

Data Ownership & Data Access

Changing Rules

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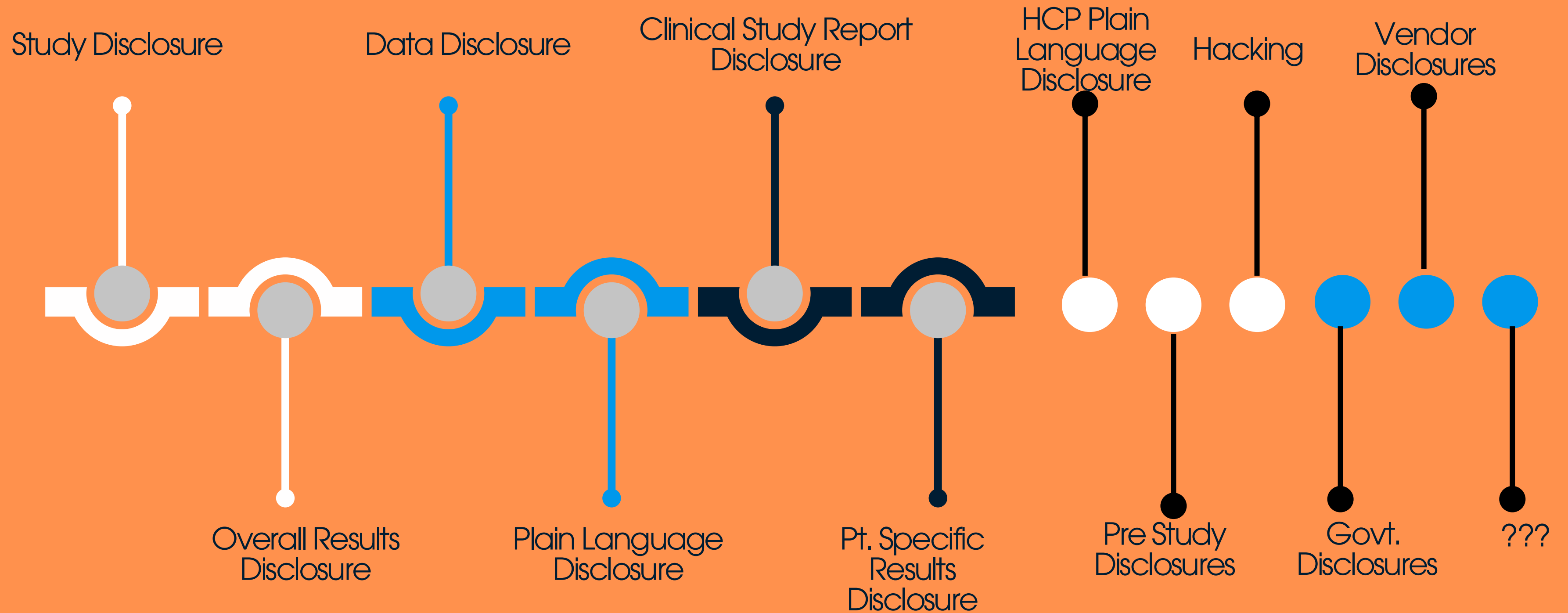
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2026



Cyber security



The HIPAA Journal is the
regulatory update

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Iran Linked Hacking Group Wipes Data of U.S. Medical Device Manufacturer

Posted By [Steve Alder](#) on Mar 12, 2026

Stryker, a U.S. medical device and medical equipment manufacturer based in Portage, Michigan, is dealing with a cyberattack linked to the current U.S. military action in Iran. The cyberattack started shortly after midnight and has caused an outage of systems across the organization. An Iran-linked hacking group has claimed responsibility for the attack.

Stryker has operations in 61 countries and has a global workforce of more than 56,000 employees. Stryker said in a filing with the U.S. Securities and Exchange Commission (SEC) that the attack has and is expected to continue to cause "disruptions and limitations of access to certain of the Company's information systems and business applications." Stryker is currently unable to provide a timeline for when systems and data will be recovered and when normal operations will resume.

This does not appear to have been a ransomware attack, but rather a data theft and wiping attack. The attack affected Stryker's Microsoft programs, including the wiping of Windows-based devices such as mobile phones and laptops. Stryker said it has found no indications that ransomware or malware was used, and said it believes it has contained the attack. An investigation has been launched to determine the impact of the attack on its computer systems.

