

AGENDA



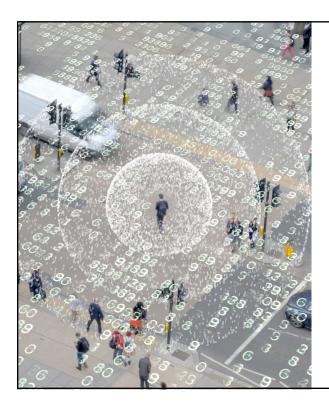
- Introduction of Risk Trends
- Data Privacy and Security Key Developments
- Health Care Research HIPAA
- International Data Transfer Developments
- Data Commercialization
- False Claims Act Liability
- Privacy Legislation Update



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DATA PRIVACY AND SECURITY KEY DEVELOPMENTS





DIGITAL PRIVACY REGULATORY CONSIDERATIONS

- Dobbs v. Jackson Women's Health Organization, June 2022
- Fractured state by state approach to privacy
- Renewed regulatory focus on digital privacy:
 - Statements from regulators regarding largescale consumer data collection: names, contact information, location, zip code, browsing activity on websites or mobile applications
 - FTC: On July 11, warned of intent to use Section 5 authority under FTC Act to investigate unfair or deceptive acts or practices related to transparency of consumer data collection
 - FCC: In July, requested information from top mobile providers regarding data retention and data sharing practices



Regulatory Enforcement	Criminal Investigations	Litigation or Civil Subpoenas
 FTC lawsuit against data broker for selling geolocation data from hundreds of millions of mobile devices Alleges that the data broker collects and sells geolocation data tied to mobile device ID that could be reidentified in combination with other data Seeks injunctive relief 	 Criminal investigation and arrest of mother and daughter in Nebraska Subpoena to Meta for private Facebook messages containing medical information 	 Third-party data collectors subject to subpoenas for civil enforcement or litigation Potential consumer litigation over online tracking Balancing competing factors, including compliance, consumer protection, and brand or reputation

FTC COMMERCIAL SURVEILLANCE & DATA SECURITY RULEMAKING

FTC voted 3-2 to file an Advanced Notice of Proposed Rulemaking on August 11

Citing the heightened risks associated with "[m]ass surveillance," the FTC "is asking the public to weigh in on whether new rules are needed to protect people's privacy and information in the commercial surveillance economy" Will FTC's actions spur Congress to act? Or create more confusion? The Commission hosted a public forum on September 8 to discuss the ANPR; public comment period closes on October 21



FTC RULEMAKING AREAS OF FOCUS

Commercial Surveillance Industry Practices

- Collection
- Analysis
- Monetization

TC Concerns

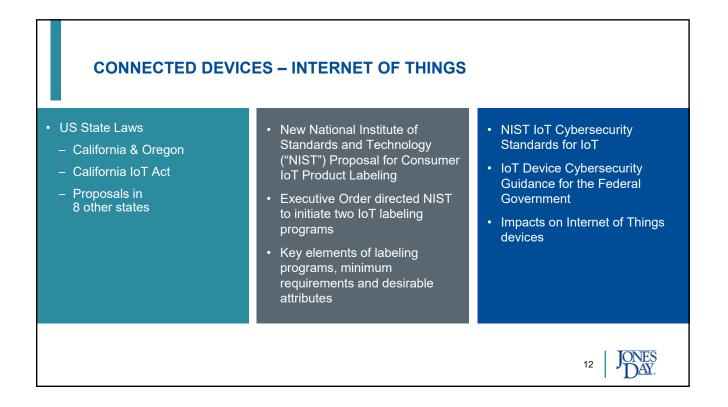
- Lax data security
- Harm to children
- Retaliation
- Surveillance creep
- Inaccuracy



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California	Virginia	Colorado
(CCPA/CPRA)	(VCDPA)	(CPA)
Applies to personnel and business contacts Exempts protected health information collected by a covered entity/business associate Exempts HIPAA-compliant covered entities Exempts PI collected as part of a clinical trial/biomedical research study Civil Penalties (Cal. AG) – • \$2,500 per violation • \$7,500 per "intentional violation"	 Does not apply to employees or business contacts Exempts businesses (including companies that must comply with HIPAA and GLBA) Exempts protected health information under HIPAA Exempts clinical trial data Civil Penalties – up to \$7,500 per violation (and attorney's fees 	 Does not apply to employees or business contacts Entity-level exemptions (but not for HIPAA-regulated entities) Data-level exemptions (including protected health information) Does not apply to "Private Information" as defined by the Regulations for the Protection for Human Subjects; PI collected as part of human subject research, o Personal Data used in research in accordance with the foregoing two categories Civil Penalties – up to \$20,000 pe violation







