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Navigating What's Next

AI, Compliance, and Regulation in Life Sciences

From Gardner Law and Fieldfisher

Thursday, November 6, 2025

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Agenda

9:00 – 9:45	*AI in Life Sciences* Nathan Downing with Paul Rothermel, Felicity Fisher and Oliver Süme
9:45 – 10:15	*Compliance and Enforcement Update* Amanda Johnston & Dr. Cord Willhöft
10:15 – 10:30	*Refreshment Break*
10:30 – 11:00	*Privacy & EU Data Act Updates* Paul Rothermel & Oliver Süme
11:00 – 11:30	*U.S. & EU Regulatory Update* Nathan Downing & Dr. Cord Willhöft
11:30 – 12:15	*General Counsel Roundtable* Moderated by Mark Gardner, with Mike Pisetsky (SI-Bone), Bernie Shay (ScimusLex Law), & Darci Teobaldi (ReCor Medical)

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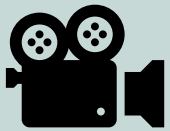
Program Introduction

- **Continuing Legal Education credits**: This course has been approved for 3 CLE credits by the Minnesota Board of Continuing Legal Education and the North Carolina State Bar – Continuing Legal Education. California MCLE approval is pending. A 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.
- **RAPS Course Credit**: This course has been approved for 3 RAC recertification credits.



This meeting will be recorded and its materials disseminated

NORTH CAROLINA STATE BAR
CONTINUING LEGAL EDUCATION

REGULATORY AFFAIRS PROFESSIONALS SOCIETY

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AI in Life Sciences

Moderated by Nathan Downing, with Paul Rothermel, Felicity Fisher, & Oliver Süme

Thursday, November 6, 2025

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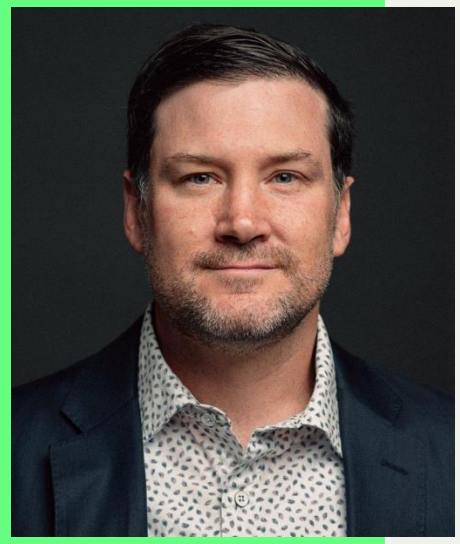
Moderator Introduction



Nathan Downing

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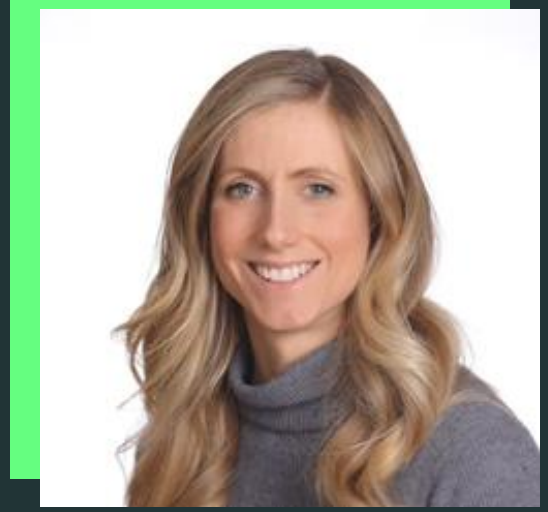
Nathan focuses his practice on FDA-regulated clients. His industry experience allows him to provide actionable legal advice on a variety of health law matters.

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.

Panelist Information

Paul Rothermel
Senior Attorney
Gardner Law



Felicity Fisher
Partner, Data
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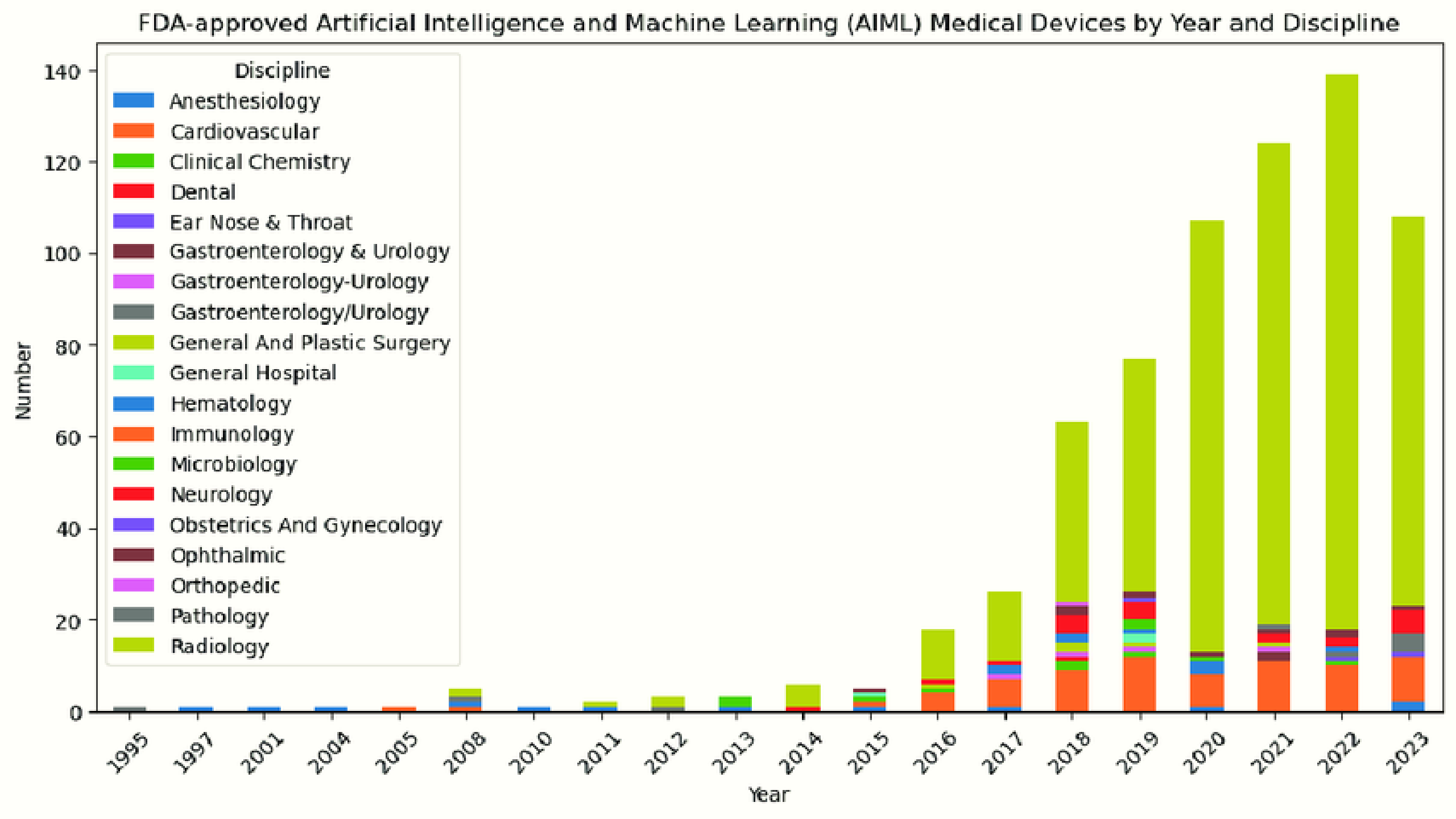
Oliver Süme
Partner, Co-Head of Technology
Fieldfisher


FDA-approved Artificial Intelligence and Machine Learning (AIML) Medical Devices by Year and Discipline
Discipline
Anesthesiology
Cardiovascular
Clinical Chemistry
Dental
Ear Nose & Throat
Gastroenterology & Urology
Gastroenterology-Urology
Gastroenterology/Urology
General And Plastic Surgery
General Hospital
Hematology
Immunology
Microbiology
Neurology
Obstetrics And Gynecology
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Private Sector Law (U.S.)