Privacy US Biosecure Act

**Section 851 of the National Defense
Authorization Act (NDAA) for Fiscal Year
2026**

2026

Goals:

1. Prohibit federal “executive agencies” from entering into contracts with companies that use “biotechnology equipment or services” produced or provided by a biotechnology company of concern (BCC) in the performance of contracts with those agencies.
2. “Executive agencies” may not extend loans or grant funds to procure biotechnology equipment or services produced or provided by a BCC.

“biotechnology equipment or services” encompasses any instrument or service in “research, development, production, or analysis” related to “biological materials”

Equipment includes such items as genetic sequencers, or any other instrument, apparatus, machine, or device, including components and accessories, and any software and firmware necessary to operate such equipment.

Services will include data storage and transmission related to biological materials, including “disease detection, genealogical information, and related services” and consulting, advising, and support services related to biotechnology equipment.

Privacy

2026

Privacy

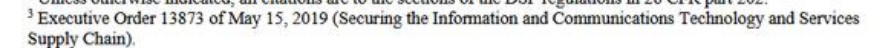
The image features the letters 'DOJ' in a large, bold, orange sans-serif font. The letters are set against a solid dark blue background. The 'D' and 'O' are connected, and the 'J' has a small hook at the bottom. The overall style is clean and modern.The image features the letters 'DOJ' in a large, bold, orange sans-serif font. The letters are set against a solid dark blue background. The 'D' and 'O' are connected, and the 'J' has a small hook at the bottom. The overall style is clean and modern.

Executive Order 14117 of February 28, 2024

By the authority vested in me as President by the Constitution and the laws of the United States of America, including the International Emergency Economic Powers Act (50 U.S.C. 1701 *et seq.*) (IEEPA), the National Emergencies Act (50 U.S.C. 1601 *et seq.*) (NEA), and section 301 of title 3, United States Code,

1. JOSEPH R. BIDEN JR., President of the United States of America, hereby expand the scope of the national emergency declared in [Executive Order 13873](#) of May 15, 2019 (Securing the Information and Communications Technology and Services Supply Chain), and further addressed with additional measures in [Executive Order 14034](#) of June 9, 2021 (Protecting Americans' Sensitive Data from Foreign Adversaries). The continuing effort of certain countries of concern to access Americans' sensitive personal data and United States Government-related data constitutes an unusual and extraordinary threat, which has its source in whole or substantial part outside the United States, to the national security and foreign policy of the United States. Access to Americans' bulk sensitive personal data or United States Government-related data increases the ability of countries of concern to engage in a wide range of malicious activities. Countries of concern can rely on advanced technologies, including artificial intelligence (AI), to analyze and manipulate bulk sensitive personal data to engage in espionage, influence, kinetic, or cyber operations or to identify other potential strategic advantages over the United States. Countries of concern can also use access to bulk data sets to fuel the creation and refinement of AI and other advanced technologies, thereby improving their ability to exploit the

Subpart A General



Privacy

2026

FTC

Data Broker: An entity that, for valuable consideration, sells, licenses, rents, trades, transfers, releases, discloses, provides access to, or otherwise makes available data of United States individuals that the entity did not collect directly from such individuals to another entity that is not acting as a service provider.



Office of the Director
Bureau of Consumer Protection

UNITED STATES OF AMERICA
Federal Trade Commission

February 9, 2026

Via Federal Express

[Name]
[Address]

Re: Protecting Americans' Data from Foreign Adversaries Act of 2024 (PADFAA)

Dear [Name]:

The Federal Trade Commission ("FTC" or "Commission") is a federal agency whose mission is to protect Americans from unfair, deceptive, and anticompetitive business practices, without unduly burdening legitimate business activity. As part of that mission, we work to educate businesses about their rights and responsibilities, and where necessary, initiate investigations and enforcement actions.

