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Overview of Legal and Regulatory Requirements for Connected Products

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Connected Products Team
Keller and Heckman LLP

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Today's Session

- Review of key regulatory changes and important enforcement actions affecting the development and sale of connected consumer products

Connected Product Legal Landscape

- Privacy and Security
- FCC
- Product Safety
- EU Product Safety Regulation
- FDA
- Advertising and Marketing Claims

Privacy & Security

CCPA Update

- California Consumer Privacy Act (AB 375) (CCPA) in effect 1/1/2020
  - AG to enforce beginning 7/1/2020
  - Employee obligations take effect 1/1/2021
- AG published 3 sets of proposed regulations; awaiting final regulations addressing:
  - Notices to consumers
  - Handling consumer requests
  - Opt-in/opt-out for “sale” of personal information
    - Parental consent (kids <13)
    - Opt-in consent from children 13 – 16 for “sale”
    - Opt-out consent from others
  - Non-discrimination for consumers exercising rights
  - Recordkeeping
  - Costs of compliance

COPPA Rule Review

FTC's July 25, 2019 Request for Comment asks:

- Is COPPA still necessary?
- Should definitions be changed?
- What is the role of Safe Harbors?
- Should changes be made to exception for "support for internal operations," modes of parental consent?
- What is the role of platforms and apps?

Platforms and Apps

- Court approves NY AG/FTC $170 million settlement with Google and YouTube for illegally tracking and collecting personal information from children
- Settlement requires channel owners to designate whether their content is directed to children

Focus on Ed Tech

- New Mexico AG second action against Google for illegally tracking children, this time targeting Google Education Suite
- NY AG investigates Zoom for potential privacy violations
  - Settlement reached: Requires students and teachers to use a NY DOE-licensed version of the program

Biometric Data

- Inconsistent approaches
- Illinois Biometric Information Privacy Act adopts specific definition covering retinal scans, fingerprints, voice or facial scans
- CCPA defines biometric data generally as personal information
- COPPA requires parental consent to collect photographs, videos and audio recordings of a child (subject to enforcement discretion)
- Other states considering biometric privacy laws

Comparison of Biometric Data Laws

COPPA	BIPA	CCPA
“Personal information” includes a photograph, video, or audio file where such file contains a child’s image or voice” (16 C.F.R. 312.2).	"Biometric identifier" means a retina or iris scan, fingerprint, voiceprint, or scan of hand or face geometry” (740 I.L.C.S. 14/10 § 10). Biometric identifiers do not include writing samples, written signatures, photographs… "Biometric information" means any information, regardless of how it is captured, converted, stored, or shared, based on an individual's biometric identifier used to identify an individual. Biometric information does not include information derived from items or procedures excluded under the definition of biometric identifiers.	“Biometric information” means an individual’s physiological, biological, or behavioral characteristics, including an individual’s deoxyribonucleic acid (DNA), that can be used, singly or in combination with each other or with other identifying data, to establish individual identity. Biometric information includes, but is not limited to, imagery of the iris, retina, fingerprint, face, hand, palm, vein patterns, and voice recordings, from which an identifier template, such as a faceprint, a minutiae template, or a voiceprint, can be extracted, and keystroke patterns or rhythms, gait patterns or rhythms, and sleep, health, or exercise data that contain identifying information. (CA Civ. Code §1798.140(b))

Status of State Privacy Laws

- COVID-19 has put many state privacy initiatives on hold
- CCPA regulations not yet released; will enforcement be delayed?
- CCPA 2.0 (CPRA) advances to ballot in November 2020

The GDPR Influence

- May 25, 2020 marked the second anniversary
  - Most EU member states have issued fines for GDPR violations
  - EU harmonization still a work in progress
- FTC enforcing against companies falsely claiming participation in EU-U.S. Privacy Shield and other international privacy frameworks
- Other countries (e.g., Brazil and India) have adopted or introduced general data protection laws modeled on GDPR

EU Cookies Consent

- 5/4/2020: European Data Protection Board (EDPB) updated its guidance on what constitutes valid consent under the GDPR
  - Addresses “cookie walls” and scrolling/swiping
  - Expands on existing Article 29 Working Party (WP29) Opinions
- 1/14/2020: French CNIL published draft recommendations
  - Explicit GDPR-compliant consent to place cookies other than analytics and strictly necessary cookies
- UK ICO guidance (2019) suggests opt-in consent is necessary for all but essential cookies
- Implications for kid-directed online services

