“Steer” Clear of Legal Lassos

Readiness Strategies for FDA-Regulated Companies

Wednesday, May 1st, 2024

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Agenda

9:00 – 9:05 AM	**Program Introduction**
9:05 – 9:30 AM	**Tips for Assessing Medtech Company Maturity** Speaker: *Nate Downing, Senior Attorney*
9:30 – 10:00 AM	**Exploring Enforcement Trends in Healthcare Compliance** Speaker: *Amanda Johnston, Partner*
10:00 – 10:30 AM	**Tips on New State Privacy Laws and HIPAA** Speaker: *Paul Rothermel, Senior Attorney*
10:30 – 10:45	**BREAK**
10:45 – 11:15 AM	**Developments in Medical Device and Drug Litigation** Speaker: *David Graham, Senior Counsel*
11:15 – 12:00 PM	**Panel Discussion** Moderator: *Mark Gardner, Managing Partner* Panelists: *Albert Li, Chief Legal Officer, General Counsel & Compliance Officer, Owlet Baby Care* *Steve Tamayo, Vice President, Chief Compliance Officer, Sight Sciences* *Scott Way, General Counsel & Compliance Officer, Impulse Dynamics*

Program Introduction

- Program is being recording and the recording will be available post-event.
- Slides are available during the presentation virtually via the handout window on the control panel.
- Remote participants: Please submit questions via the question function on the control panel.
- CLE credits: 2.75 credits have been approved by the Minnesota Board of Continuing Legal Education. CLE approval code will be sent out in a program follow up email. Please request a CLE certificate to self report in other states from office@gardner.law.

Tips for Assessing Medtech Maturity

Nathan Downing

Wednesday, May 1st, 2024

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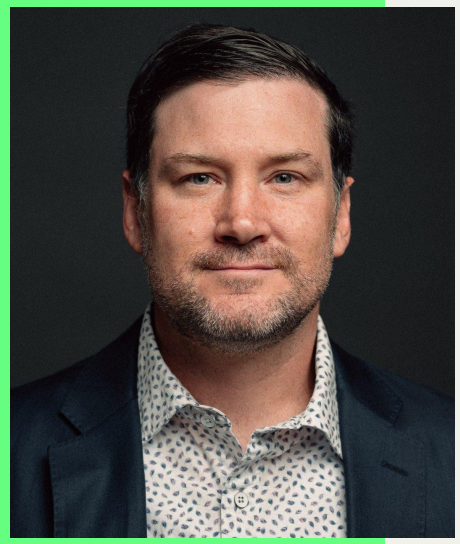
Presenter Introduction



Nathan focuses his practice on FDA-regulated clients. His industry experience allows him to provide actionable legal advice on a variety of health law matters.

Nathan regularly advises FDA-regulated clients on regulatory and compliance matters. He advises clients on their advertising and promotion programs, represents clients in front of the FDA on a variety of matters, and assesses industry initiatives for compliance concerns. Nathan's extensive regulatory experience allows him to advise clients regarding a variety of medical products, including pharmaceuticals, medical devices, medical foods, and nutritional supplements.

Nathan Downing

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Agenda

- Gauging Maturity
  - Medical Product Classification
  - Quality System Considerations
  - Submission Readiness
  - FDA Interactions
  - Post-Market Action Plan

Medical Product Classification

- Intended Use
  - Marketing plan
  - Device/Drug capabilities
  - “Predicate” in market
- Product Codes and Regulations

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Classification Issues

- Confident in assessment?
- What if it is misclassified?
- Ways to burn down risk

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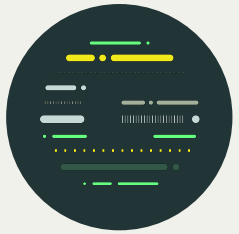
Quality System Considerations

- Design History File
- Risk management
- Global readiness
- Good documentation practices



Submission Readiness

- Complete Design History File
- Evidence to support
  - Verification and Validation
  - Clinical Evidence
- FDA Standards
- FDA Guidance Documents
- Known Issues?