PROPOSED EU CYBER RESILIENCE ACT

- EU Cyber Resilience Act proposed in September
- Aimed at improving the security of devices
- Products will have to meet various cyber standards to receive approval marking
- · Establishes vulnerability database
- Fines: 15 million euros, or 2.5% of a company's worldwide annual revenue





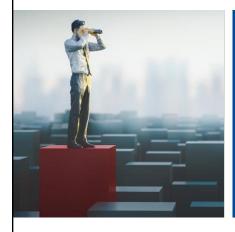
CALIFORNIA AGE-APPROPRIATE DESIGN CODE ACT

The Act expands and strengthens privacy protections within businesses with online products, services, or features that children under the age of 18 are likely to access

- 1. Data protection impact assessment
- 2. High-level privacy default settings
- 3. Age-appropriate privacy language
- 4. Clear tracking indicators and geolocation restrictions
- 5. Additional data privacy restrictions
- 6. Establishment of a Working Group
- 7. Specific enforcement and penalties provisions



NEXT STEPS FOR COMPANIES



- Identify types of personal information collected
- Update privacy policies and terms of use for websites and mobile applications
- Implement data retention and minimization
- Limit unnecessary collection of sensitive personal information (e.g., location data)
- Anonymize data before storing, sharing, or selling



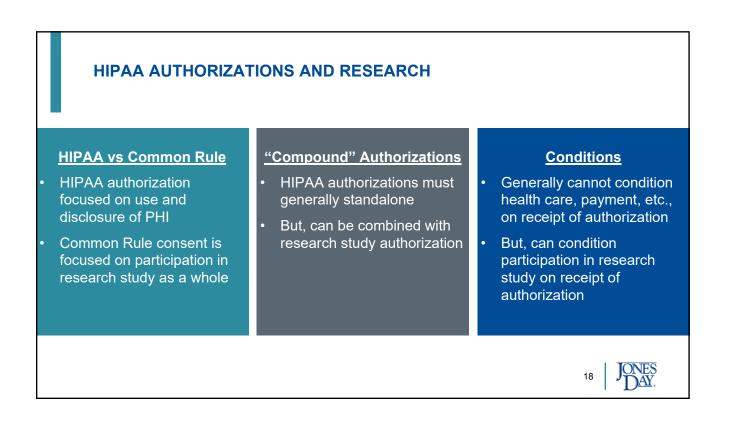


HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996 (HIPAA) AND RESEARCH

- Defined: "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to <u>generalizable</u> knowledge"
- <u>Not</u> covered function under HIPAA (e.g., not Treatment, Payment or Health Care Operations)
- So, research is never a business associate (BA) function

- Researcher might not be a Covered Entity (CE)
- CE if furnishes health care (including to research subjects) and transmits PHI electronically for HIPAA-covered transaction (e.g., billing insurance)
- CE even if third party submits transactions on their behalf
- Researcher might be part of an organization that is a CE
- CE might designate itself as "hybrid entity"
- CE can then designate research department as non-covered component since research is not HIPAA function
- But if research department bills insurance, etc., must be part of CE





HIPAA RESEARCH EXCEPTIONS

Without Authorization

- Institutional Review
 Board/Privacy Board Approval
- Preparatory to Research Exception*
- Research on Decedent's
 Information
- Limited Data Set/Data Use
 Agreement

With Authorization

- Must meet HIPAA criteria
- Compound authorization
 permitted
- Condition of participation in study permitted
- May permit use/disclosure for <u>future</u> research