I write to you regarding the Protecting Americans' Data from Foreign Adversaries Act of 2024 (PADFAA).¹ The statute went into effect on June 24, 2024, and grants enforcement authority to the Commission. The Commission treats violations of PADFAA as an unfair or deceptive practice under Section 5 of the FTC Act, 15 U.S.C. § 45(a). The FTC has authority under Section 5 of the FTC Act, 15 U.S.C. § 45(a), to investigate unfair or deceptive acts or practices in or affecting commerce.²

In relevant part, PADFAA prohibits data brokers from selling, licensing, renting, trading, transferring, releasing, disclosing, providing access to, or otherwise making available personally identifiable sensitive data of a United States individual to any foreign adversary country or any entity that is controlled by a foreign adversary.³ PADFAA defines a data broker as an entity that, for valuable consideration, sells, licenses, rents, trades, transfers, releases, discloses, provides access to, or otherwise makes available data of United States individuals that the entity did not collect directly from such individuals to another entity that is not acting as a service provider.⁴ The term "sensitive data" includes government-issued identifiers (such as Social

Privacy

2026

FTC



FEDERAL TRADE COMMISSION
PROTECTING AMERICA'S CONSUMERS

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Business Blog

Updated FTC Health Breach Notification Rule puts new provisions in place to protect users of health apps and devices

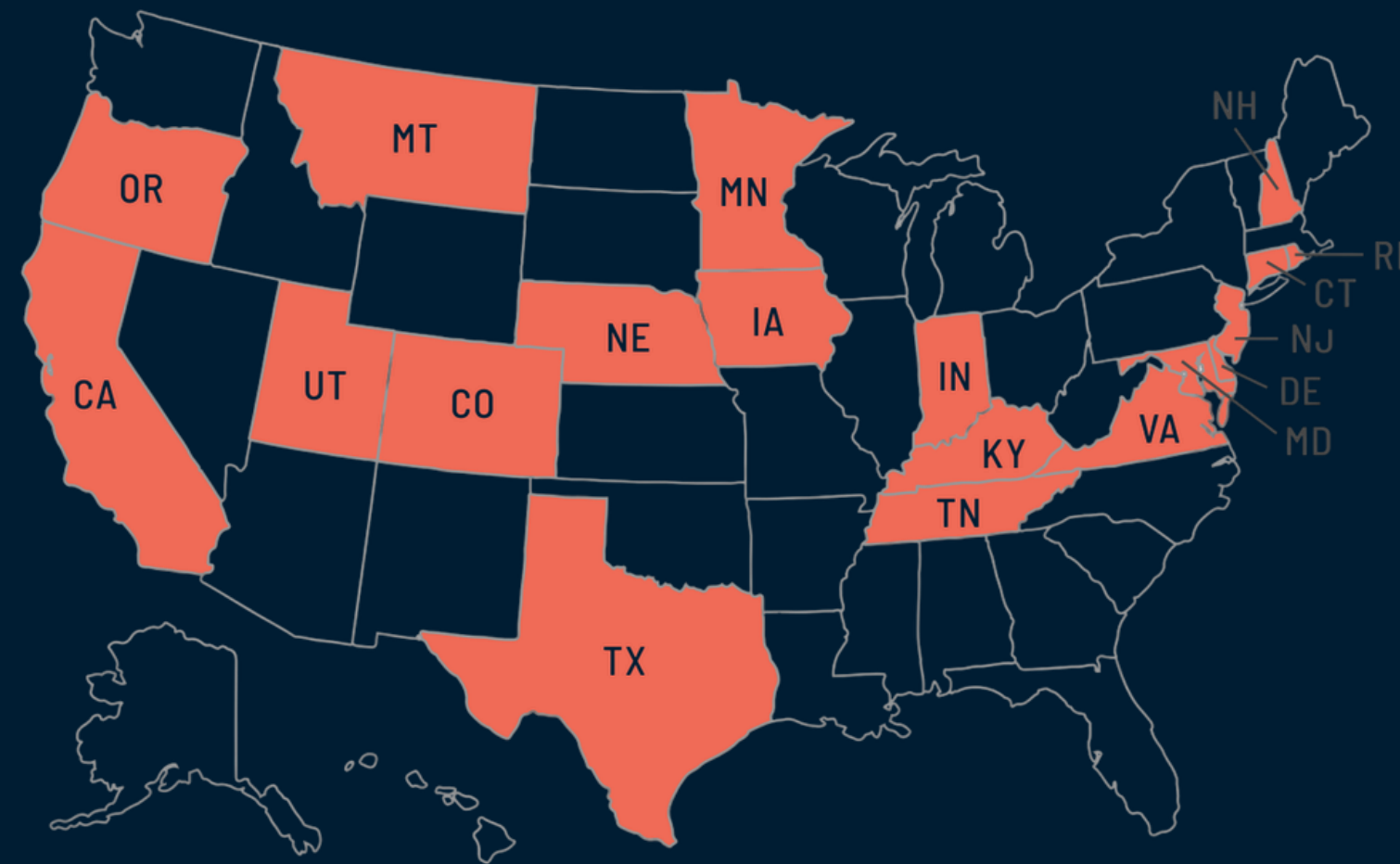
By: Lesley Fair | April 26, 2024 |   

Privacy

2026

States

with comprehensive data protection laws



Privacy

2026

States



- Covers data “collected, derived, or inferred,” including metrics from wearables.
- Requires opt-in consent and bans geofencing near reproductive health facilities (1,750 feet).

