order to obtain approval of the product. An NDA is a new drug application that's used by manufacturers of novel branded drugs to get approval. ANDA an abbreviated new drug application, which is used to obtain generic drug approvals. BLA is the most recent type of application or biologic licensing application, then that's what you use to get approval of a biologic.

I think we also should note that regarding who can participate in these meetings, FDA has set out eligibility criteria in a fair amount of detail. This will help ensure that the stakeholders needed to further the objectives are present at the meetings. In addition, before submitting a request, potential participants are going to need to submit a topic that they would like to discuss. So, certainly, entities that want to participate in the meeting part of this program will need to have the relevant experience and expertise to be able to sit down with the FDA.

Brett Mason:

So, what this sounds like to me, Judy, is it fair to say the FDA is really seeking out experts in this area to try and help further develop the use of artificial intelligence technology and pharmacovigilance?

Judy O'Grady:

Yes, Brett. That's exactly what's happening here, is FDA has limited resources, and they want to leverage the public's knowledge, but also use their time efficiently. So, certainly, potential applicants have to carefully review the criteria, and submit a robust application to make sure everyone's time is used wisely.

Brett Mason:

So Kyle, I'm guessing, since they want these outside experts to be at the meetings, will there also be representatives from the FDA present?

Kyle Dolinsky:

You guess right, Brett. EDSTMs will be attended by members of CDER's Emerging Drug Safety Technology Program, which includes representatives from CDER staff with experience in emerging drug safety technologies, pharmacovigilance activities, policy, and relevant inspection programs. Relevant interdisciplinary experts attending an EDSTM will depend on the nature of the topic proposed by the meeting requester.

Brett Mason:

This sounds like a really unique opportunity for companies in this space. So, based on your experience advising pharmaceutical and biologic manufacturers, Judy, how do you think about the pros and cons of participating in this type of meeting with CDER?

Judy O'Grady:

I think if any entity has the right experience and expertise, there really aren't any cons. Any activity directed at improving pharmacovigilance activities will only benefit everyone involved with drug products in the US. Kyle, did you have additional thoughts on that?

Kyle Dolinsky:

Yes. I would focus more on what type of regulations might come out of these meetings. It's quite possible that FDA will adopt regulations that are going to require the use of these technologies.

But at the very least, I would expect FDA to publish guidance documents on the use of AI and other emerging technologies in pharmacovigilance. While FDA guidance documents are generally not binding, effective industry members are usually best served by following them. So, whether by finding regulation or guidance, there's going to be some kind of upfront cost to implement these technologies. Those types of costs often impact small manufacturers the most. The hope though is, that the long-term use of these technologies is going to reduce the overall costs associated with pharmacovigilance.

Brett Mason:

Really, from these announcements and our discussions here today, it sounds like this is first step of a broad program and undertaking by the FDA to utilize artificial intelligence in this area. Can you share what kinds of technologies you see being used that the EDSTP might implement?

Kyle Dolinsky:

Sure. So, one example is the use of artificial intelligence to analyze large data sets from clinical trials and post-marketing surveillance. AI can identify patterns and signals that might indicate potential safety issues much faster than traditional methods. Another example is the use of blockchain technology to ensure the integrity and traceability of drug supply chains, which can help prevent counterfeit drugs from entering the market.

Brett Mason:

Judy, can you talk about some examples that you've thought of on how artificial intelligence technology can improve pharmacovigilance?

Judy O'Grady:

Sure. So, if you take an example of a widely used product, for example, oral contraceptives. If you think about the volume of women that use those products, you're gathering data on a regular basis, and it becomes like exponentially larger over the course of time. Traditionally, people would have to evaluate all of those adverse event reports and identify signals and trends. But if, for example, and we know this to be true now, individuals with Factor 5 Leiden, which puts you more at risk for bleeding are using that product and are having adverse events that are very serious. Like VTEs or venous thromboembolic events, or DVTs.

AI can scan all of that data very quickly, identify those events and then likely look at the risk factors that that individual had for one of those events, like a VTE or DVT. If they're finding all these cases where young women didn't have any of the traditional risk factors, that's where the AI can more quickly come into play. Because it can evaluate not just within one oral contraceptive, but we know there are dozens on the market. Then, it can compare with oral contraceptives versus IUDs, and are we seeing the same thing. To kind of narrow down what the cause might be. Then, you can add to the labeling that says, "Should not be used by women with…" I think that's where it'll really help in that type of situation, but certainly others.

Brett Mason:

Those are some impressive advancements. Judy, how do you see these technologies impacting the future of drug safety?

Judy O'Grady:

I think they really could kind of transform drug safety as compared to what's traditionally been done, which has involved a lot of manual review by qualified individuals. That part will not go away, but certainly it will be streamlined with the use of AI. It'll also allow for a more proactive versus reactive approach to pharmacovigilance. I think that's because by identifying potential safety issues earlier, then action can be taken to mitigate those risks before they become widespread. This protects patients, but also helps maintain public trust in the pharmaceutical industry and the FDA.

Brett Mason:

As you mentioned briefly at the outset, Kyle, the last time you were both with me here on the podcast, we talked about how the FDA is proactive in addressing AI, starting all the way back in 2019. Then, they had a more recent discussion paper in spring of 2024. So, what does this announcement tell us about how the FDA continues to view artificial intelligence and how it wants to address these issues?

Kyle Dolinsky:

Well, it shows the FDA is continuing to recognize the value of utilizing AI and other similar technologies in a variety of areas, in this case, to improve drug safety. It also suggests that the agency wants the input of others in the industry to create workable, beneficial policies.

Brett Mason:

So today, as we think about the announcement of this new program by the FDA, are there any other areas of the FDA regulatory space Judy, where you can see the FDA possibly implementing a similar type of program?

Judy O'Grady:

Yes. I think you can easily see the FDA using this type of program to evaluate device safety. In addition, there could be opportunities to leverage AI in the pre-approval context with respect to safety signals identified in both preclinical and clinical trials, I know that I for one am certainly excited to see how this progresses, not only in the pharmacovigilance context, but far beyond.

Brett Mason:

Well, Kyle, Judy, thank you so much for being on. I know that I always appreciate it, and I'm sure our listeners appreciate hearing your expertise in the FDA regulatory space. At the end of the day, it's encouraging that the FDA is wanting to leverage the use of artificial intelligence technology to improve patient safety.

So, thanks to our listeners. Please don't hesitate to reach out to me at brett.mason@troutman.com with any questions, comments, or topic suggestions. You can also subscribe and listen to other Troutman Pepper podcasts wherever you get your podcasts, including Apple, Google, and Spotify. Until next time. Thanks for joining us.