A black and white photograph of classical architectural columns, likely from a government building or courthouse, with a blue semi-transparent overlay on the right side containing the title text.

Representing the Founders, Investors, and Inventors of Healthcare AI: Venture Capital and Emerging Companies

Speakers



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Agenda



- VC Fundamentals for Healthcare AI
- How VC Investors Assess Opportunities and Evaluate Risk
- Unique Legal Considerations for VC-backed Healthcare AI Startups
- Practical Strategies for Navigating Regulatory Challenges



Why Does This Matter?



- Healthcare AI innovation not typically originated inside health systems or by regulators.
 - Venture-backed incubations
 - Founder-led startups



- Deal activity is at an all-time high in this space.

-
- Understanding these “VC” companies will deepen our understanding of the industry.



VC Fundamentals for Healthcare AI



The Problem: Healthcare AI Startups Often Have High Upfront Costs



Data acquisition



Model development



Clinical validation



Regulatory navigation



These upfront capital demands commonly require VC backing

The Solution: VC has Become a Funding Engine For Healthcare AI



RISK-TOLERANT
CAPITAL TO ENABLE
INNOVATION



SUPPORTS RAPID
EXPERIMENTATION



AVAILABLE DURING
PROOF-OF-CONCEPT
STAGE



LAYS THE FOUNDATION
FOR LATER-STAGE
INSTITUTIONAL
CAPITAL

VC: High Reward, (very) High Risk



- 3 out of 4 VC investments are likely to fail
- Only ~ 10% of investments produce substantial results
- These odds can be even worse in healthcare AI

	BAD	ALIVE	OKAY	GOOD	GREAT	TOTAL
Invested	\$200	400	200	100	100	1,000
Payout year 5	0	1x	5x	10x	20x	
Gross return	0	400	1,000	1,000	2,000	4,400
Net return	(200)	0	800	900	1,900	3,400

Example probability of success

Individual event	Probability
Company has sufficient capital	80%
Management is capable and focused	80
Product development goes as planned	80
Production and component sourcing goes as planned	80
Competitors behave as expected	80
Customers want product	80
Pricing is forecast correctly	80
Patents are issued and are enforceable	80
Combined probability of success	17



The VC Funding Landscape: Stages of Funding



Stage	Investment Focus	Investment Size
Angel/ Pre-seed	Idea development, market research, MVP creation	< \$1M
Series Seed	Product development, testing market fit	\$2-5M
Series A	Product launch, customer acquisition, building team	\$5-20M+
Series B, C, D, etc.	Scaling business, product optimization	\$20M+

The VC Funding Landscape: Exit Types



**PUBLIC LISTING
(IPO, SPAC, DIRECT
LISTING)**



M&A



SECONDARY SALE

The VC Funding Landscape: PE vs. VC



	<i>Private Equity (PE)</i>	<i>Venture Capital (VC)</i>
Company stage	Established companies	Early-stage startups
Risk Profile	Low to moderate risk	High risk, high reward
Exit timeline	3-6 years	7-10+ years
Investment size	Large, often 50%+, leveraged	Relatively smaller
Control	High control, active management	Moderate control
Industries	Varied	Focus on tech, health, life sciences
Operational Focus	Emphasizes operational improvements	Active involvement, especially in early stages