Privacy

2026

States



- Classifies wearable-derived metrics (e.g., heart rate, skin temperature, sleep) as “sensitive personal information.”
- Grants consumers the right to opt out of sale or use and mandates data protection impact assessments (DPIAs).

Privacy

2026

States



- Covers biometric identifiers and physical health indicators.
- Entities must offer opt-out rights and adhere to purpose limitation and data minimization.

Privacy

2026

States

- Targets precise geolocation and biometric data, including data collected passively by connected devices.
- No cure period for violations—raising litigation risk for platform providers and developers.



Artificial Intelligence

- **California**
- **Colorado**
- **New York**
- **Utah**
- **Texas**
- **Federal Preemption**

Artificial Intelligence

2026

States

- Effective Jan 1, 2026

AI developers must publicly disclose detailed information regarding the data used to train their systems, including sources and whether copyrighted material was used.



Artificial Intelligence

2026

States



- Effective June 30, 2026
- Applies to AI that makes or significantly influences consequential decisions including "employment ... healthcare, ... insurance."
- Risk Management: Developers must conduct annual assessments to identify and mitigate "algorithmic discrimination".
- Transparency: Deployers must inform consumers when they are interacting with AI.

Artificial Intelligence

2026

States



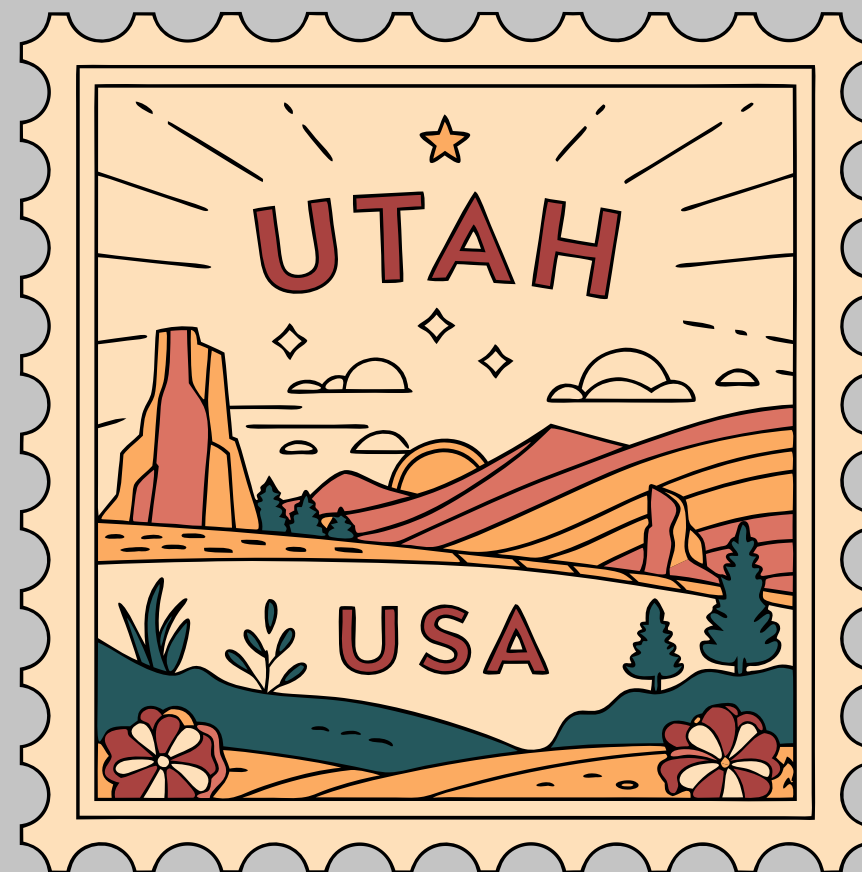
- [Responsible AI Safety and Education Act](#)
- Effective January 1, 2027
- Targeted Developers: "large developers" with over \$500 million in revenue or those spending over \$100 million on computational resources to train models.
- Penalties: Fines for violations can reach up to \$3 million for repeat offenses.