- Biden-era EO repealed/replaced with EO 14179 "Removing Barriers to American Leadership in AI"
- Bi-partisan support led to bill establishing AI Safety Institute at NIST in 2024
- Federal legislation limiting private sector AI use has been proposed
- Some states with generative AI laws
- Colorado AI Act (similar approach to EU)
- State privacy laws and ADMT
- Chatbot laws (e.g., California SB 243) and other AI laws making headway in state legislatures
- Federal Trade Commission enforcement

CCPA and Automated Decision-making

- California regulations newly issued under the CCPA (August 2025):
  - "Automated decision-making technology" or "ADMT" means any technology that processes personal information and uses computation to execute a decision, replace human decision-making, or substantially replace facilitate human decision-making.
  - […] For purposes of this definition, to "substantially replace facilitate human decision-making" means a business uses the technology's output to make a decision without human involvement.

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CCPA and Automated Decision-Making

- Must perform risk assessment for ADMT when processing of consumer personal information "presents significant risk to consumer's privacy"
- Processing of personal information that involves significant risk includes:
  - Processing "sensitive personal information"
  - Processed for a "significant decision" (i.e., a decision concerning a consumer that results in the provision or denial of various services, including health services, among others)
  - Using personal information intended to train an ADMT for a significant decision concerning a consumer

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AI and ADMT overlap

- Colorado AI Act regulates AI (which can overlap with automated decision-making):
  - "Artificial intelligence system" means any machine-based system that, for any explicit or implicit objective, infers from the inputs the system receives how to generate outputs, including content, decisions, predictions, or recommendations, that can influence physical or virtual environments."
  - "High risk AI systems" have higher regulatory burden.

Colorado AI Act

Focused on “high risk” AI systems:

- “High-risk artificial intelligence system" means any artificial intelligence system that, when deployed, makes, or is a substantial factor in making, a consequential decision.”

Exemptions include:

- HIPAA-regulated covered entities providing non-high risk health care recommendations
- Technologies approved, certified or cleared by federal agency, such as the FDA if standards are at least ”substantially equivalent.”

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Other Laws

- Many state privacy laws impact AI *development* by limiting use of personal information for training models.
- Automated decision-making tools and privacy regulation.
- Consent is frequently required to use personally identifiable health information to train AI algorithms. See for example the Washington My Health My Data Act and other consumer health data laws (NY, CT, NV).
- The FTC has discussed similar theories for enforcement.
- Data protection assessments are required in many states when data processing presents a high or heightened risk to a consumer, including where the personal information is processed automatically to make or inform “significant decisions.”

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EU: AI Act for Life Sciences

Defines "AI systems" by risk level: *prohibited,* ***high-risk (most regulated)****, limited, minimal risk*

Providers (developers) hold main compliance duties

Deployers (HCPs, pharma, research) also have obligations e.g., to ensure human oversight and safe use.

High-Risk AI includes:

- AI systems that are regulated (MDR/IVDR) med devices or safety components of regulated med devices (*Annex I: Aug 2, 2027)*
- Emergency patient triage systems (*Annex III – Aug 2, 2026*)

AIA adds to (not replaces) **MDR/IVDR & GDPR**

Compliance layers for "High-Risk" AI in medical devices**:**

- *MDR/IVDR*: safety & performance
- *AI Act*: bias, explainability, transparency
- *GDPR*: personal & sensitive health data protection

Shared requirements: QMS, RMS, technical documentation, conformity assessment, post-market monitoring

New obligations: AI data governance, bias mitigation, event logging, traceability, human oversight, robustness & cybersecurity

💬 **Chatbots** in digital health → transparency to users

🧪 **AI in drug discovery** → generally excluded if used for scientific R&D

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EU: Health Data and AI

GDPR remains the foundation for processing health data (**Article 9**):
→ AI training on patient data requires a lawful basis + special conditions + safeguards.

AI outputs used for Automated Decision Making (Art 22 GDPR):
→ Prohibited if it has a **significant effect** (e.g., on clinical outcomes) unless conditions like *meaningful human involvement* or *explicit patient consent* are met.

Data Governance Requirements (Art 10 AIA):
→ High-risk AI must use training data that is **accurate**, **representative**, **bias-controlled**, and managed under formal **data governance practices**.

European Health Data Space (EHDS, expected 2026):
→ Will enable **secure secondary use** of health data for **AI training**, **research**, and **public-health** purposes.

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UK: Regulation of AI in Life Sciences

"Pro-Innovation" Approach": Government treats AI + Life Sciences as strategic growth sectors**.**

New **Data (Use & Access) Act 2025** sets governance for access to health and research data.

£600 m investment + Health Data Research Service to make **NHS data "AI-ready."**

Principles-Based Approach: Rather than impose rigid prescriptive rules, UK's framework is built around 5 guiding principles— safety, transparency, fairness, accountability, redress (UK's AI White Paper: Aug 2023).

Sector-led regulation: Existing regulators (e.g., MHRA, HRA) empowered to apply these principles within their respective domains. Goal: ensure regulation is tailored to specific risks and opportunities of each sector vs one-size-fits all.

HRA provides research-ethics oversight and launched a National Commission on AI in Healthcare (2025).

Use-case focus: Regulates *how* AI is used, not the tech itself. Context and application of AI systems key.

MHRA oversees AI/ML medical devices under UK MDR 2002: Future device reform lead by MHRA aims to modernize UK MDR with AI-specific assurance requirements.

AI/ML-enabled devices may be **up-classified** under UKMDR so that more stringent conformity assessment and oversight applies.

"**AI Airlock**" sandbox (2024) lead by MHRA

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EU, UK & US: Different Paths, Shared Principles

EU vs. UK vs. US:

- EU: Prescriptive, risk-based regulation via the AI Act
- UK: Principles-based, innovation-friendly approach
- US: Decentralized, sector-specific guidance with no overarching AI law
- Some level of convergence on principles (e.g., need for trustworthy and risk-based AI; transparency, explainability, safety, fairness), but not yet on detail. Implementation diverges

Global convergence is emerging:

- US watching EU approach and borrowing concepts (risk classification, transparency, lifecycle governance).
- Increasingly cross-border collaboration through forums like the G7 Hiroshima AI Process, the OECD, and the EU–US Trade & Technology Council (TTC), which are attempting to align definitions and evaluation methods for trustworthy AI.
- The FDA, MHRA, and EMA already collaborate through the International Medical Device Regulators Forum (IMDRF), which has AI/ML working groups setting common expectations for adaptive algorithms and real-world monitoring.
- The ITU–WHO AI for Health initiative and ISO/IEC standards (e.g., ISO 42001, ISO /IEC 5259) aim to provide a shared technical foundation across jurisdictions.

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Compliance & Enforcement Update

Amanda Johnston & Dr. Cord Willhöft

Thursday, November 6, 2025

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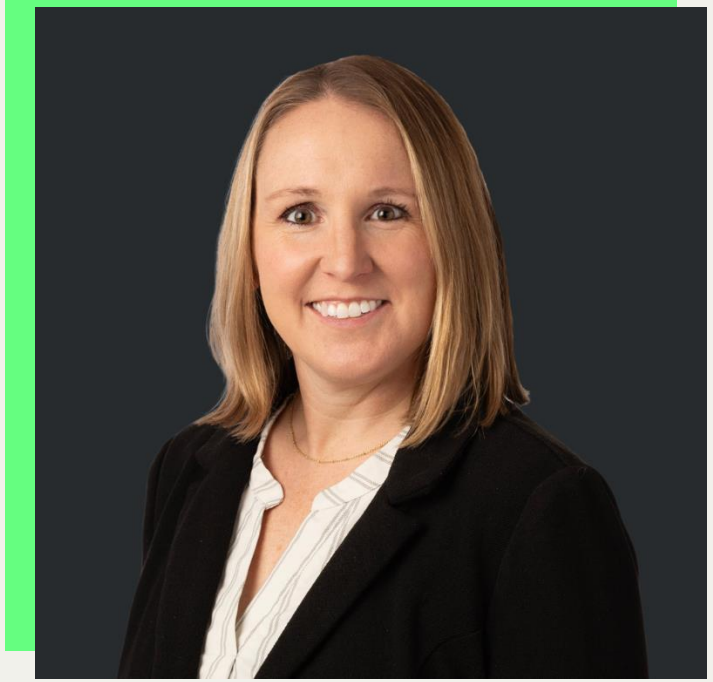
Presenter Information