Telehealth is king, but analytics and EHR deals show YOY growth

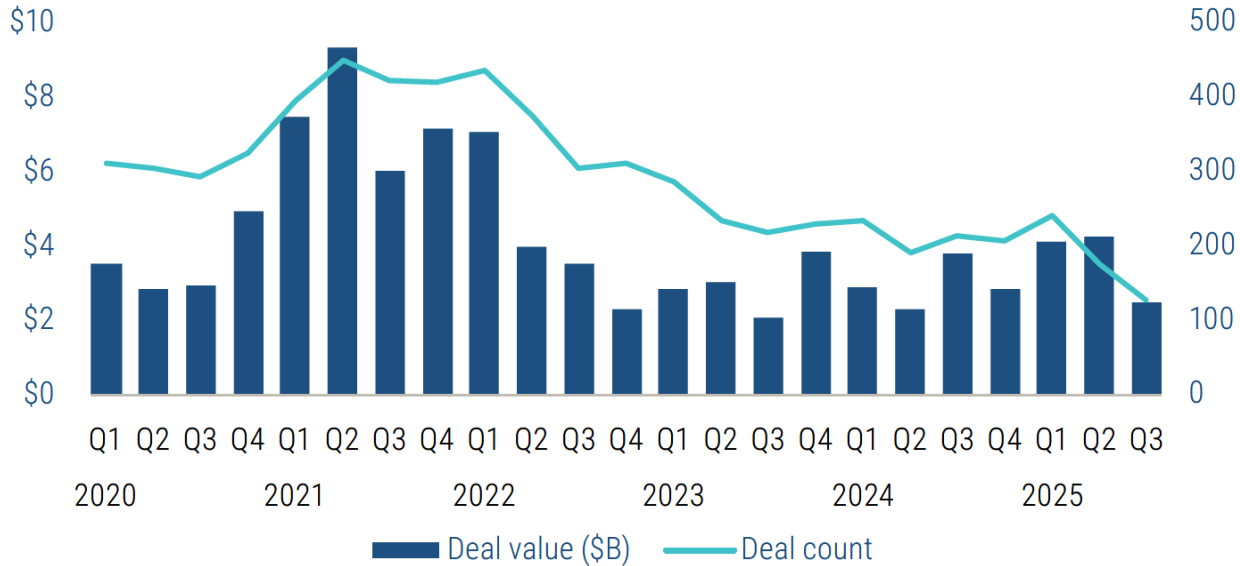
Healthtech heatmap by segment

Segment	TTM total VC deal value (\$M)	TTM total VC deal count	YoY VC deal value growth	YoY VC deal count growth
Analytics	\$2,135.2	107	165.1%	67.2%
Care management	\$1,372.8	103	-41.9%	-24.8%
Digital care & treatments	\$967.7	76	0.0%	-18.3%
EHRs & clinical information	\$2,706.9	88	179.2%	15.8%
Infrastructure & compliance	\$1,478.0	81	-23.6%	30.6%
Operations	\$2,184.8	109	70.0%	12.4%
Revenue cycle	\$917.8	46	93.8%	35.3%
Sport & wellness	\$690.1	83	-15.0%	-17.8%
Telehealth	\$3,037.9	173	-11.9%	-25.1%

Source: PitchBook • Geography: Global • As of September 30, 2025

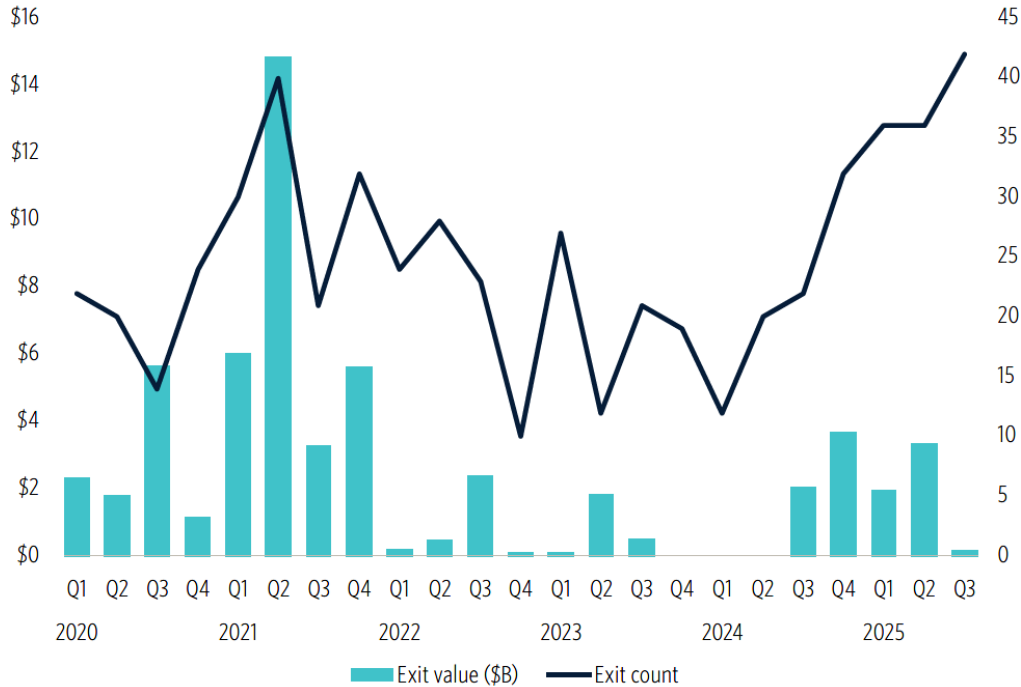
Deal values and counts are down from 2021, but show signs of growth