Artificial Intelligence

2026

States

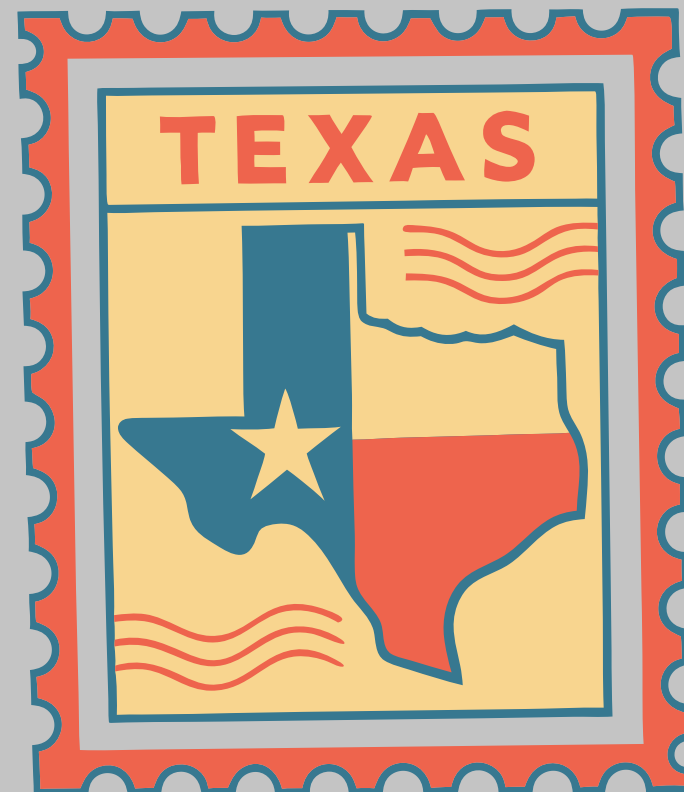
- [Utah AI Policy Act](#)
- Effective date: 1 May 2024
- Regulated Occupations:
Professionals in fields requiring state licenses (e.g., medicine, law, accounting) must proactively disclose when a consumer is interacting with GenAI.



Artificial Intelligence

2026

States



- [Texas Responsible Artificial Intelligence Governance Act](#)
- Effective date: 1 January 2026
- Prohibited AI Practices: The law bans developing or deploying AI with the intent to:
 - Unlawfully discriminate against protected classes (disparate impact alone is not enough; proof of intent is required).

Artificial Intelligence

2026

Federal

State Laws Preempted

“Within 90 days of the date of this order, the Chairman of the Federal Trade Commission shall, in consultation with the Special Advisor for AI and Crypto, issue a policy statement on the application of the Federal Trade Commission Act’s prohibition on unfair and deceptive acts or practices under 15 U.S.C. 45 to AI models. That policy statement must explain the circumstances under which State laws that require alterations to the truthful outputs of AI models are preempted by the Federal Trade Commission Act’s prohibition on engaging in deceptive acts or practices affecting commerce.”



PRESIDENTIAL ACTIONS

ENSURING A NATIONAL POLICY FRAMEWORK FOR ARTIFICIAL INTELLIGENCE

Executive Orders | December 11, 2025

Artificial Intelligence EU AI Act 2026

- Mandatory Explainability: AI systems must be designed so their decision-making processes (e.g. patient stratification or endpoint analysis) are explainable to both healthcare professionals and patients.
- Technical Documentation & Traceability: Sponsors must maintain detailed logs and technical files documenting model architecture, training methodologies, and data processing pipelines. These often become part of the Clinical Trial Application (CTA) dossier.
- Explicit Data Disclosure: High-risk systems require clear instructions for use, including disclosures about the provider, the AI's capabilities and limitations, and potential risks.
- Bias Reporting: To ensure trial integrity, sponsors must document measures taken to mitigate biases that could skew patient selection or data interpretation, particularly for marginalized groups.

Full Enforcement	August 1, 2026 (post-entry)
High-Risk Medical AI	August 1, 2026 (post-entry)

**The PI and Site Owner
are currently separating.
Who does data
collected belong to?**

**Do sites have the right to
sell the data they
acquired as part of a
clinical trial?**

Fact Pattern

You are the sponsor of a multi-center, multi national study. Your study sites have begun using AI for a variety of tasks including identifying potential subjects, writing out synopses for Adverse Events and other uses. What, if anything, are you concerned about?