Limiting Deficiencies

- Remember your audience
- Clear communication
- Address issues
- Deliver what your promise

FDA Interactions

- Pre-submissions
- Submission
- During Review
- After decision
  - Approval/Clearance
  - Rejection

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FDA Communication Strategy

- Take advantage of every opportunity
- Have a “story”
- Be consistent
- Partner with FDA

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Post-Market Action Plan

- Promotional strategy
- Change control
- Evidence generation
- Proactive, not reactive

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Key Takeaways

- Successful business plan must involve FDA strategy
  - Can save/cost many months
  - Creates consistency with FDA
  - Market authorization is just the beginning

Questions

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Exploring Enforcement Trends in Healthcare Compliance

Amanda Johnston

Wednesday, May 1st, 2024

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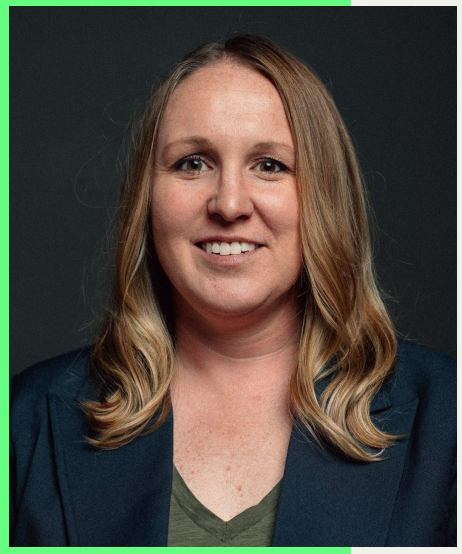

Amanda Johnston is a distinguished FDA attorney with expertise in counseling medical device and pharmaceutical companies on FDA law, regulatory submissions, healthcare compliance programs, and healthcare fraud and abuse laws. With an impressive background spanning several in-house legal, regulatory, and compliance roles within the medical device industry, Amanda brings an exceptional understanding of business and industry dynamics to her practice. Her extensive experience includes serving as interim compliance officer at a global medical device company, overseeing 130+ FDA submissions, compliance program implementation, and helping commercial teams navigate healthcare fraud and abuse laws.

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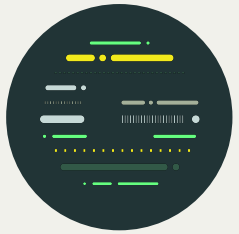
Agenda

- Recap of recent DOJ settlements and judgments
- Top 3 enforcement themes on the horizon
- Key takeaways for riding the straight and narrow
- Best practices for staying in the saddle

The DOJ's Year of Unprecedented FCA Showdowns

- FCA settlements and judgment recoveries exceed $2.68 billion in FY 2023
  - $1.8 billion in health care industry
- 543 settlements and judgments – *highest ever in a single year*
- 1,012 new matters opened – *highest ever in a single year*
- Whistleblower suits continue to increase
  - 712 suits filed in 2023
  - Government collected $2.3 billion in 2023 related to whistleblower cases
  - Government paid out $349 million to whistleblowers



Unlawful Kickbacks

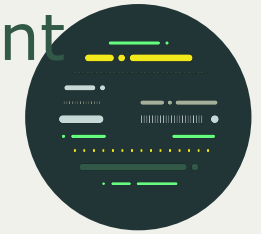
- **Modern Vascular** (complaint filed in December 2022) allegedly offered HCP investments in exchange for referrals. Pressured surgeons to increase invasive surgeries by setting aggressive targets.
- **Cardiac Imaging Inc.** (October 2023) **s**ettled for $85.5 million to resolve allegations that it paid kickbacks to cardiologists for above-fair market value supervision fees.
- **Carter Healthcare LLC** (October 2022) settled for $22.9 million to resolve allegations that it improperly paid remuneration under the guise of medical directorships to induce referrals.