Healthtech VC deal activity by quarter



Source: PitchBook • Geography: Global • As of October 31, 2025

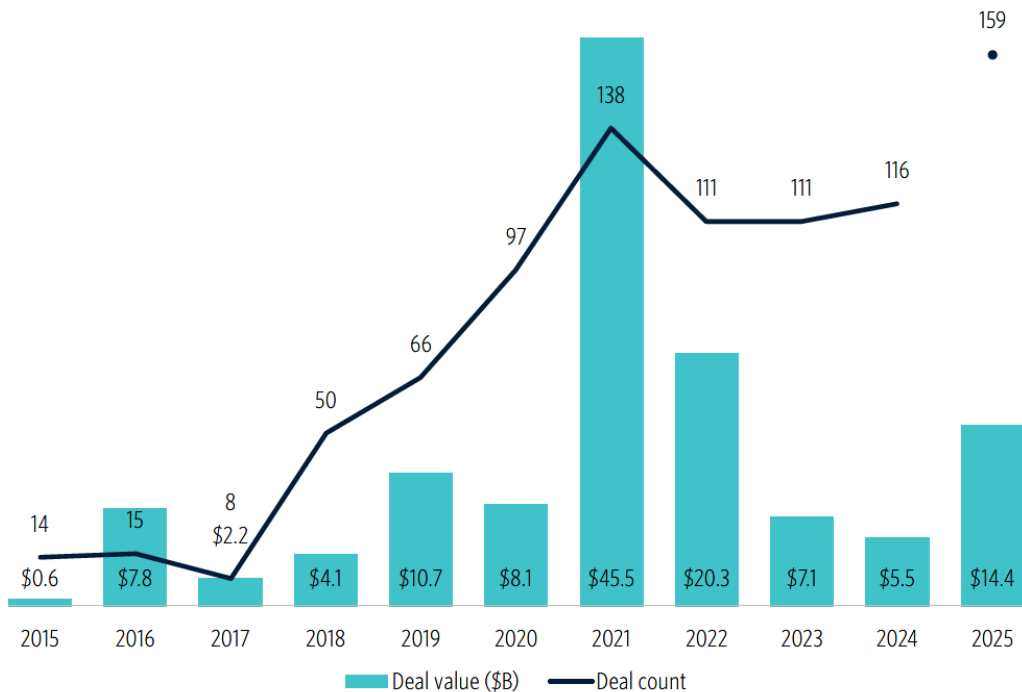
Healthtech VC exit activity by quarter



Source: PitchBook • Geography: Global • As of September 30, 2025

Exits increased rapidly from '23 - '24 lows

Healthtech M&A activity

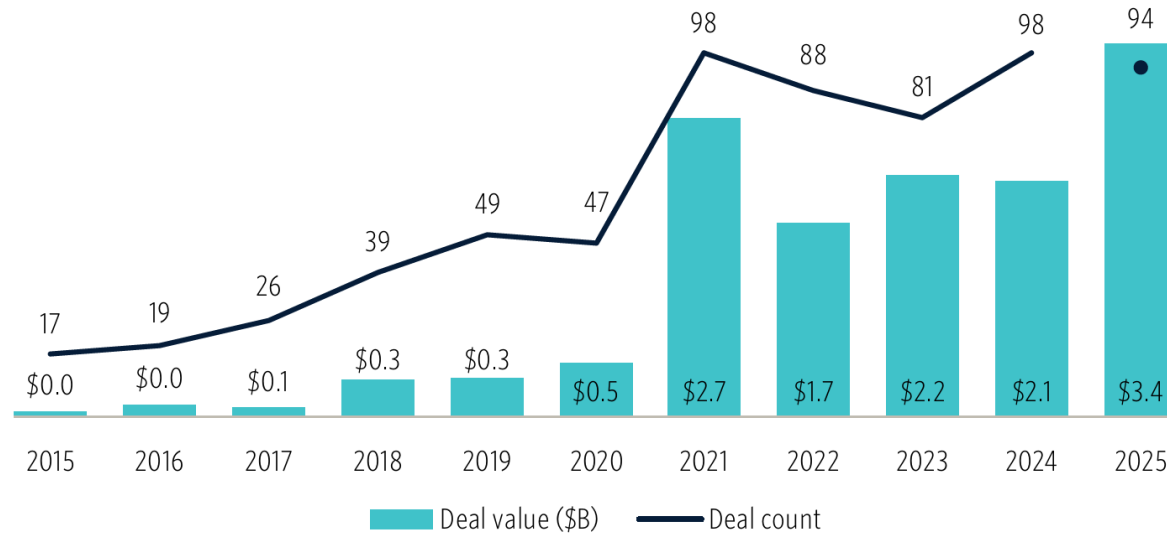


Source: PitchBook • Geography: Global • As of September 30, 2025

**M&A activity jumped
in 2025**

Healthcare services AI agent deal volume is at an all-time high

Healthcare services AI agents VC deal activity



Source: PitchBook • Geography: Global • As of September 30, 2025

How VC Investors Assess Opportunities and Evaluate Risk



Preparing for Venture Capital Funding



- **Business fundamentals**
- **Ensuring a “clean” legal due diligence process**
 - Delaware C corporation
 - Proper assignment of IP and no overlap from founders’ prior roles
 - Standard vesting on founder equity and 83(b) elections filed
 - Stock option grants only with prior board approval and a current 409A valuation report
 - In most cases, avoid unusual structures or bells and whistles (e.g., non-dilutive grants)
- **Regulatory readiness**

Regulatory Risks for Healthcare AI Companies



- **Regulatory risks look different for different types of companies**
 - Drug discovery platforms are relatively low-risk
 - Models where AI outputs are used to make decisions around human safety are relatively high-risk
- **Sometimes, the risk for a healthcare AI company is more about “will the science work” rather than “what are the regulatory risks”**
- **Investors and companies need to work with counsel that understand**
 - Where in the product roadmap regulatory risks come into play, and
 - The strategies for mitigating these risks

What Does “Regulatory Readiness” Look Like?