Privacy

On-Sale Bar

Publication

Confidentiality

Artificial Intelligence

2026

On Sale Bar

On-Sale Bar

Helsinn Healthcare S. A. v. Teva Pharmaceuticals USA, Inc., 586 U.S. __ (2019)

Docket No.

17-1229

Granted:

June 25, 2018

Argued:

December 4, 2018

Decided:

January 22, 2019

Justia Summary

Helsinn makes a treatment for chemotherapy-induced nausea using the chemical palonosetron. While developing that product, Helsinn granted another company the right to market a 0.25 mg dose of palonosetron in the United States; that company was required to keep proprietary information confidential. Nearly two years later, in 2003, Helsinn filed a provisional patent application covering a 0.25 mg dose of palonosetron. Helsinn filed four patent applications that claimed priority to the 2003 date. Helsinn's fourth application, filed in 2013 (the 219 patent), is covered by the Leahy-Smith America Invents Act (AIA). In 2011, Teva sought approval to market a generic 0.25 mg palonosetron product. Helsinn sued for infringement. Teva countered that the 219 patent was invalid under the "on sale" provision of the AIA, which precludes a person from obtaining a patent on an invention that was "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention," 35 U.S.C. 102(a)(1), arguing the 0.25 mg dose was "on sale" more than one year before Helsinn filed the 2003 application.

[Read More](#) ▾

"sale" of an invention, even if confidential, starts the one-year clock for filing a patent

**Do physicians have
the right to publish
data from
multi-center studies
they participated in
(nothing in the CTA)?**

**Do physicians have
the right to share data
from patients they
treat?**

Artificial Intelligence

2026

Publication Bar

Publication Bar

Case: 21-1888 Document: 68 Page: 1 Filed: 06/23/2022

United States Court of Appeals
for the Federal Circuit

CENTRIPETAL NETWORKS, INC.,
Plaintiff-Appellee

v.

CISCO SYSTEMS, INC.,
Defendant-Appellant

2021-1888

Appeal from the United States District Court for the
Eastern District of Virginia in No. 2:18-cv-00094-HCM-
LRL, Senior Judge Henry C. Morgan, Jr.

Decided: June 23, 2022

PAUL J. ANDRE, Kramer Levin Naftalis & Frankel LLP,
Menlo Park, CA, argued for plaintiff-appellee. Also repre-
sented by JAMES R. HANNAH, LISA KOBIALKA, HANNAH
YUNKYUNG LEE; CHRISTOPHER COTROPIA, Bey & Cotropia
PLLC, Richmond, VA; ALAN J. HEINRICH, ANDREI IANCU,
Irell & Manella LLP, Los Angeles, CA; PHILIP J. WARRICK,
Washington, DC; BLAIR A. SILVER, Banner & Witcoff, Ltd.,
Washington, DC.

MARK CHRISTOPHER FLEMING, Wilmer Cutler Pickering
Hale and Dorr LLP, Boston, MA, argued for defendant-ap-
pellant. Also represented by SOFIA CAROLINE BROOKS, I,
ANNALEIGH E. CURTIS, WILLIAM F. LEE, COURTNEY C.

Do materials related to Centripetal's RuleGATE product and early documents constitute a public publication bar?

Confidentiality

Confidentiality

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Case Law

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Oral Arguments

Judges

Financial Disclosures

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United States *v.* HEPPNER (1:25-cr-00503)

District Court, S.D. New York

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Last Updated: March 12, 2026, 3:07 p.m.

Assigned To: [Jed Saul Rakoff](#)

Citation: United States v. HEPPNER, 1:25-cr-00503, (S.D.N.Y.)