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U.S. Update

Amanda Johnston

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2025 Enforcement: What Changed and Why It Matters

- DOJ–HHS FCA Working Group (July 2025)
  - Cross-agency coordination with CMS, OIG & USAOs
- Priorities: Medicare Advantage, pricing/discounts, kickbacks, EHR manipulation
- Why it matters to device/drug makers
  - Pricing & contracting live under FCA/AKS lens
  - Data-driven investigations → monitoring & analytics expected

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U.S. Enforcement Landscape

- Aggressive DOJ and OIG focus on healthcare fraud and improper remuneration
- Increased data-driven analytics
- Whistleblowers (979 in FY 2024, highest in history)
- Coordination across agencies (DOJ, OIG, CMS, FDA, FTC)
- $2.9 B in FCA recoveries (2024 DOJ data)
    - 70% of recoveries from healthcare
- Continued focus on individual accountability

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AKS Enforcement Trends

- Charitable foundations as disguised kickbacks
- Honoraria exceeding FMV
- High-end meals, alcohol
- Speaker programs: repeat attendees, lacking educational value, repeat program content, lavish venues
- High use of the same HCP consultants
- Commission-based contract sales reps

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FCA Enforcement Trends

- Off-label promotion
- Reimbursement support programs
- Unsafe device use
- Telehealth
- Medicare Advantage
- Improper billing
- Medically unnecessary services
- False certifications to the government
- Cybersecurity vulnerabilities

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DOJ-HHS False Claims Act Working Group: Priorities

- Medicare Advantage
- Pricing (discounts, rebates, service fees, formulary placement, price reporting)
- Barriers to patient access to care
- Kickbacks
- Defective medical devices that impact patient safety
- Manipulation of EHR systems to drive inappropriate utilization
- Cross-agency collaboration
- Data mining
- Encouraging self-reporting and whistleblowers

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U.S. Compliance Enforcement Recommendations

- Tighten HCP engagement controls
  - Centralize FMV & needs assessments; cap honoraria; pre-approve venues/meals. Monitor speaker programs for repeat attendees/duplicative content; enforce FMV
- Audit High-Risk Areas
  - Speaker programs, HCP consultants, discounts/rebates, reimbursement support programs
- Investigate reports/concerns promptly and take appropriate (and consistent) corrective action, up to and including termination when warranted
- Use AI/analytics to flag outliers (T&E, consultant concentration, payments-to-sales)
  - Correlate risk signals across DOJ/OIG priority areas.

Compliance Update EU / Germany

Dr Cord Willhöft, LL.M.

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Agenda: Compliance Update

I. Legal Regime for providing Benefits to HCPs

1. European-wide prohibition to grant benefits / benefits in kind to HCPs
2. Exception 1: Gifts of Minor Value Germany / Europe
3. Exception 2: Meals Limits in Germany / Europe

II. Enforcement Update Advertisement

1. Article 7 EU MDR
2. Enforcement Update (Germany)

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I. Regime for providing Benefits

→ Prohibition to provide benefits/benefits in kind to HCPs and HCOs, in order to avoid any undue influence on therapeutical and/or purchase decisions

MedTech Europe Code of Ethical Business Practice

"It is generally prohibited to provide gifts to Healthcare Professionals and Healthcare Organizations." (Chapter 8, page 54)

DIRECTIVE 2001/83/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 6 November 2001
on the Community code relating to medicinal products for human use

"Where Medicinal products are being promoted to persons qualified to prescribe (…) them, no gifts, pecuniary advantages or benefits may be offered (…)"

→ Prohibition has been implemented by national legislators in Europe, e.g. in Germany via by the Act on Advertisement of Healthcare Products (*Heilmittelwerbegesetz*), French Anti Kick Back Statute, UK Bribery Act…

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I. Exception 1: Gifts of minor Value (1)

→ MedTech Europe Code of Conduct (2025):

*"It is generally prohibited to provide gifts to Healthcare Professionals and Healthcare Organizations. **Member Companies may exceptionally provide inexpensive (…) promotional items**, in accordance with national laws, regulations (…) where the Healthcare Professional is licensed to practice."*

→ Directive 2001/83/EC:

*"Where Medicinal products are being promoted to persons qualified to prescribe (…) them, no gifts, pecuniary advantages or benefits may be offered (…), **unless they are inexpensive (…)**"*

→ German Act on Advertisement of Healthcare Products (Section 7 [1] No 1):

*It is prohibited to offer, announce, or grant benefits and other promotional gifts (goods or services), or to accept them as a member of the medical profession, **unless the benefits or promotional gifts are items of minor value;"***

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I. Exception 1: Gifts of minor Value (2)

Exception in several countries: Gifts of Minor Value

- Austria
- Belgium
- France
- Germany
- Greece
- Netherlands
- Spain
- UK
- Italy

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I. Exception 1: Gifts of minor Value (Germany)

- History/Background:
  - German Industry Guidelines (e.g. Association of Research-Based Pharmaceutical Companies, FSA Code of Conduct) considered any item below EUR 5 as minor value
  - Self-regulatory guideline withdrawn after implementation of the German Act against Corruption in the Healthcare Sector (May 2016)
- German case law since approx. 2015: **EUR 1**, in relation to (i) HCPs, and (ii) in context of pharmaceuticals
- Higher Civil Court Hamburg on February 29, 2024: threshold of EUR 5 applicable (not EUR 1) in relation to benefits provided in context of product-related advertisement for medical devices since
  - price competition is allowed for medical devices (in contrast to Rx medicinal products), and
  - higher inflation rate / price increase in the recent years
- Higher Federal Court on July 17, 2025: Minor value at EUR 1 (*"the abstract risk of undue influence can only be excluded if the value is limited to one EUR"*)

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I. Exception 1: Gifts of minor Value (Europe)

Country	Minor Value	Comments / Source
Austria	No rules / guidelines available	Section 55 (1) Austrian Medicines Act allows gift of minor value; MoH has not yet issued threshold
Belgium	**€ 50** per gift; not more than **€ 125** per HCP/HCO per year	Article 10 of the Law on Medicinal Products; Mdeon Code of Ethics
France	→ impromptu meals/snacks: **€ 30** (up to 2 times/year) → specialist literature : **€ 30** per item (up to € 150/year) → sample products, demonstration material **€ 20** (max. 3 times/year) → office supplies: max. **€ 20** per year → professionally relevant products or services: max. **€ 20** / year	Section 1453-6, 4° of the Public Health Code: Exception for gifts of „**neglibe value**“ Ministry Order of 7 August 2020 setting the amounts (VAT included):
Germany	**€ 1**	Decision of the Higher Federal Court 2025
Greece	No rules / guidelines available	
Italy	No rules / guidelines available	
Netherlands	**€ 50** (up to € 150 per year)	Article 6.3 Wet medische hulpmiddelen: FAQs about inducements (Medical Devices Act)
Spain	**€ 12** (for training/promotional materials directly related to the practice)	Fenin Code of Ethics (Healthcare Technology Sector)
UK	**£ 6**	Note: ABHI refers to NHS, which refers to ABPI Code of Conduct (£15 since 2024)

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I. Exception 2: Meals

- Providing meals to HCPs is allowed (exception to the prohibition of providing benefits to HCPs), as "reasonable hospitality":
  - As expense in relation the HCP consultancy services
  - Educational Grants to support HCP participation at a Third Party Organized Educational Event
  - Internal training events (company-organized)
  - Business meals
- German Act on Advertisement of Healthcare Products (Section 7 [2]):
  - *"benefits provided in the context of purely professional scientific events* [are allowed]*, provided they do not exceed a reasonable scope"* (established case law: "*socially adequate*")
- International events? Cf. MedTech Europe Code of Ethical Business Practice
  - *"Member Companies must in any event meet the requirements governing hospitality (i) in the country where the Healthcare Professional carries on their profession, and (ii) give due consideration to the requirements in the country where the Event is being hosted."* (September 2024, page 21)