Clear articulation of intended use



Governance around data and model changes

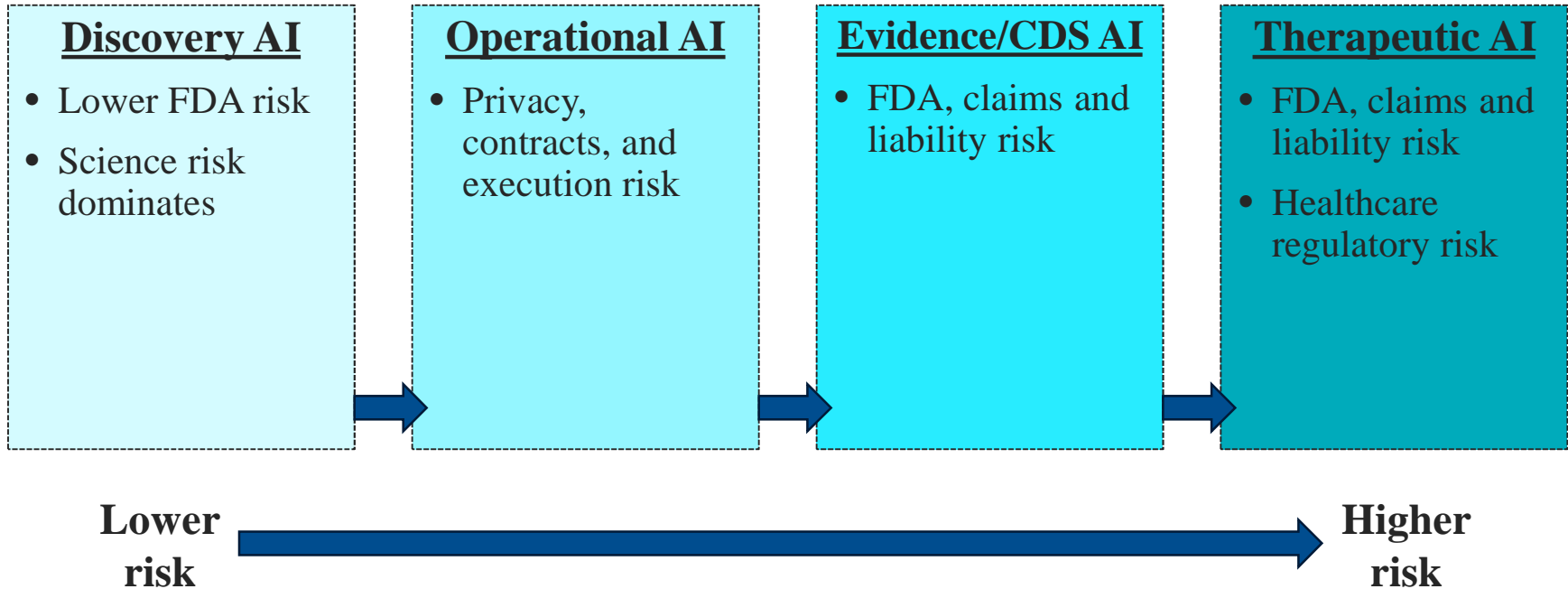


Willingness to validate AI outputs externally



Early engagement with regulators when appropriate

Different Use Cases for AI in Healthcare



Unique Legal Considerations for VC-backed Healthcare AI Startups



Counseling Early-Stage Companies



Advising early-stage companies comes with special considerations:

- Minimal legal budget
- Often the founders' first foray into healthcare (a highly-regulated environment)
- Often founders have not worked with a lawyer/law firm before
- High risk tolerance
- Desire for “creative” legal solutions
- Need to balance limited resources with innovation and compliance

Advising early-stage companies requires calibrating legal advice to stage, capital constraints and evolving regulatory posture – which can differ meaningfully from the framework used for mature PE-backed or health system clients.

Evolving Compliance Needs



- **Focus on healthcare regulatory compliance shifts as the company matures**
 - Investors are more forgiving with early-stage companies
 - No one is expecting a seed-stage company to have perfect compliance
- **For seed-stage companies, investors are looking for glaring red flags**
- **For later-stage companies, investors will conduct thorough healthcare regulatory due diligence and have “typical” regulatory compliance expectations**
 - E.g., What is market for compliance?