Communications Testing and Certification

Federal Communications Commission

- Nearly all electronic devices are regulated by the FCC
- FCC is primarily concerned with interference between devices

FCC Equipment Authorizations

- Which rules and procedures apply?
  - Which bands used
    - Limits on certain frequency bands
    - Licensed vs. unlicensed
  - Certification
    - Intentional radiators
  - Supplier's Declaration of Conformity
    - Nearly everything else

FCC Equipment Authorizations

- Two testing procedures
- Certification
  - Test Lab must be FCC accredited
  - FCC accredited labs listed on FCC's website
- SDoC
  - Accredited lab not required
  - But lab must maintain record of measurement facilities and record of measurements made
  - May be required even for modular transmitters

FCC Equipment Authorizations

- Two authorization procedures
- Certification
  - Requires approval by Telecommunications Certification Body
    - FCC has outsourced equipment certification
  - Application and testing materials made public
    - Some confidentiality available
- RF safety testing requirements
  - Mobile vs. portable vs. fixed

FCC Equipment Authorizations

- Suppliers Declaration of Conformity
  - No TCB certification required
  - Lab tests not submitted to FCC
    - But FCC may request test data in audit
  - Responsible Party warrants compliance with FCC rules
  - Responsible Party maintains documentation demonstrating compliance
  - Compliance Information Statement

FCC Equipment Authorizations

- International Requirements
- Mutual Recognition Agreements
  - Countries agree to accept test results and/or product approvals performed by labs recognized by other country parties to MRA
  - MRAs with Japan, Hong Kong, Canada, Singapore, EU, Israel, New Zealand, and others

Labeling and Disclosures

- Part 15 Interference Statement
- Digital device statement
- Instructions for mitigating interference
- Modification statement
  - Cautions the user that modifications could void authority to operate the device
- Other disclosures sometimes required by certification:
  - RF exposure most common
  - Instructions on antenna installation
  - Limits or proper use of device

Labeling

- Certification – FCC ID
- Ex. “FCC ID: ABC-1234567”
- Comprised of Grantee Code and product code
- SDoC – Any unique identifier
- Cannot resemble FCC ID
- FCC logo optional

Importation

- Importation
  - Device must generally have received equipment authorization
  - Exemptions for importation for testing, product development, demonstrations
    - Limit on number that may be imported

Product Safety

CPSC and IoT

- CPSC remains interested in connected products
  - Potential for enhancing product safety
  - Potential product risks arising from connectivity
    - Physical safety and privacy and data security are separate concerns
- Does connectivity alter foreseeable use and misuse assessment?
- Consumer groups again called for mandatory standards at CPSC's recent priorities hearing and specifically raised risks associated with e-scooters' vulnerability to hacking

CPSC and IoT

- CPSC Status Report on IoT Efforts published last fall lists three main focus areas for CPSC
  - Assessing safety implications of software and firmware updates
  - Connected heating appliances and risks of remote activation
  - “Smart toys” – effort to identify physical safety hazards

CPSC and IoT

- CPSC's ongoing role with respect to IoT is uncertain
  - No recent recalls due to hazards associated with connectivity
    - Recalls related to battery hazards are common and can be expensive to implement
  - CPSC staff acknowledges need to continue developing internal expertise

Draft ASTM IoT Guidance Standard

- New ASTM Standard Guide for Ensuring the Safety of Consumer Products is out for ballot
- The proposal is limited to physical safety
  - Harms from privacy, data security unrelated to safety are out of scope
- Intended to apply in conjunction with applicable product-specific standards
- Provides guidelines for remote updates, software and firmware configuration, and cybersecurity risk controls

Updates on EU Product Safety Regulation

EU Product Certification

- Conformity with essential safety requirements based on EU harmonized regulations + CE marking
  - Applicability and types of standards
  - GPSD is the overarching safety standard for IoT consumer products

Product Safety and IOT Update

- New standards under development in the EU specifically for IoT, namely
  - (i) proposal for Delegated Regulation to RED on Internet-connected radio equipment and wearable radio equipment,
  - (ii) draft European Standard EN303645 on Security for Consumer IoT

Regulations Affecting IoT Design

- Energy Efficiency
  - U.S. (DOE, CEC)
    - Category-specific
    - External power supply (EPS) and battery charger restrictions
- EU Ecodesign Directive
  - 31 total categories (8 updated and 2 new in 2019)
  - Example: electronic displays (>100 cm2), EPS, household products, motors
- Chemical restrictions
  - DEHP in articles – REACH 7/7/2020
  - RoHS
  - Flame retardants in displays – Ecodesign 3/1/2021
- New EU Market Surveillance Regulation