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I. Exception 2: Meal Limits

Country	Limit	Please note:
Austria	< **€ 85** incl. VAT per meal	-
Belgium	**€ 45** incl. VAT for lunch **€ 90** incl. VAT for dinner	*The maximum hospitality can only be offered if the programme includes at least 6 hours of scientific activities, € 23/hour up to the maximum for stand-alone events*
France	**Meal Limits for Physicians** (February 2024, **other HCPs € 70**): **€ 90** incl. VAT (Paris, and major cities in France) **€ 85** incl. VAT (province/countryside) **€ 100** incl. VAT for high-price countries (e.g. Canada, Nordics, USA, Israël, Japan, CH, etc.)	*prior CNOM (physicians) / CNOP (pharmacists) authorisation required if meal limit is above* € 50 Note: meal limits apply to MedTech companies and physicians; for Leem (French Pharmaceutical Industry Association), and other HCPs a meal limit of **€ 70 applies.**
Germany	**€ 75** incl. VAT	*Press release BVMed May 2023*
Greece	**€ 70** incl. VAT per day	*limit for events inside Greece; € 150/day abroad*
Italy	**€ 80**	-
Netherlands	**€ 75** incl. VAT per meal	-
Spain	**€ 80** incl. VAT	-
UK	**75 GBP** plus VAT	*NHS limit; ABHI: "reasonable"*

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II. Enforcement Update: Advertisement (1)

EU MDR sets out EU-wide rules for the advertising of medical devices (May 26, 2021)

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

of 5 April 2017

on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Article 7

Claims

In the labelling, instructions for use, making available, putting into service and advertising of devices, it shall be prohibited to use text, names, trademarks, pictures and figurative or other signs that may mislead the user or the patient with regard to the device's intended purpose, safety and performance by:

(a) ascribing functions and properties to the device which the device does not have;

(b) creating a false impression regarding treatment or diagnosis, functions or properties which the device does not have;

(c) failing to inform the user or the patient of a likely risk associated with the use of the device in line with its intended purpose;

(d) suggesting uses for the device other than those stated to form part of the intended purpose for which the conformity assessment was carried out.

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II. Enforcement Update: Advertisement (2)

- Several European Countries prohibit direct-to-consumer advertising of medical devices

Country	Advertising aimed at the general public / patients / laypersons is prohibited in...for...:
Austria	Medical devices that (i) are only available on prescription and/or (ii) may only be used by HCPs.
Spain	Medical devices that (i) are reimbursed by health insurance and/or (ii) may only be used by HCPs.
Poland	Medical devices that may only be used by HCPs.
France	Medical devices that (i) belong to class IIb and III and/or (ii) are reimbursed by the national health insurances.
Switzerland	Medical devices that may only be used by HCPs.
Belgium	Implantable medical devices.
Netherlands	Medical products in pharmaceutical form with a physical effect.

- No restrictions on direct-to-consumers advertisement in Germany and UK

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II. Enforcement Update: Germany

- Strict requirements for product-related safety /efficacy claims in Germany (Regional Court Duesseldorf June 21, 2023; 12 O 115/22):

  "it is generally required that a randomized, placebo-controlled double-blind study with adequate statistical analysis is available, which has been incorporated into the discussion process of the scientific community through publication"

  ⇒As for Medicinal Products: RCT required to provide sufficient scientific evidence!

- However: German promotional market is self-regulatory, German authorities are rather passive in monitoring the promotional market for medical devices
- Legal proceedings (civil courts) are more likely to be initiated by competitors or consumer protection agencies (warning letters, and preliminary injunctions)
- Consequences: Reimbursement of legal costs (EUR 5,000 – 10,000)

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Questions

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We are taking a brief break.

The program will resume at 10:30 a.m. PST

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Privacy and EU Data Act Update

Paul Rothermel & Oliver Süme

Thursday, November 6, 2025

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Presenter Information

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Privacy Enforcement Trends

Masimo faces operational disruption after cybersecurity breach, triggers law enforcement coordination

MAY 08, 2025

PRESS RELEASE

Illumina Inc. to Pay $9.8M to Resolve False Claims Act Allegations Arising from Cybersecurity Vulnerabilities in Genomic Sequencing Systems

Thursday, July 31, 2025

For Immediate Release

Attorney General Bonta Announces Largest CCPA Settlement to Date, Secures $1.55 Million from Healthline.com

Press Release / *Attorney General Bonta Announces Largest CCPA Settlement to ...*

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2 State AGs Slap DNA Testing Lab With HIPAA Fines for Hack

Compromised Database With PHI on 2.1M People Had Not Been Used for a Decade

Marianne Kolbasuk McGee (HealthInfoSec) · February 17, 2023

Warby Parker to Pay $1.5 Million To Resolve HIPAA Violations

Posted By Steve Alder on Feb 21, 2025

Solara Medical Supplies Pays $3M to Settle Alleged HIPAA Security and Breach Notification Rule Violations

Posted By Steve Alder on Jan 15, 2025

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Federal Laws

- Health Insurance Portability and Accountability Act of 1996 (“HIPAA”), 42 U.S.C. 1320d, as amended, and implementing regulations at 45 C.F.R. §§ 160-164
- Health Information Technology for Economic and Clinical Health Act’ (“HITECH”) 42 U.S.C. § 17935
- Federal Trade Commission Act (“FTCA”) 15 U.S.C. § 45
- CAN-SPAM Act of 2003
- Telephone Consumer Privacy Act (“TCPA”) 47 U.S.C. § 227
- Children’s Online Privacy Protection Act (“COPPA”) 15 U.S.C. §§ 6501–6506
- Federal False Claims Act
- Federal Anti-Kickback Statute
- Food, Drug & Cosmetic Act
- 21st Century Cures Act

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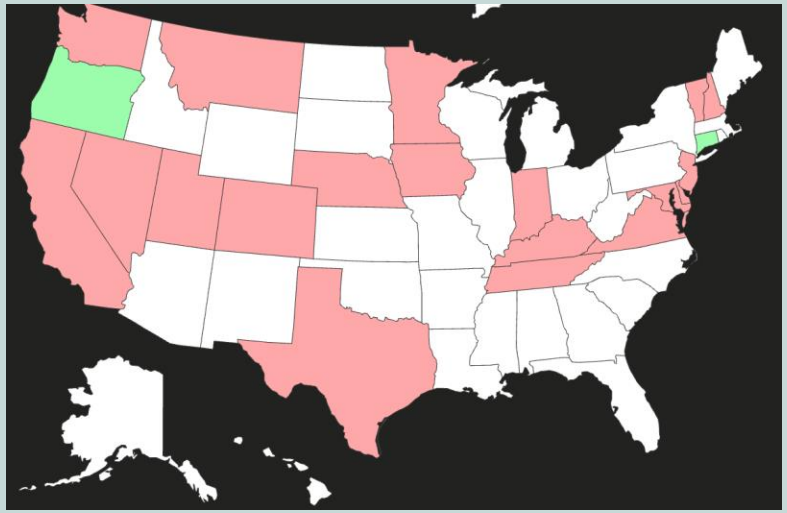
State Privacy Laws

Numerous states have enacted comprehensive and/or consumer health data* privacy laws:

- California
- Colorado
- Connecticut*
- Delaware
- Indiana
- Iowa
- Kentucky
- Maryland
- Minnesota
- Montana
- Nebraska
- *Nevada
- New Hampshire
- New Jersey
- Vermont
- Virginia
- Washington
- *Oregon
- Tennessee
- Texas
- Utah



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California Consumer Privacy Act/Privacy Rights Act

- Applies to Californian's personal information
- Requires businesses to inform consumers about categories of personal information collected and the purpose, including if it will be "sold" or "shared" through a privacy notice
- No uses "incompatible with the disclosed purpose" without notice -- this applies to first-party collection and use, not just shared/sold data
- If personal information is sold or shared*, must offer opt-out rights to Californians

(California Civil Code Title 1.81.5 California Consumer Privacy Act 1798.100-1798.199.100)

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Key Terms

Sold means...

