Increased Scrutiny Has Boards of Directors in the Hot Seat
Sam Gandhi, Holly Gregory, and Dr. Paul Kalb
November 2021

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Sam Gandhi:
Life is getting harder for boards of directors. Increased scrutiny of companies, particularly those that are heavily regulated, has led to greater risk of criminal and civil liability, and recent Delaware cases have ratcheted up the pressure. What should directors know about the responsibilities for compliance and risk, when can they be held liable for corporate failures, and what can they do to mitigate those risks? We'll find out in today's podcast.

Holly Gregory:
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Dr. Paul Kalb:
Three of the six most recent Delaware cases have involved, broadly speaking, companies in the life sciences space.

Holly Gregory:
What we have here is a line of cases that gives a road map for plaintiffs on how to overcome that presumption of good faith.

Dr. Paul Kalb:
Boards should assess whether they are properly populated; that is whether people with the right set of skills are on the board.

Sam Gandhi:
From the international law firm, Sidley Austin, this is *The Sidley Podcast,* where we tackle cutting-edge issues in the law, and put them in perspective for business people today. I'm Sam Gandhi.

Hello, and welcome to this edition of *The Sidley Podcast*, episode number 22. Today we're talking with Holly Gregory and Dr. Paul Kalb about the legal and regulatory risks facing highly regulated public companies, and the implications for directors and how they govern.

Holly is the co-chair of Sidley's global Corporate Governance and Executive Compensation practice, and currently serves as the president to the American College of Governance Council. She is a partner in the firm's New York office and counsels publicly held, private, and not-for-profit corporations on the full range of governance issues. She is frequently called on to advise boards regarding sensitive and unusual matters.

Paul serves as the global leader of the firm's Healthcare and FDA group, and is leader of its COVID-19 taskforce. He is also a member of the firm's Executive Committee. A partner in the firm's Washington, D.C. office, Paul has represented many of the world's leading drug, biotech, and device manufacturers, as well as hospitals and other providers, in a wide array of enforcement actions involving healthcare fraud, abuse, and off-label promotion.

Holly, Paul, great to have you on the podcast.

Holly Gregory:
Great to be here, Sam, looking forward to this discussion.

Dr. Paul Kalb:
Thank you, Sam, me too.

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Sam Gandhi:
Holly, let me start with you. Boards of directors today are governing in an age of heightened scrutiny, and especially high-profile companies are facing criminal and civil inquiry, and worse, some of them, there are actual findings of wrong doing, yet the vast majority of directors of public companies are independent outsiders, and they're not involved, even though they may have the responsibility in running the company from day-to-day, yet they're charged with providing oversight. What does oversight mean in the governance context, and how do directors perform oversight without standing over the shoulders of officers and employees?

Holly Gregory:
Great question. Oversight has to be understood in the context of the fiduciary duties that directors owe — the duties of care, the duty of loyalty — which require directors to act prudently on an informed basis, and in good faith in the best interest of the company. So, importantly, the board delegates to management the day-to-day operations of the company, and it may rely on management, and on the information that management provides, but here's the kicker, so long as it is reasonable to do so.

So, oversight can be thought of as the ongoing inquiry into whether it's reasonable to rely on those to whom the board has delegated and the information that they provide, and it requires having information about how the company and its management are performing in an environment that poses significant risk to the business, including risks of compliance and other failures. It's in this context that the courts now are emphasizing the importance of director attention to risk and compliance, and the systems within the company that are designed to bring information about risk and compliance to the attention of the board.

So, in sum, directors can't have blind faith in management or in the information and compliance systems, and they can't have blinders on and hope that problems will reach them. When bad news does reach the board, they can't ignore it.