Executive Order Targets State AI Laws



- On December 11, the White House issued an executive order (EO) that establishes a new federal policy on AI
- The EO seeks to challenge “onerous” and “excessive” state AI laws through various federal actions
- The Secretary of Commerce is directed to publish list of state AI laws to target
- Unclear if the Secretary of Commerce will focus on industry sector AI laws, like those in healthcare



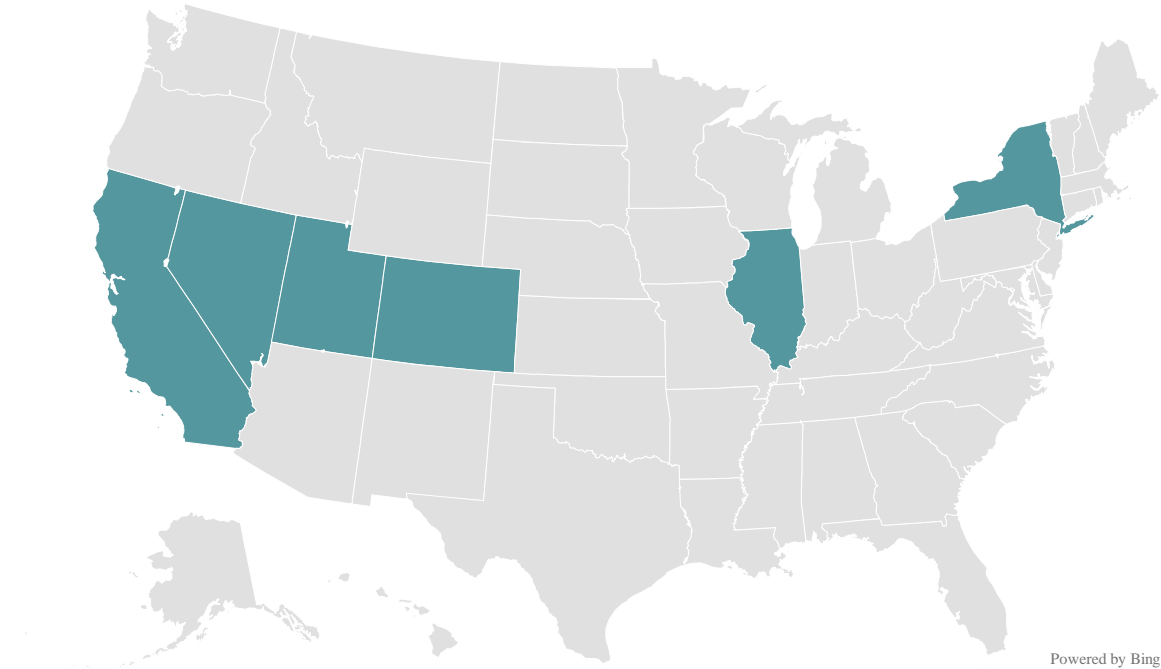
By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered:

Section 1. Purpose. United States leadership in Artificial Intelligence (AI) will promote United States national and economic security and dominance across many domains. Pursuant to Executive Order 14179 of January 23, 2025 (Removing Barriers to American Leadership in Artificial Intelligence), I revoked my predecessor’s attempt to paralyze this industry and

Notable State Healthcare AI Laws



- California
- Colorado
- Illinois
- Nevada
- New York
- Utah



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Practical Strategies for Navigating Regulatory Challenges



Navigating Regulatory Challenges: VC vs. PE



VC underwrites uncertainty; PE underwrites compliance

- **PE:** Lower risk tolerance, particularly with respect to regulatory and compliance exposure
- **VC:** Invests earlier; expects regulatory gray areas, particularly where business model still evolving



VC's Approach to Highly-Scrutinized Areas



Corporate practice of medicine (CPOM) and fee-splitting



Stark Law and the Anti-Kickback Statute (AKS)



Emerging state AI laws



Data privacy



Telehealth rules and prescribing/dispensing controlled substances



FTC scrutiny (e.g., health claims, data security)



