

### **NEWS**



## **AUGUST 4, 2025**

Winston & Strawn was pleased to host its fifth annual <u>Health Care & Life Sciences Summit</u>. This year's event brought together clients, colleagues, and industry leaders for an afternoon of insightful discussions, networking, and perspectives on the shifting dynamics across the health care and life sciences sector.

If you were not able to attend in person this year, CLE-eligible recordings of our panels and keynote conversation are now available to watch on-demand. Request access the recordings here.

Below are the key takeaways from each of the panels.

# Navigating the Health Care Compliance Landscape: Key Regulatory Updates and Enforcement Trends

## **TAKEAWAYS**

- FCA enforcement remains a top priority, evidenced by the \$2.9 billion recovered across 558 settlements/judgements and a record 979 qui tam lawsuits in 2024.
- The regulatory landscape remains uncertain with proposed Medicaid reforms, Medicare and value-based care, and drug pricing and market reforms, among others. Among other notable developments, the Centers for Medicare and Medicaid Services announced a 5% increase in payments to Medicare Advantage insurers and the U.S. Department of Health and Human Services has proposed an update to the HIPAA Security Rule which would require enhanced cybersecurity measures.
- Development and maintenance of a robust compliance program remains imperative for health care organizations, including smaller and newer entrants into the market.
- Regulatory scrutiny of the use of Al in health care continues to evolve, including limitations on Al-generated communication and the introduction of PCCPs for Al-enabled medical devices.
- The combination of recent sweeping Executive Orders (EOs) and Department of Government Efficiency (DOGE) actions have created a fractured, unstable and uncertain federal contracting environment in the heath care gov

con space and elsewhere.

Health care contractors, subcontractors and grantees are now subject to audit, termination and potential liability
under the civil False Claims Act with respect to their DEI policies and programs as they are now required to certify
DEI compliance, including that they do not operate "illegal" DEI programs, which are not defined. When faced with
a contract or grant termination, a contractor has a choice to a) renegotiate or rescope the contract or grant, (b)
close out and recover documented costs owed, or (c) file an administrative appeal challenging the termination.

### **PANEL**

- Nathan Leong, General Counsel, Memora Health (former)
- Denise Zamore, Chief Legal Officer and Corporate Secretary, agilon health
- Amandeep Sidhu, Health Care Partner, Winston & Strawn
- Larry Sher, Health Care Partner, Winston & Strawn

## We Are Never Ever Getting (Breached Again): Health Care Cybersecurity Lessons That We Won't Shake Off

### **TAKEAWAYS**

- Cyber security incidents are inevitable for even the most secure organizations, so preparation is key.

  Organizations should focus on mitigating liability by understanding potential threats, defining a strong incident response plan, and fostering collaboration across the organization and with external vendors.
- State attorney generals are becoming more aggressive in investigating breaches, emphasizing a need for organizations to be prepared to demonstrate compliance with privacy regulations.
- An effective incident response plan should be concise, actionable, and regularly reviewed and updated.
   Conducting a thorough postmortem after an incident provides an opportunity to identify root causes and prevent repeat occurrences, enabling your organization to do better the next time.

#### **PANEL**

- Dina Masiello, SVP, Head of Legal, iA
- Eric Shinabarger, Partner, Global Privacy and Data Security, Winston & Strawn
- Alessandra Swanson, Co-Chair, Global Privacy and Data Security Practice & Co-Chair, IP/Privacy, Winston & Strawn

# Meeting the Moment: Business Opportunities and Regulatory Risks in Life Sciences in 2025

## **TAKEAWAYS**

- FDA Reorganization Impact
  - · Oversight of life sciences industry stakeholders continues to evolve in response to the FDA's reorganization.
  - Effective strategies for engaging with the FDA going forward include maintaining robust records of communication with FDA staff regarding product reviews and approvals so that the timeliness of agency action is properly documented.
  - Closely monitor product approval timelines for drugs and devices to ensure that product launches are not adversely affected.

- Counseling stakeholders on new inconsistencies between the U.S. and other global regulators, as U.S. regulators
  adopt new positions on regulatory enforcements that may be inconsistent with historical practices and with other
  global regulators' current positions. Counseling clients on the necessity of staying within the guardrails of
  international compliance and being aware that U.S. regulators may again reverse course.
- Supply Chain Risk Management Considerations from Tariffs
  - Considering tariff impacts, free trade zone opportunities and maintaining supply availability are essential to an
    effective supply chain risk management strategy.
- Policy changes may affect biosimilar availability.

### **PANEL**

- Shelby Buettner, Senior Regulatory Affairs Director, Medtronic
- Rodney Emerson, Vice President, Pricing and Contracts, Sandoz
- Reed Stephens, Co-Chair, Health Care & Life Sciences Industry Group, Winston & Strawn

## The Road Ahead – Trends in Health care & Life Sciences M&A

## **PANEL**

- Eric Mayeda, Managing Partner and Leader, Strategic Transformation, Chartis
- · Emily Wildes, Managing Director & Co-head of Healthcare, Lincoln International
- Eric Knickrehm, Health Care M&A Partner, Winston & Strawn
- Conor Reidy, Antitrust Partner, Winston & Strawn

# Keynote Conversation: AI Insights and Outlook

- Kathi Vidal, Former Under Secretary of Commerce for Intellectual Property and Director of the USPTO, 2022– 2024; Partner, Intellectual Property, Winston & Strawn
- · Gael Tisack, Chief IP Counsel, Abbott Laboratories

3 Min Read

## **Related Capabilities**

Intellectual Property		Mergers & Acquisitions	Privacy & Data	Security	
Government Program Fraud, False Claims Act & Qui Tam Litigation				Health Care	
Life Sciences	Gove	ernment Contracts & Grants			

# Related Professionals



<u>Kathi Vidal</u>



T. Reed Stephens



<u>Justin Levy</u>



<u>Amandeep S. Sidhu</u>



Eric J. Knickrehm



Conor Reidy



Alessandra Swanson



Eric Shinabarger



Lawrence S. Sher