Unlawful Kickbacks

- **Modernizing Medicine Inc.** (2022) EHR vendor agreed to pay $45.5 million to resolve allegations of kickbacks for referrals and donations as kickbacks. System which failed to meet applicable standards.
- **NextGen Healthcare Inc.** (July 2023) agreed to pay $31.2 million to resolve allegations of misrepresenting its EHR software's capability and incentivizing referrals with credits and event tickets to boost sales.
- **Arthrex, Inc.** (2021) agreed to pay $16 million to resolve AKS and FCA allegations related to paying kickbacks in the form of royalty payments intended to induce referrals.
- **Kaléo Inc.** (2021) agreed to pay $12.7 million to resolve allegations related to causing false claims by knowingly sending Rx to preferred pharmacies to submit prior authorization requests containing misrepresentations.

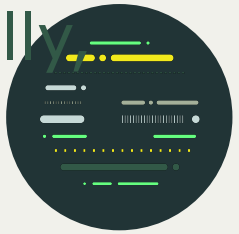
Tales of Fraud and Enforcement

- **COVID Fraud** (April 2024) CEO sentenced to 7 years for a securities fraud scheme causing $28 million in losses and obstructing SEC investigation. Falsely claimed the development of a 15-second COVID-19 test, leading to investor fraud. Misled about FDA approval, used fake personas for deception.
- **Phillips Respironics** (April 2024) Court ordered Phillips Respironics to halt manufacturing at three Pennsylvania sites due to non-compliance with GMPs and for distributing adulterated and misbranded devices.
- **Family Dollar** (February 2024) agreed to pay $41.7 million and pled guilty to adulteration due to unsanitary conditions (rodent infestation) at the distribution center.



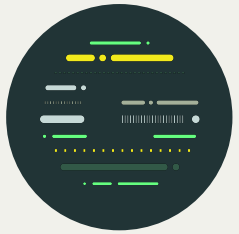
Tales of Fraud and Enforcement

- **FDA Fraud** (January 2024) Former Reg Affairs employee sentenced to 12 months in prison for forging two FDA clearance letters leading to distribution of misbranded and adulterated medical devices (high-speed surgical drill). He never submitted.
- **BioTelemetry and LifeWatch** (December 2023) agreed to pay $14.7 million to resolve allegations of submitting claims for higher-level cardiac monitoring than what was needed/ordered by misleading customers with deceptive sales & ordering tactics.
- **Dolor Technologies** (December 2023) settled allegations related to selling an unapproved device (nerve block for migraines) and encouraging improper billing codes. CEO charged criminally pled guilty.



Top 3 Enforcement Themes

1. False Claim Act
   - Claiming reimbursement for services not provided/not medically necessary
   - Off-label promotion
   - Deception/misrepresentations
2. Anti-Kickback Statute
   - Direct financial incentives and indirect benefits
   - Payments for consulting services over FMV
3. Billing and reimbursement
   - Legitimacy and accuracy of claims and coding



Key Takeaways

- DOJ continues to focus on the health care industry
- Whistleblower suits continue to rise
  - DOJ Pilot & Whistleblower Programs incentivize reporting
- AKS/FCA is the predominant area of enforcement
- "Off-label promotion" is making a comeback (FCA)
- Patient safety and potential for harm drive enforcement
- Billing accuracy is critical, with a focus on medical necessity and proper coding practices/guidance

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Best Practices

- **Ride with a strong compliance crew:** Establish and maintain a robust compliance program.
- **Keep your marketing spurs aligned:** Ensure promotional activities ride the trail of approved uses and evidence-based claims.
- **Audit the trail regularly:** Perform routine audits and monitoring.
- **Compliance quest:** Provide comprehensive compliance training to affected staff.
- **Scout the horizon**: Closely scrutinize HCP arrangements and programs to identify remunerative streams and potential risks.
- **Stay on top of the regulatory rodeo:** Keep your ear to the ground adapt to the evolving landscape of laws and enforcement trends.