So, most recently, on September 7, the Delaware Chancery Court allowed a derivative action for breach of oversight obligations to proceed against the Boeing directors. The shareholder plaintiffs had alleged the directors breached their oversight obligations with respect to safety issues with the 737 MAX aircraft. You'll recall that there were two fatal accidents that occurred in a five-month span, and the plaintiffs claim, in essence, that the board had failed to oversee airplane safety. The plaintiffs supported these allegations with documents that they had received in a books and records demand on the company, as well as on publicly available information in the committee charters, and according to the plaintiffs, these documents showed that while the audit committee was tasked with overseeing legal and regulatory compliance, its focus was principally on financial and production risks. Moreover, no committee charter addressed responsibility for overseeing airplane safety, and from the board and audit committee minutes, before the court, it appeared that the airplane safety issues were not regularly discussed in board or audit committee meetings, nor addressed in the board's yearly updates on compliance. Additionally, the company's enterprise risk disability promises didn't specifically emphasize airplane safety, and the board did not appear to receive and review internal reports and complaints about safety.

So, on a motion to dismiss, where the court must take the well pled allegations as true, the court found that the plaintiffs had pled sufficient evidence to support a failure of oversight claim, and specifically that the board had failed to establish a reporting system for airplane safety and had also effectively ignored red flags about airline safety issues. So, this case is being allowed to move forward into discovery and, potentially, trial.

Now, this case is the latest in a relatively new line of cases that have allowed failure of board oversight claims to proceed beyond a motion to dismiss, and this line of newer cases is unusual because in the past, the courts have recognized that these claims are among the most difficult series to establish director liability.

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Sam Gandhi:
This sounds like it's a continuation of some of the legal cases that have been furthering greater liability and obligations on directors. How would you summarize those key legal developments, Paul?

Dr. Paul Kalb:
Sam, you're absolutely right that the starting point here is the 1996 Caremark case, which is a case in which the Delaware Chancery Court first set out the doctrinal basis for director liability for corporate losses resulting from corporate noncompliance, and as Holly suggested, in that case, the court held that directors could only be liable for sustained or systemic failure of a board exercise oversight. About a decade later, the Delaware Supreme Court embraced that doctrine in a case called, *Stone v. Ritter*. Notably, the court grounded its decision in the duty of good faith, and element of the duty of loyalty, which is neither subject to exculpatory charter provisions, nor indemnifiable under Delaware law. So, really a serious set of issues.

What’s interesting is that those two cases laid out the theory of liability, but in both cases, as Holly suggested, the courts granted, or in one case affirmed, the defendant’s motion to dismiss, thereby precluding liability. Both cases highlighted, both in words and deeds, that a failure of oversight claim is among the most difficult for a plaintiff to prevail on.

To get to your specific question, fast forward to 2019. Since then, we’ve seen about a half dozen cases in which the Delaware courts have allowed plaintiffs to proceed through the motion to dismiss phase.

There are several notable aspects to these cases. The first is simply the velocity of these cases. We’ve just not previously seen so many cases like this in a short period of time. Second, the courts are increasingly focused on board oversight of “mission critical regulatory or safety risks,” such as food, drug, oil pipeline, or airline safety. As to those risks, the courts have made clear that board oversight must be more rigorously exercised. So, boards now have an obligation, more rigorously, to oversee mission critical risks. Finally, and I hope we come back to this point, the courts are increasingly focusing, not just on board function, for example, the nature and frequency of board reviews of critical issues, but also on board structure, that is, whether a board has a committee specifically designated to oversee corporate compliance and relevant risks.

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Sam Gandhi:
Holly, in practical terms, how are boards reacting to these developments? It seems like that’s a change in attitude or expectation from what boards are typically expecting in a sense that they’re not really getting their hands dirty on a day-to-day basis, yet the courts seem to be pushing them in a direction of far greater oversight than what they were probably expecting when they were appointed or elected to the board.

Holly Gregory:
It should come as no surprise that these cases are raising anxiety with directors about their personal liability, and also heightening their interest in how they position the board to oversee information and reporting systems, compliance, and, importantly, the mission critical risks that Paul mentioned, and so, we’re fielding many more questions on these issues from our clients, and seeing boards focus more time and attention in discussing with

management how is risk identified and mitigated, and how are information systems within the company designed to make sure that the relevant information will be brought to their attention. In other words, what are the controls in place to make sure we know about things that we can't know because we're not in the company on a day-to-day basis.