De-Identified Information

If PHI is properly de-identified, not subject to HIPAA

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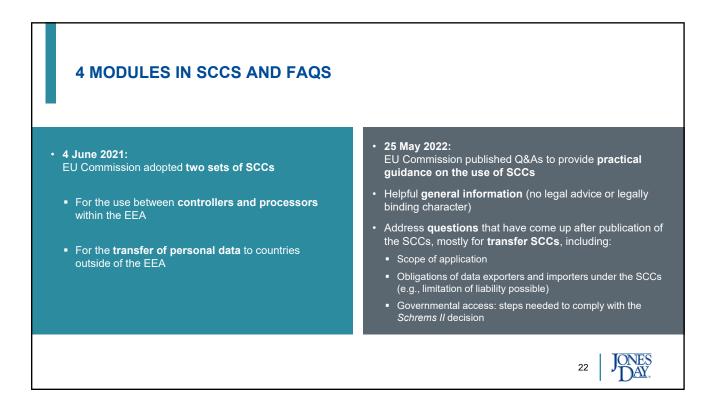
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 BAA may be required if researcher will handle deidentification process

* Often helpful for study subject recruitment

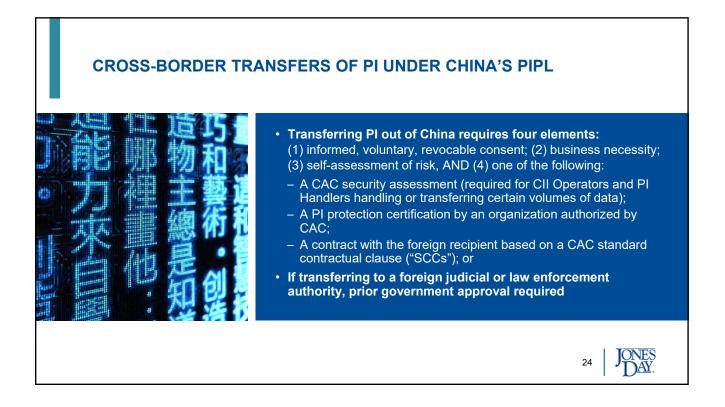






THREE PRONGS OF CHINA'S DATA PRIVACY AND CYBERSECURITY REGIME

Cybersecurity Law 2017	Data Security Law 2021	Personal Information Protection Law 2021
 Imposes cybersecurity obligations to protect national security Regulates all operators of computer networks (essentially all organizations) 	 Imposes data security and localization obligations based on nature of data and national security considerations Regulates all data handlers 	 Imposes GDPR-inspired obligations related to personal information combined with localization obligations Regulates all handlers of personal information
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CROSS-BORDER TRANSFERS OF PI UNDER CHINA'S PIPL (CONT.)



Recent Developments:

- Guidelines on Security Assessments, effective Sept 1, 2022
 - Mandatory under certain circumstances (data controller processes PI of more than 1 million; previously transferred our PI of >100k or SPI of 10k)

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- · Guidelines on Certification
 - No authorized certification institutions
- Draft Regulation on SCCs and draft sample SCCs
 - Monitored by PRC authority / notify of a data breach





Penalties

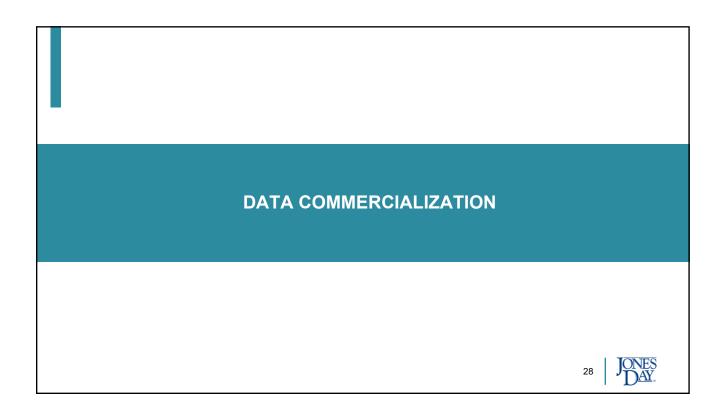
- Generally not criminal; can be a correction request with provisional suspension
- Up to RMB 50 million (\$7.7 million USD) or 5% of previous year's revenue
- · Suspend entity's operations or business license
- Private cause of action if an individual's right under PIPL is violated (e.g. right to access, correct, delete)



NEXT STEPS

- 1. Risk self-assessment (data protection impact assessment with added factors)
- 2. Update IT policies / employment contracts/ employment manuals -- Consents
- Understand how business data generated is being automatically stored / duplicated by your IT systems
- 4. Understand if localization is required
- 5. Identify the appropriate cross-border data transfer mechanism and mitigation strategy