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Questions

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Tips on New State Privacy Laws and HIPAA

Paul Rothermel

Wednesday, May 1st, 2024

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Presenter Introduction

Paul Rothermel specializes in privacy and cybersecurity, including HIPAA, GDPR, TCPA, CAN-SPAM, consumer privacy and data protection laws, and other state and international laws as well as health care compliance matters. Before practicing at Gardner Law, Paul advised on privacy requirements for innovative health care technologies and clinical research activities at a large medical device manufacturer. Before that, Paul counseled on state and federal privacy laws, including HIPAA compliance and implementation, as an associate general counsel for the Minnesota Department of Human Services.

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Agenda

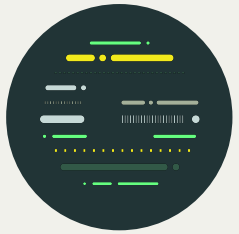
- Introduction
- HIPAA 101 for Manufacturers
- State Privacy Laws
- Navigating
- Case Studies
- Key Takeaways

Introduction

- State privacy law pileup continues
- HIPAA implications are critical for device and drug makers of all kinds
- Intersection of HIPAA and state privacy laws in device and drug manufacturing

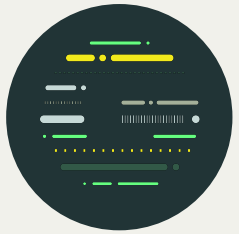
HIPAA Applicability for Drug and Device Makers

- Purpose and scope of HIPAA (Health Insurance Portability and Accountability Act)
- HIPAA applies only to “covered entities” and “business associates” – this excludes many device and drug makers
- Definition of Protected Health Information (PHI)
- Requirements for covered entities and business associates
  - Privacy Rule
  - Security Rule
  - Breach Notification Rule



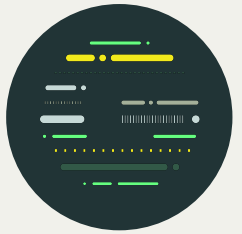
Examples: Business Associates and Covered Entities

- Covered entities include durable medical equipment manufacturers and laboratories if they bill health insurance plans directly for their services and products
- Business associate functions can include (fact dependent):
  - Connected products or services that process PHI in the cloud on behalf of the customer
  - Reimbursement/product support programs designed to support prior authorizations or other related processes



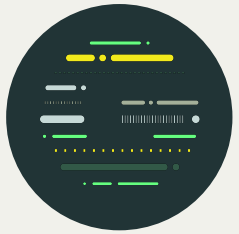
HIPAA Disclosure Exceptions

- Treatment, payment, health care operations (45 C.F.R. 164.506(c))
- Business associates (45 CFR 164.502(e))
- Patient authorization (45 C.F.R. 164.508)
- Public health including FDA regulatory disclosures, including adverse events (45 C.F.R. 164.512(c))



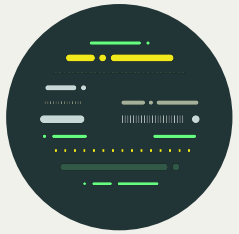
Patient Authorization

- Patient authorization allows use and disclosure of PHI when other exceptions are not applicable
- Patient authorization is always required for using or disclosing PHI for marketing or sale of PHI
- See 45 C.F.R. 164.508(c) for implementation specifications for patient authorizations



Business Associates

- See 45 C.F.R. 164.314 for implementation specifications for business associate agreements
- Business associates must sign an agreement meeting these specifications and execute agreements containing the same restrictions with subcontractors
- Business associates are restricted from using or disclosing PHI except as a service provider for the covered entity, with limited exceptions