So, we're being called in on boards to help assess their ability to provide oversight of risk and compliance, including with respect to, I think, four really specific areas. First, the strength of internal information from boarding systems, enterprise, risk management processes, and compliance programs and controls. Second, how the boards structure their oversight activities through board committees. Third, the time and attention that's spent by the board, and board committees, on oversight of mission critical risks and enterprise risk management and compliance matters, and finally, the quality and completeness of board and committee minutes.

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Sam Gandhi:
Paul, let's talk about specific examples, because you would think that for highly regulated industries, such as the healthcare and the life sciences industry, that this obligation seems to be almost implicit on a board. What are you seeing in the healthcare and life sciences space?

Dr. Paul Kalb:
Sam, the healthcare and life sciences space is being disproportionately impacted by this development. Three of the six most recent Delaware cases have involved, broadly speaking, companies in the life sciences space, and I think we're seeing this focus for two related reasons.

First, those companies operate in a highly regulated environment, or environments, and secondly, we're seeing judicial focus on those companies. Let me tease out those statements. The starting point is that companies, both in the provider space and in the life sciences industry, are among the most heavily regulated in the world. That's understandable because they take care of patients, or manufacture drugs or devices that impact the health and welfare of patients.

As a result, these companies are among the most heavily scrutinized by both regulators and law enforcement authorities, and as a consequence of that, such companies are disproportionately represented in government enforcement actions. Penalties paid by such companies, for example, represent the lion's share of False Claims Act recoveries over at least the last decade, and they represent a substantial chunk of FCPA settlements as well.

As an upshot of that phenomenon, such companies appear to comprise a disproportionate share of defendants in these so-called Caremark cases, where shareholders attempt to hold directors responsible. To be more precise, while the recent set of Delaware decisions involve companies in the airplane, pipeline, and vehicle parts industries, as I said, three of the sects involve companies in the life sciences space. One such case was about listeria contamination in ice cream — that is a food company. Another involved alleged improper reporting of drug safety and efficacy results in a clinical trial. The third involved the specialty pharmacies allegedly improper packaging and shipping of prefilled syringes. And the Caremark case itself was a healthcare case involving a company which pled guilty to a violation of the healthcare fraud laws and entered into a civil settlement in corporate integrity agreements.

So, in short, healthcare and life sciences cases are at the vortex of all of this because they are so heavily regulated. Therefore, they are disproportionately the subject of government enforcement, and as a result, are disproportionately impacted by the shareholder derivative actions.

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Sam Gandhi:
You're listening to *The Sidley Podcast*, and we've been speaking with two thought leaders in the area of cooperate governance and compliance, Holly Gregory and Paul Kalb, and we're talking about the evolving legal landscape for boards of directors and their organizations, and how best to mitigate their legal and regulatory risks.

So, let's just follow up on that last point, Paul. Let's talk a little bit more about what liability looks like in light of recent court decisions, and you referred to the Bluebell ice cream case, for example, where the court reinstated claims against the company's board, alleging that the directors failed to implement reasonable monitoring and reporting systems, as you said earlier on mission critical issues. Holly, what do mission critical issues mean? Does that mean that there's a special type of issue that the board has a higher duty than all the other duties that they normally have to evaluate?

Holly Gregory:
A mission critical risk can be thought of as a risk that could impair the viability or survival of the company. It is defined in the ERM literature as something that would materially impact the ability of the company to achieve its long-term goals and objectives. The key takeaway for boards and directors is that oversight is context dependent. When something is more important to the company, when mission critical risks exist, the oversight of the board needs to be more rigorous. So, in other words, you have to align the level of the board's attention and focus with the degree of risk that is posed by a particular issue. Clearly, the risk of liability is heightened with respect to oversight of mission critical risks, especially when they relate to health and safety issues and compliance with regulations that are designed to ensure health and safety, as Paul pointed out, and these risks are greater in certain industries than in others — food, pharmaceuticals, airplane and other manufacturing, energy — where safety or compliance failures could cause loss of life or significant harm.