Practical Considerations

- Market surveillance in the EU
  - Differences between EU and U.S.
  - Withdrawal/recall of non-compliant products (formal non-compliance vs. unsafe product)
  - RAPEX
- Online sales: who is responsible for compliance in case of online sales from outside EU
- Who is considered as EU importer; need for EU representative

Food and Drug Administration

“Medical Devices” vs. “General Wellness” Products

Overview:

- FDA policy
- Legislative changes (21st Century Cures Act)
- Understanding “general wellness”
- Understanding “low risk”
- Policy application
  - Examples of claims
  - Potential expanded applicability

Document Involved

- FDA final guidance document
- "General Wellness: Policy for Low Risk Devices"
  - Draft announced in 80 *Fed. Reg*. 2712 (January 20, 2015)
  - Final announced in 81 *Fed. Reg*. 49995 (July 29, 2016)
  - Slightly revised version issued September 27, 2019
- Covers "low risk products that promote a healthy lifestyle"

FDA Policy

- FDA does not intend to examine low risk general wellness products to determine:
  - (1) whether they are “devices” or
  - (2) if they are devices, whether they comply with pre- and post-market regulatory requirements
- FDA will not enforce
  - Device establishment registration and listing provisions
  - Device labeling
  - Compliance with Quality System Regulation (QSR)
  - Medical Device Reporting (MDR)

Legislative Changes

- 21st Century Cures Act (signed December 13, 2016)
  - Modifies “device” definition to exclude a “software function” that is intended (among other things) for
    - “maintaining or encouraging a healthy lifestyle and is unrelated to the diagnosis, cure, mitigation, prevention, or treatment of a disease or condition”
  - Language is consistent with FDA policy, therefore no immediate change
    - General wellness and mobile medical app guidance documents useful to provide FDA’s interpretation of this exemption

"General Wellness Product"

- Has an intended use that relates:
  - (1) to maintaining or encouraging a general state of health or a healthy activity, [*i.e.*, functions associated with a general state of health, but no reference to diseases or conditions], or
  - (2) the role of healthy lifestyle with helping to reduce the risk or impact of certain chronic diseases or conditions and where it is well understood and accepted that healthy lifestyle choices may play an important role in health outcomes for the disease or condition
- Presents a "low risk to the safety of users and other persons"

“General State of Health” Examples

- Weight management
- Physical fitness (products for recreational use)
- Relaxation or stress management
- Mental acuity
- Self-esteem (*e.g.*, devices with only a cosmetic function related only to self-esteem)
- Sleep management
- Sexual function

"General State of Health" Claims

- General wellness claims related to:
  - Weight management
    - OK: Promote or maintain a healthy weight, encourage healthy eating, or assist with weight loss goals
    - Not OK: treat or diagnose obesity or eating disorder (anorexia)
  - Physical fitness (including for recreational use)
    - OK: Help log, track, or trend exercise activity; measure aerobic fitness; improve physical fitness; develop or improve endurance, strength or coordination, or improve energy
    - OK: improve general mobility in recreational activity
    - Not OK: restore a structure or function impaired by disease (e.g., prosthetic enables amputees to play sports); treat muscle atrophy

“General State of Health” Claims (cont)

- General wellness claims related to:
  - Relaxation or stress management
    - OK: Increase, improve, or enhance the flow of qi
    - Not OK: help treat anxiety disorders
  - Mental acuity
    - OK: Improve instruction-following, concentration, problem-solving, multitasking, resource management, decision-making, logic, pattern recognition or eye-hand coordination
    - Not OK: computer game will help diagnose or treat autism, help reduce effects of Alzheimer’s disease

“Reduce Risk or Impact”

- Products intended to:
  - Promote, track, and/or encourage choice(s), which, as part of a healthy lifestyle, may help to reduce the risk of certain chronic diseases or conditions
  - Promote, track, and/or encourage choice(s) which, as part of a healthy lifestyle, may help living well with certain chronic diseases or conditions

“Reduce Risk or Impact” (cont)

- Only where it is “well understood” that healthy lifestyle choices may reduce the risk or impact of chronic disease or condition
  - Typically, association is described in peer-reviewed scientific literature
- FDA: association currently recognized with
  - Heart disease
  - High blood pressure
  - Type 2 diabetes

“Reduce Risk or Impact” Claims

- “Software Product U coaches breathing techniques and relaxation skills, which, as part of a healthy lifestyle, may help living well with migraine headaches.”
- “Software Product V tracks and records your sleep, work and exercise routine which, as part of a healthy lifestyle, may help living well with anxiety.”
- “Product X promotes physical activity, which, as part of a healthy lifestyle, may help reduce the risk of high blood pressure.”