State Privacy Laws: Scope

- State privacy laws go beyond HIPAA
  - Washington "My Health My Data Act" (RCW § 19.373)
  - California Consumer Privacy Act (Cal. Civ. Code § 1798.100)
- Many state laws exclude HIPAA protected health information from their scope. E.g.,
  - California Civil Code 1798.145(c) exempts "protected health information that is collected by a covered entity or business associate"
  - Revised Code of Washington 19.373.100(a) exempts "[…] information that meets the definition of … protected health information for purposes of [HIPAA]"
- If state law does not exclude PHI:
  - HIPAA does not preempt a state law provision if it is related to "privacy of individually identifiable health information" and "more stringent" than the HIPAA rules (see 45 C.F.R. 160.203(b))

State Privacy Law Example: MHMDA

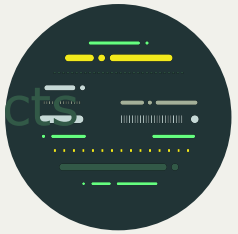
- Applies to any entity that "collects" consumer health data in Washington
- Collect means to "buy, rent, access, retain, receive, acquire, infer, derive, or otherwise process consumer health data in any manner" (RCW 19.373.010)
- Implements new privacy requirements, including:
  - Provide privacy notice details about processing and sharing -- must post via website/apps (RCW 19.373.020)
  - Obtain explicit consent before collecting or sharing consumer health data for various purposes – no broad terms of use (RCW 19.373.030)
  - Execute data processing agreements with service providers (RCW 19.373.060)
  - Respond to privacy rights requests; grant appeal rights (RCW 19.373.040)
  - Address data security (19.373.050)
  - No "geofencing" of various types of health care services (RCW 19.373.080)

HIPAA and State Laws

- How state laws complement or supplement HIPAA requirements
  - HIPAA only regulates covered entities and business associates
  - State privacy laws are designed to protect personal information more broadly and cover health information that falls outside of HIPAA
- What laws apply? This requires some evaluation:
  - Confirm if exception for HIPAA PHI or for covered entities/business associates in state law – identify exactly what is excluded
  - Is a business associate agreement in place? Is the company a covered entity?
  - Is data received through TPO, public health, patient authorization or other exceptions (i.e., no BAA)?
- **HIPAA compliance does not = state law compliance for most drug and device makers**

Case Study 1: The Patient App

- A drug manufacturer (ACME) designs a patient-facing app (the “App”) that helps patient better understand their therapy and provide feedback. ACME is not a covered entity or business associate.
- The App collects patient information including name, email address, password, patient feedback/surveys, mobile device ID, IP address, geolocation data, and phone number.
- This information is collected directly from the patient by ACME. ACME plans to share this information with the patient’s primary care doctor through a web-based physician portal linked to the App.
- In the future, ACME plans to use the patient information to improve products and services.



Case Study 2: Product Safety Data

- ACME has expanded its portfolio and is now manufacturing medical devices.
- It has a program for FDA adverse event reporting requirements.
- ACME launches the program and begins to receive adverse event information from its customers (HIPAA covered entities). The information includes patient information.
- ACME recognizes that HIPAA permits disclosure of PHI by covered entities to persons related to FDA-regulated product or activity for activities related to the quality, safety or effectiveness of the FDA-regulated product or activity.

Key Takeaways

- HIPAA considerations do not address all state law requirements for drug and device makers.
- HIPAA applies only to covered entities and business associates; not all drug and device makers.
- State privacy laws can directly apply to information handled by drug and device makers in patient access and marketing as well as other programs.
- Data security and privacy are not just HIPAA requirements. State regulators may bring enforcement against companies with lax data security.