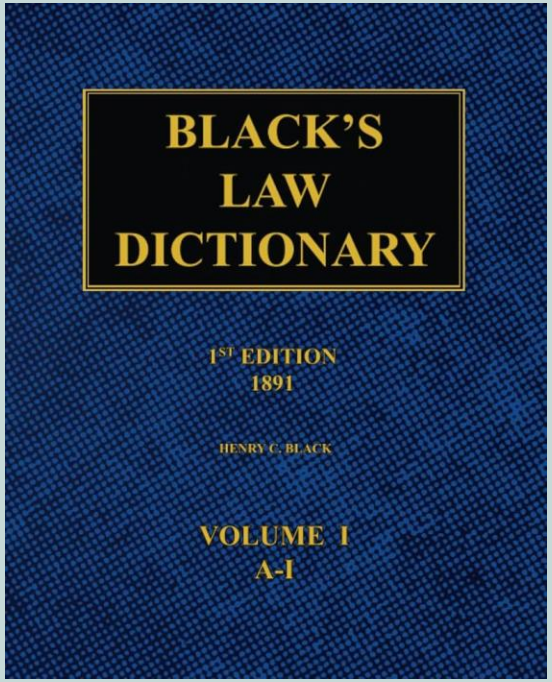
- [providing personal information] **to a third party for monetary or other valuable consideration**

Shared means...

- [providing personal information] to a third party for **cross-context behavioral advertising, whether or not for monetary or other valuable consideration**, including transactions between a business and a third party for cross-context behavioral advertising for the benefit of a business in which no money is exchanged

Cross-context behavioral advertising means...

- the targeting of advertising to a consumer based on the consumer's personal information obtained from the consumer's activity across businesses, distinctly branded internet websites, applications, or services, **other than the business, distinctly branded internet website, application, or service with which the consumer intentionally interacts**



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Colorado Privacy Act (CPA)

- Right to opt out applies to targeted advertising and sales of personal information:
  - "Targeted advertising means displaying to a consumer an advertisement that is selected based on personal data obtained or inferred over time from the consumer's activities across nonaffiliated websites, applications, or online services to predict consumer preferences or interests”
  - ”Sale” is worded nearly identically to CCPA
  - Regulations require honoring of “Universal Opt-Out Mechanism” (e.g., Global Privacy Control signal) much like CCPA regulations

Texas Data Privacy and Security Act (TDPSA)

- Right to opt-out applies to targeted advertising and sales of personal information:
  - "Targeted advertising means displaying to a consumer an advertisement that is selected based on personal data obtained or inferred over time from the consumer's activities across nonaffiliated websites, applications, or online services to predict the consumer's preferences or interests"
  - "Sale" is worded nearly identically to CCPA/CPA
  - Regulations require honoring of "Universal Opt-Out Mechanism" (e.g., Global Privacy Control signal) much like CCPA regulations

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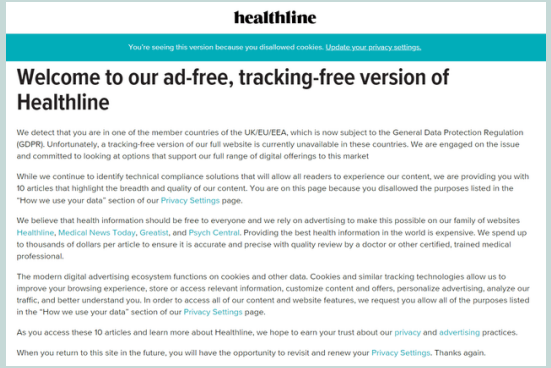
Healthline.com (California)

- CA attorney general announced settlement July 1, 2025 resolving allegations that use of online tracking technology violated CCPA
- Key issues identified:
  - Failure to allow consumers to opt-out of targeted advertising
  - Shared data with third parties without CCPA-mandated privacy protections (including data indicating consumer may have specific diagnoses such as article titles intended for individuals with specific conditions)
- The Healthline website featured a consent banner and a “Do Not Sell Or Share My Personal Information” that did not actually disable tracking cookies



healthline

You're seeing this version because you disallowed cookies. Update your privacy settings.

Welcome to our ad-free, tracking-free version of Healthline

We detect that you are in one of the member countries of the UK/EU/EEA, which is now subject to the General Data Protection Regulation (GDPR). Unfortunately, a tracking-free version of our full website is currently unavailable in these countries. We are engaged on the issue and committed to looking at options that support our full range of digital offerings to this market

While we continue to identify technical compliance solutions that will allow all readers to experience our content, we are providing you with 10 articles that highlight the breadth and quality of our content. You are on this page because you disallowed the purposes listed in the "How we use your data" section of our Privacy Settings page.

We believe that health information should be free to everyone and we rely on advertising to make this possible on our family of websites Healthline, Medical News Today, Greatist, and Psych Central. Providing the best health information in the world is expensive. We spend up to thousands of dollars per article to ensure it is accurate and precise with quality review by a doctor or other certified, trained medical professional.

The modern digital advertising ecosystem functions on cookies and other data. Cookies and similar tracking technologies allow us to improve your browsing experience, store or access relevant information, customize content and offers, personalize advertising, analyze our traffic, and better understand you. In order to access all of our content and website features, we request you allow all of the purposes listed in the "How we use your data" section of our Privacy Settings page.

As you access these 10 articles and learn more about Healthline, we hope to earn your trust about our privacy and advertising practices.

When you return to this site in the future, you will have the opportunity to revisit and renew your Privacy Settings. Thanks again.

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Healthline.com (California)

- Quotes from the California AG complaint:
  - "[Healthline.com] included titles like "The Ultimate Guide to MS for the Newly Diagnosed" and "Newly Diagnosed with HIV? Important Things to Know." As result, Healthline was sharing with third parties article titles strongly suggesting a current diagnosis that data brokers could add, and indeed may have added, to a consumer profile."
  - "[…] Healthline shared data of a potentially highly intimate nature—article titles suggesting a possible medical diagnosis—with unseen advertisers and their vendors. And even if Healthline's privacy policy discussed targeted advertising briefly, it never mentioned sharing article titles. Nor would consumers see those titles being shared in the digital background. Healthline therefore could not establish that consumers reasonably expected that Healthline would share potentially health-related data, as the purpose limitation principle requires."

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BetterHelp

- Federal Trade Commission (FTC) Act, 15 U.S.C. § 45 prohibits "unfair and deceptive acts or practices", which FTC relies on for data privacy and security enforcement actions

- July 14, 2023:

> FTC Gives Final Approval to Order Banning BetterHelp from Sharing Sensitive Health Data for Advertising, Requiring It to Pay $7.8 Million
>
> FTC alleges online counseling service shared consumers' sensitive data with third parties after promising to keep it private

BetterHelp

FTC alleged in its complaint that the company, which offers online mental health services:

> [r]epeatedly promised to keep [health information] private and use it only for non-advertising purposes such as to facilitate consumers' therapy [and] continually broke these privacy promises, monetizing consumers' health information to target them and others with advertisements for the Service. For example, from 2018 to 2020, Respondent used these consumers' email addresses and the fact that they had previously been in therapy to instruct Facebook to identify similar consumers and target them with advertisements for the Service.

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United States v. Monument Health

- Federal Trade Commission enforcement action against alcohol addiction treatment company Monument for allegedly sharing sensitive health data with advertising tech companies without consent.

- "According to the complaint, the company contradicted its privacy promises. From 2020-2022, the company allegedly disclosed users' personal information, including their health information, to numerous third-party advertising platforms via tracking technologies, known as pixels and application programming interfaces (APIs), which Monument integrated into its website. Monument used the information to target ads for its services to both current users who subscribe to the lowest cost memberships and to target new consumers [...]."

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United States v. Monument Health

- "Monument used these pixels and APIs to track "standard" and "custom events," meaning instances in which consumers interacted with Monument's website.

- "[...] Monument gave the custom events descriptive titles that revealed details about its users such as "Paid: Weekly Therapy" or "Paid: Med Management," when a user signed up for a service.

- "Monument disclosed this custom events information to advertising platforms along with users' email addresses, IP addresses, and other identifiers, which enabled third parties to identify the users and associate the custom events with specific individuals [...]

Solara Medical Supplies

HHS Office for Civil Rights Settles HIPAA Phishing Cybersecurity Investigation with Solara Medical Supplies, LLC for $3,000,000

- Jan 14, 2025
- Diabetes medical supplier, distributor (CGM, insulin pumps, etc.)
- ePHI exposed in phishing incident impacting 114,007 individuals
- Breach notification letters were misdirected resulting in additional breach
- Resolution agreement resulted in monitoring for 2 years and $3m settlement
- Cited failure to conduct security risk analysis for ePHI, inadequate security measures, and failure to timely notify individuals/HHS/media

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FTC: United States v Cerebral, Inc.