Date Filed: Oct. 28, 2025

Date of Last Known Filing: March 12, 2026

DOCKET ENTRIES

PARTIES AND ATTORNEYS

AUTHORITIES

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to

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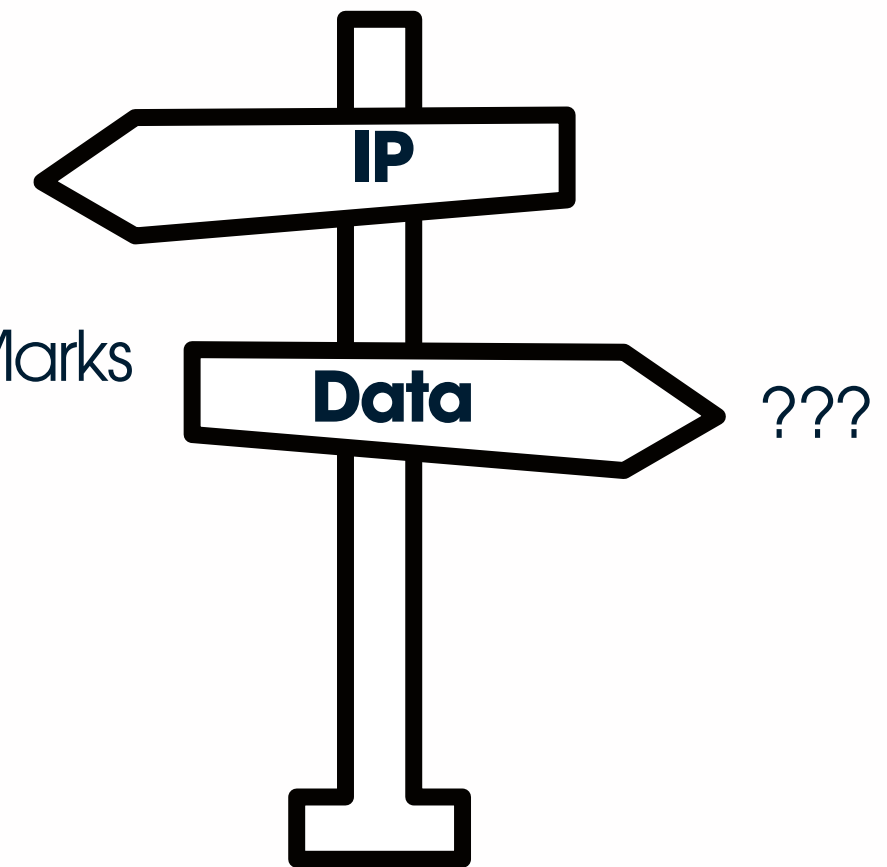
Document Number	Date Filed	Description	
2	Oct 28, 2025	UNREDACTED INDICTMENT FILED as to Sealed Defendant 1. (jm) (Not for Public view pursuant to Standing Order of the court, 24-mc-184.) (Entered: 11/04/2025)	
		Main Document	Indictment - Unredacted
			Buy on PACER
			0
3	Oct 28, 2025	REDACTED INDICTMENT FILED as to Bradley Heppner (1) count(s) 1, 2, 3, 4, 5. (jm) (Entered: 11/04/2025)	
		Main Document	Indictment
			Download PDF

Are a defendant’s chats with a public AI tool (Claude) protected by attorney-client privilege or work-product doctrine?

Disclosures

IP Impact

Patents
Trademarks
Trade Secrets
Copyrights
Geographic Marks



Disclosures

2026

FDA

- Failure to register an applicable clinical trial
- Failure to submit required clinical trial information for an applicable clinical trial
- Submission of false or misleading clinical trial information

Pre-Notices of Non Compliance

Search:

Export Excel

Show 10 entries

Responsible Party	NCT Number(s) (if any)	Pre-Notice (YYYY-MM-DD)
Andras Bratincsak, MD, PhD	NCT01917721	2025-12-18
Peter S. Hendricks, PhD	NCT02037126	2025-12-18
PolyPid Ltd.	NCT03558984	2025-12-18
Andrea R. Levine, MD	NCT04394416	2025-12-03
Lumosa Therapeutics Co., Ltd.	NCT04091945	2025-12-03
Palatin Technologies, Inc.	NCT04318145	2025-12-03
Alexion Pharmaceuticals Inc.	NCT02226146	2025-09-16
Alkeus Pharmaceuticals, Inc.	NCT03845582	2025-09-16
TNF Pharmaceuticals, Inc.	NCT05283486	2025-09-16
Viking Therapeutics, Inc.	NCT02578095	2025-09-16

Showing 1 to 10 of 226 entries

Previous 1 2 3 4 5 ... 23 Next

FDA

Notices of Non Compliance

- Failure to register an applicable clinical trial
- Failure to submit required clinical trial information for an applicable clinical trial
- Submission of false or misleading clinical trial information