So boards need to assess what poses mission critical risks for their company, and ensure that the information and reporting systems, and the compliance systems, are really built for purpose, if you will. In other words, that they relate to the risks and compliance issues that are most material to the company, and on those issues, the board is spending more focused time and attention to make sure it understands those risks, and is set up to receive information around those risks as they are developing. And the board is responsible for seeing, not only that the systems are in place, but that they are monitoring them on an ongoing basis. So, the courts expect that they do so rigorously when it comes to the mission critical risks.

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Sam Gandhi:
Are the courts basically telling boards of directors that this is what you are supposed to do as part of your duty, or are they creating a new duty, or an extension of a duty, to add more burdens onto boards of directors?

Holly Gregory:
It’s not a new duty. What the courts are emphasizing is that all of the board’s duties have to relate to the context. So, that’s why I call them, they are context dependent, and so the courts are saying look, there are situations that can face a company that could really impair the ability of the company to continue functioning, and the boards have to adjust their level of oversight to the level of the risk that’s posed. So, if you’re a food company, you need to be paying attention to food safety, and if you’re an airplane manufacturer, you need to be paying attention to aircraft safety, and if you’re in the energy field, you need to be paying attention to the risks that could be significant that could arise from a major explosion or environmental failure.

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Sam Gandhi:
Paul, let’s focus on that question in the context of the companies that you counsel on a regular basis. What are those mission critical risks in the life sciences and healthcare sectors that the courts are asking boards to really focus on?

Dr. Paul Kalb:
Sam, the cases are actually answering those questions for us in real time. Life sciences companies are principally involved in two or three things: they study the safety and efficacy of drugs or devices through clinical trials; they have to manufacture — or many of them manufacture and distribute — products, and they have to do that appropriately; and they are under the obligation to promote their products in a manner consistent with a whole set of carefully crafted rules.

On the provider side, providers are principally responsible for caring for patients, and those are the mission critical tasks, and all of them carry with them mission critical risks, because noncompliance with these rules in life sciences and the healthcare industry carries with it serious consequences. There’s criminal liability for many violations of the healthcare and food and drug rules. That criminal liability, as well as civil liability, often carries with it significant collateral consequences. For example, companies in healthcare and life sciences space may be excluded from participating in federal healthcare programs, or they may be required to execute costly corporate integrity agreements as a quid pro quo for not being excluded from federal healthcare programs. On the civil side, the government has principally used the federal False Claims Act as a means of imposing sanctions on companies in this space, and the FCA, of course, carries with it treble damages, as well as other penalties. And so, these critical tasks carry with them critical consequences, and as a result, those are the tasks that require enhanced board oversight.

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Sam Gandhi:
Holly, from your perspective, what are companies doing? Do they have specific compliance committees, and how are they handling these mission critical issues within their governance?

Holly Gregory:
So, that’s a great question, Sam, and Paul and I worked on an article that will be published soon, where we looked at some of the data to understand how boards were structuring their committees for compliance and risk oversight in relationship to the real regulatory risks that they face. It should come as no surprise that the data we found highlights that the cost of settlements and judgments for regulatory failures is very high. Since 2015, False Claims Act recoveries against healthcare companies totaled $14b, and that is just one industry and one set of regulations. Recoveries for Foreign Corrupt Practices Act violations are also significant, and since 2015, the SEC has recovered more than $25b for compliance failures, and of course these figures don’t account for the follow-on costs from claims by private plaintiffs, or the defense costs, and time demands on executives.

So, in terms of oversight structure, the vast majority of companies rely on their audit committee to oversee compliance regulatory risks. Only five percent of S&P 500 companies have a specialized compliance committee, and similarly, risk committees outside of the financial service industry, and safety focused committees, are not widely adopted.

So, we preformed our own small survey about the prevalence of compliance focused committees, looking at the top ten S&P companies in several highly regulated industries, and we found that only 15 percent overall have specialized compliance committees; however, the number is higher, 40 percent, at life sciences companies. So all along we are saying that there’s a disconnect between regulatory and compliance risk, and the committee structures that many companies in highly regulated industries are adopting.

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Sam Gandhi:
Paul, from your experience dealing with life sciences and healthcare companies, was that a surprising result?