- April 15, 2024: FTC order restricting use and disclosure of sensitive data plus $7m penalty

> "As the Commission's complaint lays out, Cerebral violated its customers' privacy by revealing their most sensitive mental health conditions across the Internet and in the mail," said FTC Chair Lina M. Khan. "To address this betrayal, the Commission is ordering a first-of-its-kind prohibition that bans Cerebral from using any health information for most advertising purposes."

Cerebral

- FTC complaint alleged privacy violations through use of tracking tools on company websites and apps that shared sensitive customer information with Snapchat, LinkedIn, and TikTok (plus cancelation policy issues)
- Sensitive information included names, medical/Rx history, demographics, pharmacy and health insurance information, among other health info on nearly 3.2 million consumers

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Shah v. Capital One Financial Corporation (March 3, 2025)

- Class brought action for alleged violation of CCPA, claiming unauthorized disclosure of personal information through trackers qualifies as a personal information breach
- Cal. Civ. Code § 1798.150(a)(1) says private right of action is available to any "consumer whose nonencrypted and nonredacted personal information . . . is subject to an unauthorized access and exfiltration, theft, or disclosure as a result of the business's violation of the duty to implement and maintain reasonable security procedures and practices appropriate to the nature of the information."
- Court rejected Capital One's motion to dismiss; a traditional "data breach" was determined not necessary for there to be an "unauthorized disclosure" of personal information under the statute

Shah v. Capital One Financial Corp., No. 24 CV 5985, 2025 WL 714252 (N.D. Cal. Mar. 3, 2025)

Illumina, Inc. & FCA Cybersecurity Initiative

- $9.8 million settlement
- The DOJ alleged Illumina:
  - Failed to incorporate cybersecurity into the design, development, installation, and marketing of software-enabled medical devices;
  - Did not adequately support product security teams or correct known vulnerabilities; and
  - Misrepresented compliance with FDA cybersecurity requirements over a seven-year period (2016–2023).
- The complaint did not allege any confirmed cybersecurity breach or patient harm. Instead, the government's theory of liability was based on misrepresentations—or omissions—regarding compliance with cybersecurity standards that were deemed material to federal reimbursement. *See United States ex rel. Lenore v. Illumina Inc., 1:23-cv-00372 (D.R.I.)*.

illumina

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The new EU Data Act

A Gamechanger for the MedTech Industry?

6 November, 2025

Oliver Süme

Data Act - Brief overview

Very broad scope, especially **products** in the **IoT (Internet of Things)** sector, smart devices and related **services** (e.g. connectable apps)

Application begins **from 12 September 2025**

The **market location** principle applies

- The decisive factor is the **placing on the market** of the product / **providing** the service **in the EU**
- The registered office of a company is irrelevant!

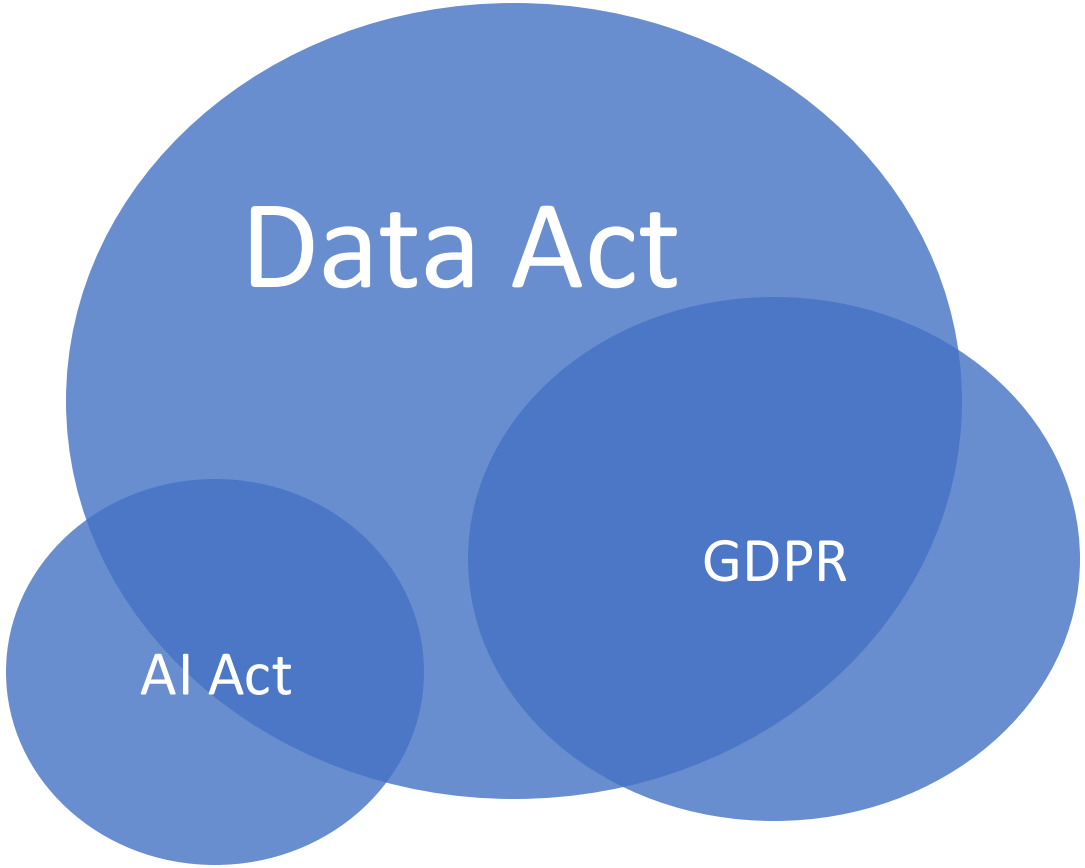
Data Act - Brief overview

The Data Act applies to **B2B** and **B2C**

The Data Act **complements the GDPR**

The GDPR has priority for personal data (machine-generated data can also include personal data!)

The European **AI Act** might kick in as well, e.g. for smart medical devices containing AI components



What does the Data Act apply to?

The Data Act applies to...

Connected product: Item,

- **that obtains, generates or collects data concerning its use or its environment**
- **and** is **able to communicate** product data via an electronic communication service, physical connection or on-device access [...]
  - ➢ Medical devices, vehicles, game consoles, smart home devices, elevators, fitness trackers

Related service: digital service, including software, which is **connected with the product** at the time of purchase, rent or lease **in such a way that** its **absence would prevent the connected product from performing** one or more of **its functions** (including additions to the product)

- ➢ Software and updates, navigation services, cloud-based smart TV platforms, building software

Adressees of the Data Act

Data Holder	Natural or legal person that has the right or obligation to use and make available data, including product data or related service data which it has retrieved or generated during the provision of a related service
User	Natural or legal person who buys, rents, leases or uses a connected product
Data Recipient	Natural or legal person, acting for purposes which are related to that person's trade, business, craft or profession, to whom the data holder makes data available, including a third party following a request by the user to the data holder