Responsible Party/Submitter	NCT Number	Notice of Noncompliance	Response Letter (if any)	Civil Money Penalty Amount (if any)
Mantia-Smaldone, Gina M., M.D.	NCT03099499	08/04/2025		
Mezzion Pharma Co. Ltd	NCT03013751	3/14/2025	1/28/2026	
FADOI Foundation	NCT03045406	12/19/2024	09/30/2025	
Light Sciences Oncology	NCT02326454	7/19/2023	11/22/2023	
Ocugen	NCT03785340	4/15/2022	08/01/2022	
Petrikovets, Andrey M.D.	NCT03052816	8/31/2021	12/20/2021	
Accutis Inc.	NCT03064438	7/26/2021	05/26/2022	
Acceleron Pharma, Inc.	NCT01727336	4/27/2021	12/13/2021	

Disclosures

2025



Exempt BESH from
clinicaltrials.gov

Basic Experimental Studies in Humans (BESH) Will No Longer Be Considered Clinical Trials by the NIH

Notice Number:
NOT-OD-26-032

Key Dates

Release Date: January 29, 2026

Related Announcements

None

Issued by

NATIONAL INSTITUTES OF HEALTH (NIH)

Purpose

NIH is notifying the community that Basic Experimental Studies Involving Humans (BESH) will no longer be subject to the requirements under the NIH Clinical Trial Definition.

Background

In 2014, the NIH revised its clinical trial definition to increase transparency, accountability, and precision in tracking research:

A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of those interventions on health-related biomedical or behavioral outcomes.

This new definition was part of a broader stewardship initiative to ensure all NIH-supported research involving human participants is subject to rigorous standards and that results are rapidly disseminated, even if not considered an Applicable Clinical Trial under Section 801 of the Food and Drug Administration Amendments Act. As part of this effort, the categories of research considered clinical trials were expanded to include Basic Experimental Studies Involving Humans (BESH).

Because policies related to results dissemination have changed since 2014, and as part of ongoing efforts to reduce administrative burden, effective for applications submitted to due dates on or after May 25, 2026, the NIH will no longer characterize BESH as clinical trials. In the context of the definition of clinical trials, the NIH now considers a health-related biomedical or behavioral outcome as having the potential for direct advancement of health. Although BESH research, which produces fundamental information about biology or behavior, might eventually inform advances in health, it is not conducted with the express intent of changing clinical practice or health but rather aims to understandfundamental aspects of phenomena without immediate clinical applications. Therefore, BESH research is no longer considered to meet the NIH definition of a clinical trial.

Applicability

Effective with applications submitted to due dates on or after May 25, 2026, BESH will no longer be considered clinical trials by the NIH. Going forward, BESH will not have to follow the requirements for clinical trials, including registration and reporting in ClinicalTrials.gov. BESH must continue to follow all other applicable clinical research laws, regulations, and policies, including, but not limited to human subjects protections and the NIH Data Management and Sharing Policy. Currently funded BESH studies should follow their established Terms and Conditions of Award as well as NOT-OD-25-134 (Flexibilities for Registration and Results Reporting of Prospective Basic Experimental Studies with Human Participants).

The NIH will provide further guidance and examples for how to assess if a study is BESH, a clinical trial, or an observational study involving humans. NIH is actively reviewing current instructions and system validations and will provide detailed guidance in a forthcoming Guide Notice on any instruction or system changes, as needed, to reflect the updated classification. NIH also anticipates expiring all BESH-specific NOFOs for due dates on or after May 25, 2026 because BESH research can now be accepted through the Clinical Trials Not Allowed companions of these NOFOs.



Data Disclosure

Can you use data shared
for regulatory reasons for
other purposes?

**What prevents use of data
acquired via a
BAA or data disclosure
agreement
for inappropriate purposes?**

Lawsuit

GuardDog Telehealth admits to improper record sharing in Epic court case

In an agreement between the two companies, GuardDog admitted it masqueraded as a healthcare provider in order to gain access to medical records to provide to law firms.

Published March 16, 2026



Sydney Halleman
Editor

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Rebecca Pifer/Healthcare Dive

Listen to the article 5 min

A defendant in the lawsuit brought by Epic accusing health information network Health Gorilla and several of its clients of improperly accessing patient records has admitted to fraudulently requesting patient data, according to a [new legal filing released Friday](#).

Company A has asked a patient advocacy group to help enroll patients in their study.

The group reaches out to its own patients to share their data to support that purpose.

Who owns the data?

Thank you, we are happy to work with you.



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