Dr. Paul Kalb:
Sam, it was a bit of a surprise because these companies, as I said earlier, operate in such a highly regulated environment, and yeah, I was taken aback a bit by the relatively small percentage of boards in the healthcare and life sciences space that have separate compliance committees. Now, to be clear, that's not necessarily improper. Audit committees or other committees can, of course, appropriately oversee risk, but it does raise the important question, which boards should be asking, which is whether they would be better off assigning responsibility for oversight of mission critical regulatory or safety risks to a separate committee.

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Sam Gandhi:
So, Holly, let's maybe get down to brass tacks for a board member who may be listening to this. Based on that, what do you recommend organizations do to really mitigate their risk?

Holly Gregory:
I think boards of all companies, but especially the medicine, healthcare, and life sciences spaces, and other highly regulated industries, should be looking to see that mechanisms are in place to support rigorous board oversight of compliance and safety efforts, and I recommend that boards do the following. They should periodically conduct a review of the business to identify mission critical operations and risks. They should then review the reporting processes that are in place to make sure that information about these risks is brought to the board's attention in a manner that's not unduly dependant on management discretion. They should then ensure that the board itself is well positioned to engage in oversight in this area, and this can include a number of things: establishing a regular cadence for discussion of compliance, and safety, and similar risks at board meetings; considering whether the board has clearly and adequately delegated to a

board committee responsibility for assisting the board in its oversight efforts with respect to these issues; and considering, to Paul's point, whether the board should establish a more specialized committee than relying on the audit committee or another one of the standard committees.

It's really important, especially in light of the learnings from the Boeing case, that the committee charters clearly reflect who has responsibilities, delegated from the board, for compliance and safety and other kinds of important risks. And finally, give some consideration to whether the board itself has the experience and skillsets that it needs to be able to understand the risks facing the company.

One last point. It's really important to document the board and committee efforts in this area in minutes, given that the plaintiffs bar will ask for books and records and be able to get these minutes before they file their claim, and that's what allows them to withstand a motion to dismiss, is reliance on records of the company in their allegations, so that the allegations satisfy the well-pled standard.

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Sam Gandhi:
And Paul, from a board members perspective, how is this going to help me manage, and direct, and advise the company in their daily operations? Will a board member feel more protected by this proposed revised structure, and will it help that board member effectively help manage the company better?

Dr. Paul Kalb:
Sam, oversight of mission critical risks requires engagement, it requires time, it requires effort. And all of that can come from a member of an audit committee, but audit committees have a whole range of other responsibilities, and so, among the principal advantages of a separate committee is that their primary responsibility is to oversee mission critical risks. Their attention is not spread across a whole range of obligations.

That, by definition, elevates oversight of mission critical risk, because it becomes the primary focus of the agenda of at least one board committee. If that board committee is comprised of people with relevant expertise, then you have those mission critical risks overseen by people with relevant expertise on those issues. Such a committee can step in as necessary to oversee, or engage in, or question any red flags or urgent issues that arise, and that may reduce the burden on the audit committee, on the board as a whole, if these issues are taken up by a different committee.

There may be other advantages. a chief compliance officer may find him or herself with an easier audience to approach. Having a separate committee may allow a company to adjust or adapt more rapidly in an evolving regulatory environment. And finally, the existence of a separate committee may send a positive external message to regulators or to enforcement agencies — it may send a message that this board really is focusing on these issues as appropriate.

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Sam Gandhi:
The business judgment rule protects directors and boards in exercising their judgement, even if the result or the event that occurs as a result of that is not in the company's or the shareholder's interests. Do you see these lines of cases as effectively protecting the board if they've got the right process, even if the ultimate result doesn't turn out to be good for the company? Holly, I'll ask you first.

Holly Gregory:
That's a great question. So, the business judgement rule is a presumption that courts apply. They apply a presumption that the board and directors acted in good faith and abided by the duty of loyalty and were prudent, and it's on the plaintiff to overcome that burden in its allegations. And what we have here is a line of cases that gives a roadmap for plaintiffs on how to overcome that presumption of good faith, and so, to my mind, what's important in these cases is plaintiffs now know how to overcome the presumption that the board acted in good faith, such that the business judgement rule would not apply to the decisions that they've made, and of course, as Paul mentioned, when you don't abide by good faith, when that presumption is gone, you're in a zone where the protections of an exculpatory clause in the charter, and indemnification, no longer apply, and so, you're personal wealth as a director is at risk.