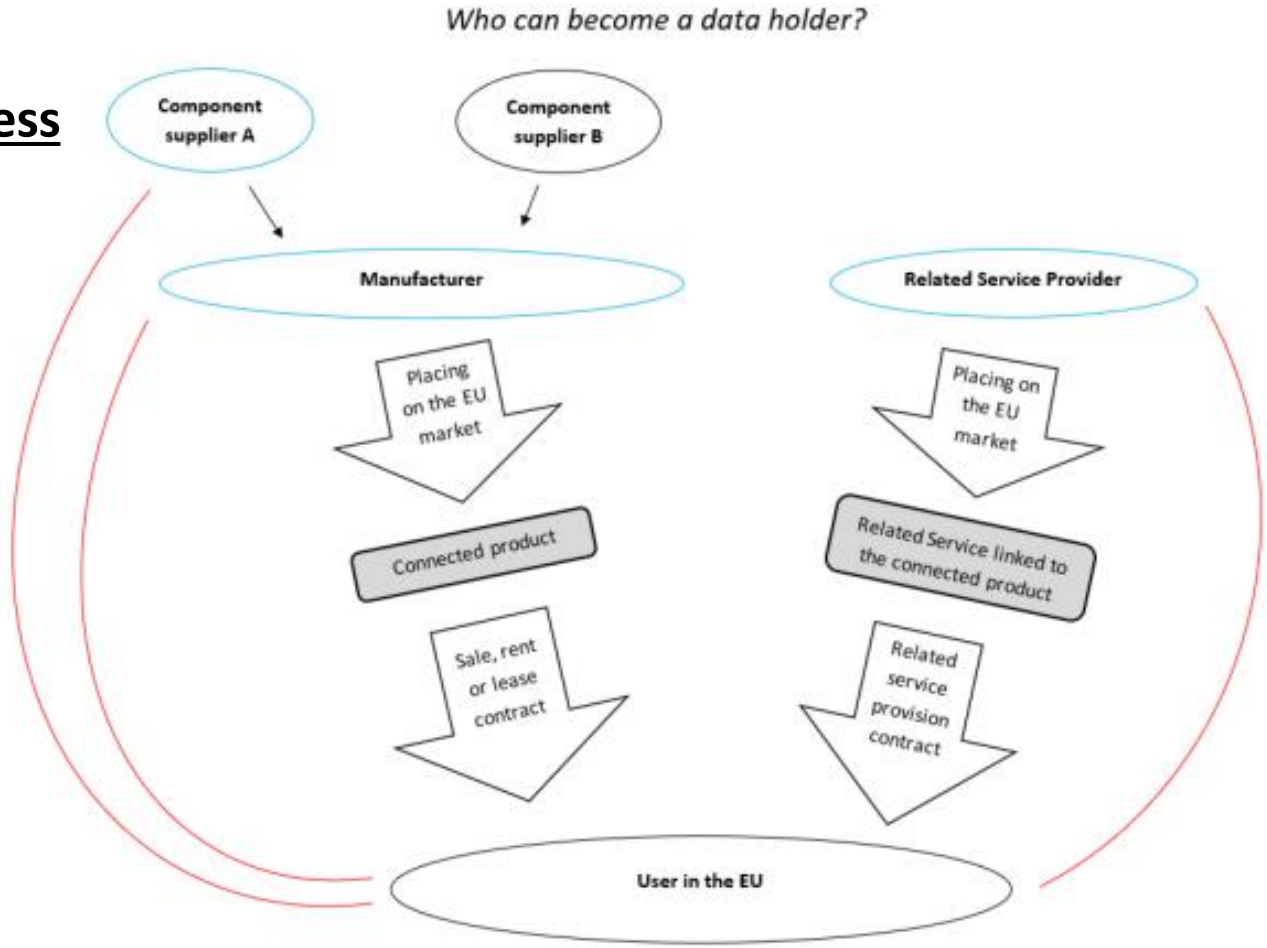
What is „Data“ under the Data Act

Data	Any digital representation of acts, facts or information and any compilation, including in the form of sound, visual or audio-visual recording
Metadata	Structured description of the contents or the use of data facilitating the discovery or use of that data
Product Data	Data generated by the use of a connected product that the manufacturer designed to be retrievable, via an electronic communications service, physical connection or on-device access, by a user, data holder or a third party
Related Service Data	Data representing the digitisation of user actions or of events related to the connected product
Readily Available Data	Product data and related service data that a data holder lawfully obtains or can lawfully obtain from the connected product or related service, without disproportionate effort

Whom does the Data Act apply to?

Data holder =
natural/legal **person who <u>controls access</u> to the** readily available **data**

- Medical device manufacturer



Source: The FAQs on the Data Act answered by the EU-Commission

How can you use product data?

Spotlight:

- As a data holder, how can I use product data myself?

How can you use product data?

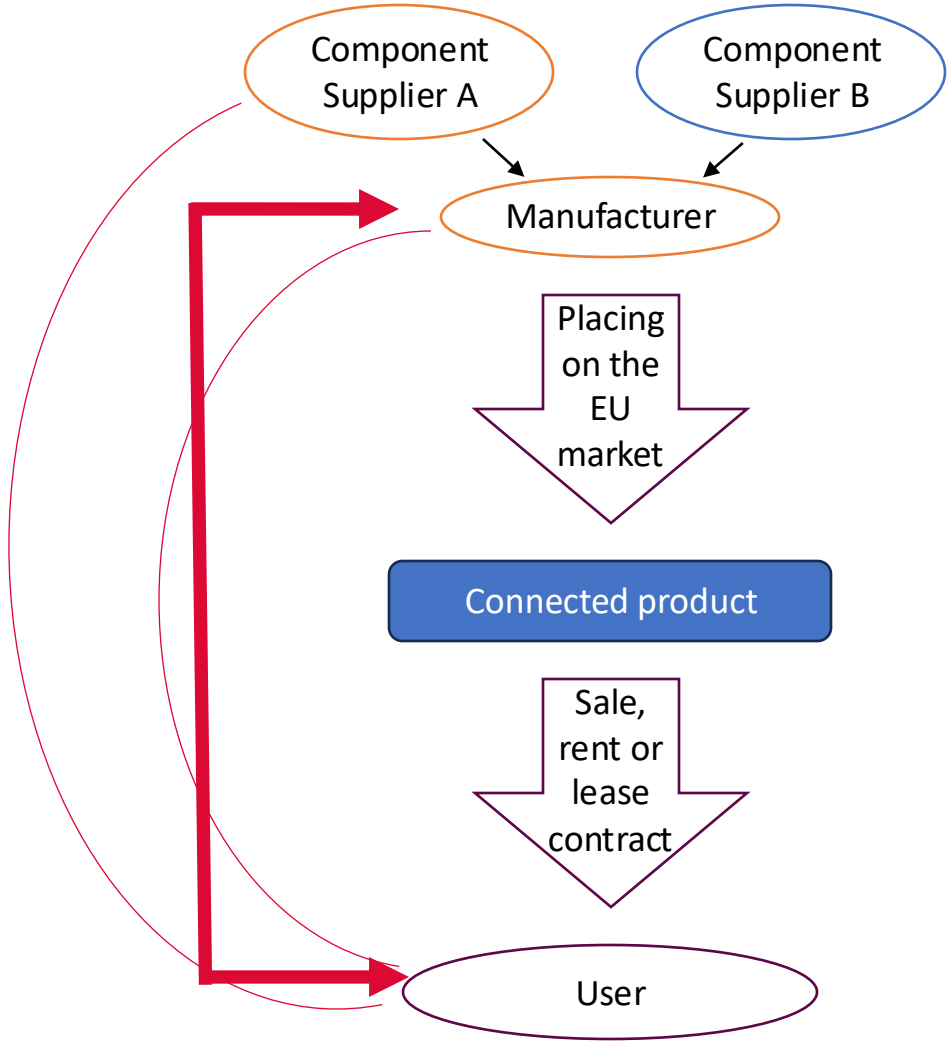
Article 4 (13) Data Act

*"(13) **A data holder shall only use** any readily available data that is **non-personal data** **on the basis of a contract** **with the user."***

How can you use product data?

Explicit grant of a **right of use** upon conclusion of the contract!

- Who wants to use it? Group, R&D?
- For what purposes?
- Disclosure to third parties (also within the Group)?
- How long?
- Exclusive?
- Remuneration to users?



To whom do I have to disclose product data?

Article 5

Right of the user to share data with third parties

1. Upon request by a user, or by a party acting on behalf of a user, the data holder shall make available readily available data, as well as the relevant metadata necessary to interpret and use those data, to a third party without undue delay, of the same quality as is available to the data holder, easily, securely, free of charge to the user, in a comprehensive, structured, commonly used and machine-readable format and, where relevant and technically feasible, continuously and in real-time. The data shall be made available by the data holder to the third party in accordance with Articles 8 and 9.

To whom do I have to make product data available?

The right to data access - "Access by design„

- Connected products and related services must be designed and manufactured in such a way that the **data is directly or at least indirectly accessible to the user.**
- If the user cannot access the data directly, the data must be made available **without undue delay** and in the same quality as it is available to the data holder.
- The user must receive **certain information before concluding the contract**, including whether the data holder intends to use the data for its own purposes and whether he intends to pass it on to third parties.