FDA (e.g., clinical decision support, SaaS)

Navigating Healthcare Reps for VC-backed Companies



- Representations for early-stage VC-backed companies typically include broader materiality qualifiers, shorter lookback periods, and more narrowly defined parties.
- Representations frequently track the company's business stage rather than hypothetical future states, with express carve-outs for anticipated business expansion.
- Reps are tailored (or narrowed) where an early-stage VC-backed company does not involve government payors (healthcare compliance reps required for Medicare or Medicaid billing).
- VC investors generally accept higher regulatory uncertainty at signing, relying on (post-closing) covenants and disclosure schedules rather than PE-style, absolute compliance reps at closing.

Case Study: Class Action over Use of Ambient AI in Health System (11/25)



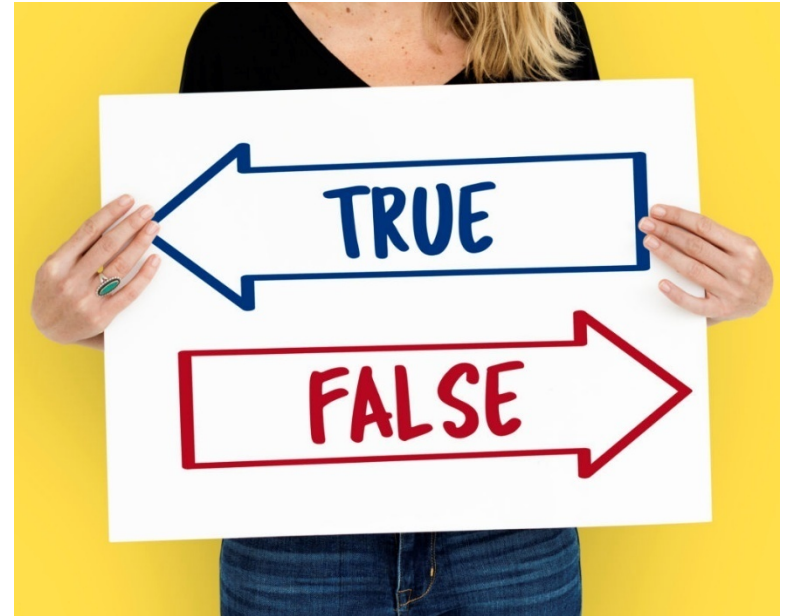
- Patients sued a San-Diego based health system for using an AI scribe during their treatment
- Patients allege the AI scribe recorded their clinical conversations without their consent
- Complaint seeks statutory penalties, punitive damages, injunctive relief, and full correction of allegedly inaccurate medical records for a class that may exceed 100,000 patients



Case Study: Pieces Technology Settlement (9/24)



- Texas AG investigated AI healthcare technology company Pieces Technologies for deceptive trade practices
- Pieces develops healthcare products for use by inpatient healthcare facilities, such as AI-generated clinical documentation
- Settlement resolves allegations that Pieces made false and misleading statements that the outputs of its Gen AI product were highly accurate and that Texas hospital patients were potentially harmed as a result



Hot Topics



- AI competitor lawsuits
 - E.g., OpenEvidence v. Doximity
- Loss of talent with regulatory expertise
 - E.g., FDA brain drain



Side Note On Navigating FDA Review Process



- **Documentation over precedent**
- **Early framing is key**
 - What is the technology doing/not doing?
- **Limit novelty where it doesn't exist**
 - Not a marketing exercise
- **Clarity over cleverness**
 - Teach the regulator how to think about the product



Final Thoughts



- Where do you see lawyers over-lawyering early-stage AI companies?
- What regulatory issue do VCs consistently underestimate?
- At what point does regulatory immaturity kill an exit?



Venture-backed healthcare AI doesn't succeed despite regulation. It succeeds because sophisticated counsel help companies navigate regulation without stalling innovation.