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Questions

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Developments in Medical Device and Drug Litigation

David Graham

Wednesday, May 1st, 2024

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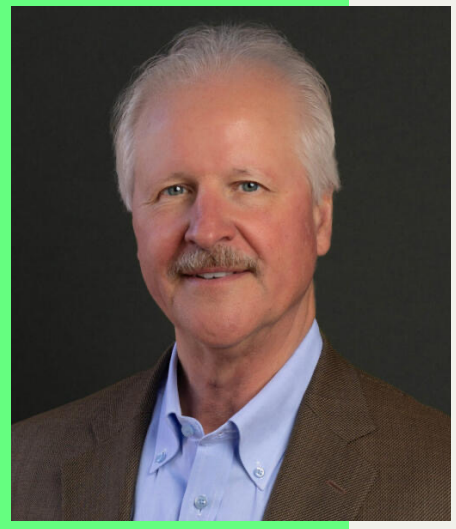

David Graham focuses on product liability, health law and food law litigation and counseling. He also works with clients in the food, cannabis, and psychedelics industries with regulatory matters, labeling and advertising, recalls, and food borne illness investigations and defense. David's focus in the health care area is defending entities in false claims act cases and other allegations of fraud. David teaches food law at Mitchell Hamline School of Law, the University of Minnesota School of Law, and is the chair of the Mitchell Hamline Food Law Center.

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Agenda

- State ex. Rel. Shikada v. Brystol Meyers Squibb
- OTC Class Action Cases
- Chevron Defense Reexamined
- Learnings

Hawaii Supreme Court

- Do you know the genetic profile of your end-users? The Hawaii Supreme Court thinks you should.
- Do you need to warn consumers and doctors? The Hawaii Supreme Court thinks you should.

State ex. rel. Shikada v. Brystol Meyers Squibb

- UDAP claims against makers of Plavix-anti-clotting medication
  - Plavix arguably not as effective for certain patients with a mutation in the gene affecting a metabolizing enzyme and an increased ability of their liver to metabolize the drug
  - Claim-failure to disclose efficacy of Plavix for these patients
  - Claim upheld because manufacturer had suppressed research to support drug sales
  - Duty to warn of the impact of genetic variations on efficacy

OTC Class Action Cases

- Use of food class action strategy on OTC drugs (and maybe others?)
- Focusing on ingredients, efficacy and more
  - OTC decongestants-efficacy of recommended dosage of phenylephrine
  - Valsartin-carcinogens
  - Zantac-carcinogens
    - Fueled in part by non-lawyer litigation funds
    - Suing retailers and focusing on their marketing activities
    - Use of “independent” labs, e.g. Valisure

Chevron Deference Reexamined

- Doctrine from Chevron v. Natural Resources Defense Council
    - Federal judges must defer to agencies reasonable interpretations of ambiguous laws in litigation
    - Two-part test: Is the law ambiguous? Is the agency's interpretation reasonable?
- Tension at the U. S. Supreme Court between those who want to scrap it, those who want to tweak it, and those who want to preserve it. What are the alternatives?

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Chevron Deference Reexamined

- Instruct Justices not to quickly determine that laws are ambiguous
- Better define reasonableness
- Make sure agency is acting with the force of law
- Look for statutory indications that Chevron may not apply
- Instruct courts on how to deal with silence
  - No deference unless consistent agency interpretation over time and across administrations

Key Takeaways

- Developments in Medical Device and Drug Litigation
- Do you know the genetic makeup of your end users?
- State ex. rel. Shikada v. Bristal Meyers Squibb
- UDAP claims against manufacture of Plavix-anti-blood clot medicine

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Panel Discussion

Wednesday, May 1st, 2024

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Moderator Introduction

Mark founded Gardner Law, an FDA law firm that specializes in regulatory, compliance, and privacy matters. His specialties include guiding clients through complex FDA matters, performing due diligence for buyers and sellers, assessing sales and marketing programs and commercial transactions, designing and implementing compliant ways to interact with healthcare providers, facilitating government transparency reporting, and auditing and investigating company activities for compliance with the law. Mark works with regulators at the FDA, CMS, and OCR, and with law enforcement at the DOJ and OIG.

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Panel Discussion

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Steve Tamayo
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Sight Sciences

Scott Way
General Counsel &
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