Dr. Paul Kalb:
Sam, I would point out the flipside of what Holly just said so well, which is that these cases in laying out a path for the plaintiffs are also laying out the path for boards. They're pointing out, in so many specific ways, the bases for a claim of the absence of good faith, but, at the same time, that the same facts — the same information — lays the groundwork, or the foundation, for a defence of good faith, which is of course the critical defense, and so, Holly's absolutely right in her analysis of these cases. I think the takeaway for directors is the flipside, that these cases are laying out the basis for establishing good faith, which is precisely why all of the steps that Holly was explaining earlier are so critical.

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Sam Gandhi:
We've talked about companies creating a larger governing structure and a process to protect their interests, identify issues better, and insulate themselves better from risks, but if I'm the chairman of a board, or I'm the cooperate secretary, or the general counsel, and I don't have any of that right now in my company, what do I need to start with to try to help insulate risk in a greater way?

Holly Gregory:
I'd be happy to jump into that one, and I would be troubled by a company that doesn't have any of this. I think companies, by and large, or boards of companies, are focused on compliance, and really trying hard to do the right thing. So, this is a good time for boards to undertake the review that I talked about before, undertake a review of how they approach oversight of risk and compliance, and it's just a series of basic questions to ask: are we well positioned to provide oversight of mission critical and other risks; have we identified what those risks are; are we confident that we will get information we need when we need it and what is the basis for that confidence; are we spending appropriate meeting time focused on these issues generally and also when a specific issue comes to our attention; and do our minutes reflect our activities in this regard, and of course, do we have the right committee structure to help us in these tasks. And I don't mean to suggest that all boards should have compliance or risk committees that are specialized; it's going to be different for different companies, in different industries, and in different circumstances.

Committee structure should be designed to help the board dig deeper when and where it needs to, and so, asking the question about, do we have a good committee structure that's aligned with our needs, is really what we're suggesting boards do, and finally, I think it's always good for boards, even when they think they got all of this nailed down, to ask, what could we do to improve, what could we be doing even better to make sure that we're giving enough attention to these critical matters?

Dr. Paul Kalb:
Sam, in addition to what Holly said about board structure and function, there's one other point that I'd like to make, which is that boards should assess whether they are properly populated, that is whether people with the right set of skills are on the board. If board oversight of mission critical risks is a critical board function, then boards need to have on them people who are capable of providing that oversight. My guess is, that most boards do, but it is a critical question the board should be asking as to whether in fact they do, and if they don't, they really should consider bringing that kind of expertise and talent on board.

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Sam Gandhi:
Paul, I'll end it with you and your thoughts in terms of what a company should start doing.

Dr. Paul Kalb:
Sam, I think a company should start evaluating the effectiveness of its compliance program. That, of course, is a separate question from what boards should do to oversee their compliance, but from a company's perspective, the first step, I think, always should be do they have a compliance program that is adequately assessing risk, and is it structured and appropriately functioning to mitigate those risks?

Sam Gandhi:
We've been speaking with Holly Gregory and Dr. Paul Kalb about the evolving legal landscape for boards of directors, and how establishing separate compliance committees can help mitigate legal and regulatory risks. Holly and Paul, it's been a great look at the landscape. Thanks for sharing your insights on the podcast.

Holly Gregory:
Thanks, so much Sam for having me, and thanks, Paul, for engaging in this discussion. I really enjoyed it.

Dr. Paul Kalb:
Thank you, Sam and Holly. It's been a great pleasure.

Sam Gandhi:
You've been listening to *The Sidley Podcast.* I'm Sam Gandhi. Our executive producer is John Metaxas, and our managing editor is Karen Tucker. Listen to more episodes at Sidley.com/SidleyPodcast, and subscribe on Apple Podcast, or wherever you get your podcasts.