Corporate Deals

- Not addressing data access needs, protection, and compliance mechanisms early in the deal
- Not understanding the importance of data assets
 - Failure to properly determine importance of data assets and commercialization (pre/post close)
- Not mapping how data will be assessed in terms of their management, protection, and sharing (due diligence, purchase terms, and post closing obligations)
- Not accounting for data commercialization constraints in post-closing / integration

Commercial Deals

- Failing to define the data values, sources, and use needs in commercial transactions
- Not addressing data "ownership" or "property rights" for derivative data
- Unclear data license rights and sale restrictions
- Understanding limits of automated processing under data protection laws and evolving Al policies (deidentification/ anonymization)
- Not accounting for data transfers
 - Model contracts
 - Transfer impact assessments
- Avoiding unclear liabilities and indemnification obligations

Marketing Arrangements

- Not properly defining the regulatory role of the parties (independent/joint controllership, business purpose processing, data processor or service provider, hybrid roles)
- Failing to address sale and donot-sell obligations
- When the marketing arrangement amounts to a data brokerage arrangement, not addressing state registration obligations
- Not addressing obligations related to cookies and other tracking technologies, use restrictions, and consumer notice and choice obligations

SAMPLE KEY DATA PROTECTION REPRESENTATIONS AND WARRANTIES

DEFINITIONS	Data Protection Laws (DPL), Personal Data/Information, HIPAA, GDPR, Etc.
No Violation of Law	Rep in compliance with DPLs, contractual obligations, authorizations/consents, privacy policies, etc.
No Actions	Rep that there is no action pending, asserted or threatened
Data Protection Measures	Rep that reasonable measures have been taken to protect information against loss, unauthorized access, etc.
Data Breaches	Rep for no data breaches or notifications (including no pending investigations or notices)
Other	Addressing other reps, such as "transaction not breach" and "sale of data"

Closing Covenants/Conditions	Post-Closing Issues
 Notice of certain events (e.g., "Seller shall notify Purchaser within X of the occurrence of a Data Breach") Cyber insurance (e.g., "Seller shall maintain Cybersecurity Insurance for 3 years with respect to matters occurring prior to Closing") Referencing cybersecurity incident(s) in the "no Material Adverse Effect" clause 	 Negotiate ancillary services agreements Adjust existing contracts Identify data controllers v. processors Adjust technology arrangements Re-negotiate data use rights Implement data transfer mechanisms Draft intercompany data sharing arrangements Conduct data impact assessments Draft required policies, notices and consents



Federal Trade Commission	Department of Justice	SEC
 Consent decrees and ongoing representations to the Agency: Twitter, Facebook, others. Significant Fines: \$5 Billion penalty on Facebook August 2022: Proposed rulemaking on "commercial surveillance and lax data security" 	 United States ex rel. Brian Markus v. Aerojet Rocketdyne Holdings Inc., et al. Cisco Systems, Inc. multi-state settlement October 2021: DOJ Civil Cyber- Fraud Initiative announced 	 Pay attention to representation and risk factors in regulatory filings Proposed Cybersecurity Disclosure Rule Significant potential enforcement





American Data Privacy and Protection Act ("ADPPA") was voted out of committee on July 20, and remains subject to extensive debate in Congress

Will this reconcile the "patchwork quilt" of US privacy laws?

ADPPA comes closest to a viable bill to win bipartisan support, but it is ambitious

Much can still change, including who would be subject to the law, what the law would require, how the law would be enforced, and what laws are preempted by the ADPPA

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TWO KEY AREAS OF DEBATE IN ADPPA	
Preemption	 Federal laws: GLBA, FCRA, FERPA, or HIPAA? State laws: CCPA, BIPA, and others?
Private Right of Action	 Private right of action is possible 2-4 years after effective date of ADPPA But first, individuals must give FTC and their state AG the chance to pursue the matter
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CALIFORNIA PRIVACY PROTECTION AGENCY'S RESPONSE



The CPPA called a special meeting in response to the ADPPA after the House Energy and Commerce Committee voted the bill out of committee on July 20

On July 28, the CPPA Board met and voted to oppose the ADPPA and any federal legislation that would preempt or undermine California's privacy protection laws On September 1, Speaker Pelosi issued a statement implying she would not hold a vote on the bill as currently drafted but that she will continue to work with Chairman Pallone to address California's concerns





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