To whom do I have to disclose product data?

The right to data access

- The data must be made available **to a third party** at the request of a user

- The data holder and the data recipient must enter into a **fair, reasonable, non-discriminatory and transparent agreement**
  - EU Commission will publish proposals for contract clauses in summer 2025

- The data holder must take appropriate **technical security precautions** against unauthorized use or disclosure of data and trade secrets (e.g. smart contracts and encryption)
  - (Rare) possibility for a "Trade Secret Handbrake" and "Safety and Security Handbreak" to object to data disclosure request

Next Steps?

- Product assessment: Which (smart) products and related services fall under the scope of the Data Act?

- Review or adjustment of relevant contracts with regard to the new user rights and data sharing obligations

- Protection of trade secrets and intellectual property
- Labeling of data
- Introduction of specific TOMs

- Access by design
- Ensure that data is directly accessible or can be made available at any time

- Provision of comprehensive information about the networked products before the contract is concluded

Questions

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U.S & EU Regulatory Update

Nathan Downing & Dr. Cord Willhöft

Thursday, November 6, 2025

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Presenter Information

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Charting A Path Forward

- FDA During the Shutdown
- Recent FDA Activity
- Looking Ahead
- Navigating the Future

Government Shutdown

- High-Level FDA Considerations
- CDRH
  - Impacts on Current Work
  - Impacts on Pending Submissions
- CDER
  - NDAs Under Review
  - Future Submissions
- How to Mitigate Industry Disruptions

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Recent FDA Activity

- Ad Promo Considerations
  - Untitled Letters
  - HHS Communications
- Product Review Impacts
- Inspections
- Other Initiatives

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Looking Ahead

- Digital Health Advisory Committee Meets Today
- FDA Announced Proposed Guidances for FY2026
- MDUFA Talks
- Ensuring Patient Access to Critical Breakthrough Products Act

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Navigating FDA

Mindful Planning

Pre-submissions and Other Touchpoints

Industry Working Groups

Partnership

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In Closing

CURRENT ISSUES AT FDA IMPACT INDUSTRY

MITIGATION IS POSSIBLE

BE READY TO ASSERT YOUR RIGHTS

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Regulatory Update EU / Germany

Dr Cord Willhöft, LL.M.

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Agenda: Regulatory Update EU

I. **Medical Device Software (MDSW) + AI:**
   1. Reimbursement: A Momentum in Europe for Digital Health Applications
   2. MDSW: Regulatory headwinds through EU MDR and AIA?
   3. AIA: What does this mean for your QMS?

II. **Other Regulatory Updates**
   1. Notification Requirements for Manufacturers
   2. MDR / IVDR Revision
   3. EUDAMED
   4. Joint HTA for Medical Devices
   5. eIFU

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I. Digital Health Applications: Reimbursement

- Momentum is building up in Europe for Digital Health Applications (Medical Apps; MedTech Europe Facts & Figures 2025)
- The two largest Europea healthcare markets France and Germany established reimbursement frameworks for medical apps
- Germany remains benchmark for digital health integration through its DiGA (*Digitale Gesundheitsanwendungen*) reimbursement framework
  - German *Digitale-Versorgungs-Gesetz* (DVG)
  - 73 DiGAs are currently listed in the BfArM DiGA Registry (= reimbursement in the SHI system)

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I. Digital Health Applications: Regulatory Headwind (1)?

- A minor but relevant change through the EU MDR Annex VIII Chapter III:

> 6.3. Rule 11
>
> Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause:

- Consequence:
  - All MDSW is to be classified as – at least – class IIa
  - EU MDR conformity assessment procedures of medical devices class IIa require the involvement of a notified body, incl. review of TD and certification of QMS:

"*Manufacturers of devices (…) shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation*" (Article 10 [9] EU MDR)

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I. Digital Health Applications: Regulatory Headwind (2)?

- **Article 10 (9) EU MDR:**

  "Manufacturers of devices (…) shall establish, document, implement, maintain, keep up to date and continually improve a quality management system that shall ensure compliance with this Regulation " (Article 10 [9] EU MDR)

  ⇒ Common practice: DIN ISO 13485:2016 (harmonised standard for QMS since 2022)

2017/745	CEN	EN ISO 13485:2016, EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)	05/01/2022	OJ L 1 - 05/01/2022

- Article 17 (1) EU AIA

  "Providers of high-risk AI systems shall put a quality management system in place that ensures compliance with this Regulation. That system shall be documented in a systematic and orderly manner in the form of written policies, procedures and instructions,…"

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I. Digital Health Applications: Regulatory Headwind (3)?

- **MDCG 2025-6 Interplay between MDR &IVDR and AIA (June 2025):**

  "To (…) avoid unnecessary administrative burden, manufacturers of AI systems may include the elements of the quality management system provided by the AIA as part of the existing quality management system provided by the MDR and IVDR."

  ⇒ Confirmed by Recital 81 AIA, and Article 17 (3) AIA

- Therefore, "only" additional requirements such as data and data governance, record-keeping, transparency, human oversight must be integrated into the existing MDR/IVDR QMS by MDSW manufacturers.

I. Digital Health Applications: Regulatory Headwind (3)?

- **MDCG 2025-6 Interplay between MDR and IVDR and AIA (June 2025):**

  "To (…) avoid unnecessary administrative burden, manufacturers of AI systems may include the elements of the quality management system provided by the AIA as part of the existing quality management system provided by the MDR and IVDR."

  ⇒ Confirmed by Recital 81 AIA, and Article 17 (3) AIA

- Therefore, "only" additional requirements such as data and data governance, record-keeping, transparency, human oversight must be integrated into the existing MDR/IVDR QMS by MDSW manufacturers.

II. Regulatory Updates EU (1)

New Information/Notification Requirements for Manufacturers (January 2025):

⇒ If manufacturer anticipate interruption of the supply of a device, and

⇒ Interruption could result in serious harm to patients/public health,

⇒ Manufacturer shall inform the competent authority where its/EU AR is established

⇒ Deadline: 6 months in advance (if no exceptional circumstances)

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II. Regulatory Updates EU (2)

MDR / IVDR Revision

⇒ EP Resolution for urgent revision of MDR / IVDR (October 2024)

⇒ Risk of shortages of medical devices HTA for Medical Devices, due to the regulatory burdens & bottleneck (NB) to comply with MDR / IVDR

⇒ Transitional Periods for legacy devices December 31 2027 for class III, or IIb Implantable device, and December 2028 for class IIb (excl. implants), or class IIa.

AdvaMed: *"manufacturers still face unpredictable timelines and costs in securing device certification in the EU. Different interpretations and implementation of regulations by different NBs have led to inconsistent outcomes for similar products. A lack of publicly available performance data from NBs, as well as clear timelines and costs, makes it difficult for companies to make informed decisions."*

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II. Regulatory Updates EU (3)

Electronic Instructions for Use

⇒ Use of eIFU extended to all medical devices intended to be used by professional users (September 2025)

⇒ Formerly only allowed for: (i) implantable and active implantable medical devices, (ii) fixed installed medical devices, and (iii) medical devices fitted with a built-in system visually displaying the instructions for use.

⇒ If an eIFU is provided, it must be available on the manufacturer's website

⇒ MedTech Europe: Call to extend eIFUs also to lay-person devices

⇒ Major step toward digitalization and environmental protection (will save an average of around 500 tons of paper per company per year)

Questions

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General Counsel Roundtable

Moderated by Mark Gardner, with Mike Pisetsky, Darci Teobaldi, and Bernard Shay

Thursday, November 6, 2025

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Moderator Introduction

Mark Gardner
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Mark founded Gardner Law, specializing in FDA regulatory, compliance, and privacy matters. Leveraging extensive in-house and private practice experience since 1999, including roles with major healthcare companies, Mark helps clients manage complex FDA issues, regulatory due diligence, sales and marketing compliance, transparency reporting, and internal audits and investigations.

He regularly interacts with FDA, CMS, OCR, DOJ, and OIG officials and teaches at Mitchell Hamline School of Law, University of Minnesota Law School, and Carlson School of Management.

Panelist Information

Mike Pisetsky
Chief Business & Legal Affairs Officer

SI-BONE®

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Recor Medical™

Bernie Shay
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Thank You

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