Is the Device "Low Risk"?

- Look to whether or not product:
  - (1) Is invasive
    - i.e., pierces skin or mucous membranes of body
  - (2) Is implanted
    - Not defined in guidance
    - In FDA's device regulations: "device that is placed into a surgically or naturally formed cavity of the human body if it is intended to remain there for a period of 30 days or more"
  - (3) Involves an "intervention or technology that may pose a risk to a user's safety if device controls are not applied" – examples:
    - Lasers (e.g., for "rejuvenating skin" to improve self-confidence)
    - Radiation exposure (e.g., sunlamp products)
    - Implants (e.g., improve self-image or enhance sexual function)
    - Neurostimulation (e.g., improve memory)
- If any answer is "yes," then device is <u>not</u> "low risk"

Opportunities for Industry

- Policy is expansion of FDA's previous (reasonable) position on fitness/exercise equipment
- Reduce uncertainty and open new options for "wearables"
- Ability to make statements about reducing risk or impact of chronic disease/condition is welcome
- Potential for abuse, inappropriate products
- Practical enforcement may now fall to Federal Trade Commission (FTC) and states
- FDA presumably may still take action in appropriate cases

Advertising and Marketing Claims

Claims 101

- Claims material to consumers must be substantiated by a reasonable basis:
  - Privacy, security claims
  - Safety claims
  - Green claims
  - “Made in USA” claims
  - Price claims
- Endorsements and testimonials adopted by advertisers are “owned” by the advertiser
- Claims are interpreted by the “reasonable consumer” standard
- Claims can be misleading by omission

Privacy and Security Representations

- Failure to adhere to privacy/security representations in privacy policies can constitute false advertising
  - FTC has entered into numerous consent agreements over the years on these grounds
- FTC also asserts that failure to implement basic security measures is an unfair practice in violation of Section 5

FTC Advertising Guidance

- "Disclosures 101 for Social Media Influencers," published November 5, 2019
  - Explains what triggers the need for a disclosure and offers examples of both effective and ineffective disclosures

FTC Endorsement Guides Review

- On February 12, 2020, FTC announced it would review the Endorsement Guides, first enacted in 1980 and amended in 2009
  - Guidance to businesses to ensure that use of endorsements or testimonials in advertising complies with FTC Act
- Comment period closes June 22, 2020

“Made in USA” Cases

- FTC Continues to pursue “Made in USA” cases vigorously
  - $1 million settlement on March 30, 2020 with Williams-Sonoma for allegedly false claims that several products lines were made in the USA
    - This was not the first time Williams-Sonoma made such claims
  - FTC sent a closing letter to epoxy manufacturer J-B Weld on March 19, 2020 on referral from NARB after company refused to accept all NARB’s recommendations regarding its “Made in USA” claims
    - The FTC declined further action after advertiser took remedial steps, including updating packaging and removing U.S.-origin “line” claims from its website and social media channels

Mail Order Rule Violation Case

- FTC Settlement with Fashion Nova on April 21, 2020 over allegations of slow shipping, despite promises to the contrary, and damaged or substituted merchandise

Safe Harbor Claims

- On May 19, 2020, the FTC settled with children's gaming company Miniclip for falsely claiming participation in the Children's Advertising Review Unit (CARU)
  - From 2015 to 2019, Miniclip advertised its CARU membership on its website and Facebook games privacy policy page despite having its membership terminated by CARU in 2015
- Recent FTC enforcement actions re: safe harbor participation:
  - Sent warning letters to 13 companies for misrepresenting participation in the U.S.-EU Safe Harbor and the U.S.-Swiss Safe Harbor frameworks, which no longer exist.
  - Sent warning letters to 2 companies for falsely claiming to participate in the Asia-Pacific Economy Cooperation Cross-Border Privacy Rules
  - Settled with screening company SecurTest over similar claims

Conclusion

Looking Forward

- Effects of COVID-19 on marketplace
- AI
- Biometrics
- More privacy and security legislation
- Energy consumption/efficiency of connected products

Questions

Want to Know More?

- Our IoT team discusses **The Lifecycle of a Connected Product: Practical Considerations** on Tuesday, June 9 at noon EDT
- This 90-minute webinar focuses on some key practical considerations in bringing a connected product to market
- Sign up at www.khlaw.com

THANK YOU

Connected Products Team

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