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Top Legal Developments Life Sciences Companies Need to Watch

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Agenda

Day 1

- **Compliance with the FCPA and Anticorruption Laws for Life Sciences Companies**
  - Jacqueline Wolff
- **False Claims Act Litigation**
  - Kimo Peluso
- **Antitrust Issues**
  - Lisl Dunlop

Day 2

- **340-B Program**
  - Helen Pfister
- **Emerging Environmental Regulations: Life Sciences**
  - Ted Wolff
- **Wearables, Devices and Cybersecurity**
  - Helen Pfister, Kimo Peluso
- **Advertising and Marketing: Communicating with Consumers**
  - Marc Roth

340-B PROGRAM

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What Does the 340-B Program Do?

- Enables eligible healthcare providers and programs ("covered entities") to purchase *outpatient drugs* for their patients at discounted prices:
  - DSH hospitals, free-standing cancer hospitals, children's hospitals and sole community hospitals with a DSH adjustment percentage > 11.75%
  - Critical access hospitals
  - FQHCs and FQHC look-alikes
  - Family planning projects funded under Section 1001 of the Public Health Service Act
  - Ryan White clinics
  - State AIDS Drug Assistance Programs
  - Black lung clinics
  - Hemophilia treatment centers
  - Native Hawaiian health centers and urban Indian organizations
  - Federally funded STD and tuberculosis clinics
- Does not apply to inpatient drugs

What Patients Are Eligible to Receive 340-B Drugs?

- Individuals who qualify as patients of a covered entity by meeting the following three requirements:
  - Covered entity maintains records of individual's healthcare
  - Clinician providing services to individual is employee of covered entity, or provides healthcare under another arrangement so that responsibility for care remains with covered entity
  - For covered entities other than DSH hospitals, healthcare services individual receives are services for which federal grant funding (or, for FQHC look-alikes, look-alike status) is provided
- Individual does not qualify as patient if the only healthcare services individual receives from covered entity is dispensing of drugs for subsequent self-administration at home

- In addition to dispensing 340-B drugs through its in-house pharmacy, covered entity may enter into "contract pharmacy arrangements" with outside pharmacies
  - Covered entity buys 340-B drugs, but drugs are shipped to contract pharmacy ("ship to/bill to" arrangement)
  - Drugs are dispensed by contract pharmacy only to patients of covered entity, in exchange for dispensing and/or administrative fee

The GPO Exclusion and the Prohibition on Duplicate Discounts

- GPO Exclusion: DSH hospitals, children's hospitals and cancer hospitals that participate in 340-B program may not purchase "covered outpatient drugs"—i.e., drugs covered by 340-B program—through GPO
  - These hospitals may, however, continue to use GPO to purchase inpatient drugs
- Prohibition on Duplicate Discounts: A drug may not be subject to both a 340-B discount and a Medicaid rebate
  - Thus, covered entity may only use 340-B drugs for Medicaid patients if:
    - Medicaid reimburses for drugs as part of a bundled or all-inclusive rate so that Medicaid program is unable to identify and request rebates for the drugs or
    - Covered entity makes the State aware that drug was purchased under 340-B so that State does not request Medicaid rebate for drug
  - HRSA maintains a Medicaid Exclusion File that indicates, for each covered entity, whether that covered entity will use 340-B drugs for Medicaid patients

Office of Pharmacy Affairs (OPA)

- Office within HRSA that is responsible for overseeing the 340-B program
- To participate in the 340-B Program, covered entities must register with OPA and be listed on OPA's 340-B database
- Historically, OPA did not issue formal regulations governing the 340-B program - instead, guidance was provided primarily in the form of Federal Register notices and "frequently asked questions" documents
- In August 2015, OPA released a comprehensive proposed rule covering many aspects of the 340-B program—the "Omnibus Rule"

The Proposed Omnibus Rule

- Highlights of proposed Omnibus Rule
  - Provides significantly more detail on who qualifies as a patient of a covered entity for 340-B purposes
  - Provides that GPO prohibition does not apply where hospitals cannot access a drug at the 340-B price or at wholesale acquisition cost to prevent disruptions in patient care
    - Does not specify the patient care disruptions that would justify this exception
  - Provides that where a hospital can demonstrate that a violation of the GPO prohibition was an "isolated incident" the hospital would not be removed from the 340-B program
    - Does not specify what would constitute an "isolated incident"
  - Notwithstanding comments of pharma manufacturers, does not put any limits on contract pharmacy networks
  - Requires covered entities to conduct annual independent audits of each contract pharmacy location
  - Rejects suggestions that only government-insured and uninsured patients be eligible to receive 340-B drugs
- Proposed rule published in August 2015; final rule previously scheduled for September 2015; now anticipated in December 2016

Other Regulatory Activity

- Final rule that would impose civil monetary penalties on pharmaceutical companies that intentionally overcharge covered entities for 340-B drugs
  - Required under Affordable Care Act
  - Initially set for publication in May 2016; now anticipated to be published in November 2016
- Proposed rule that would establish dispute resolution process to resolve claims by covered entities that they have been overcharged for 340-B drugs
  - Required under Affordable Care Act
  - Initially set for publication in May 2016; now anticipated to be published in September 2016

OIG Report on State Efforts to Identify 340-B Drugs Paid for by Medicaid MCOs

- In 2010, ACA expanded Medicaid drug rebate program to cover drugs paid for by MCOs
- Accordingly, states must have methods in place to identify MCO claims for 340B drugs to ensure states don't request rebates for those drugs:
  - Provider-level methods: State identifies covered entities that use 340-B drugs for MCO enrollees and excludes drug claims submitted by those entities from rebate requests
  - Claims-level methods: Require covered entities and MCOs to identify individual claims for 340-B drugs paid for by MCOs for their enrollees so state can exclude from rebate requests
- OIG report findings:
  - Most states use provider-level methods, such as relying on the Medicaid Exclusion File, but provider-level methods may not accurately identify 340-B claims
  - Claims-level methods can improve accurate identification of 340-B claims, and can also be used in the contract pharmacy context
- OIG report recommendations:
  - CMS should require states to use claims-level methods to identify MCO drugs purchased under 340-B
  - HRSA should clarify guidance on preventing duplicate discounts for MCO drugs

EMERGING ENVIRONMENTAL REGULATIONS: LIFE SCIENCES

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Manatt's Environmental Practice

- Specializes in supply chain, cradle-to-grave management for materials handling programs and sustainability
- Representative industries served include retailers, healthcare, logistics, transportation and manufacturing, including OTC and Rx processors
- Holistic counseling focused on understanding client environmental processes from a technical perspective to implement sound scientific and legal solutions for compliance

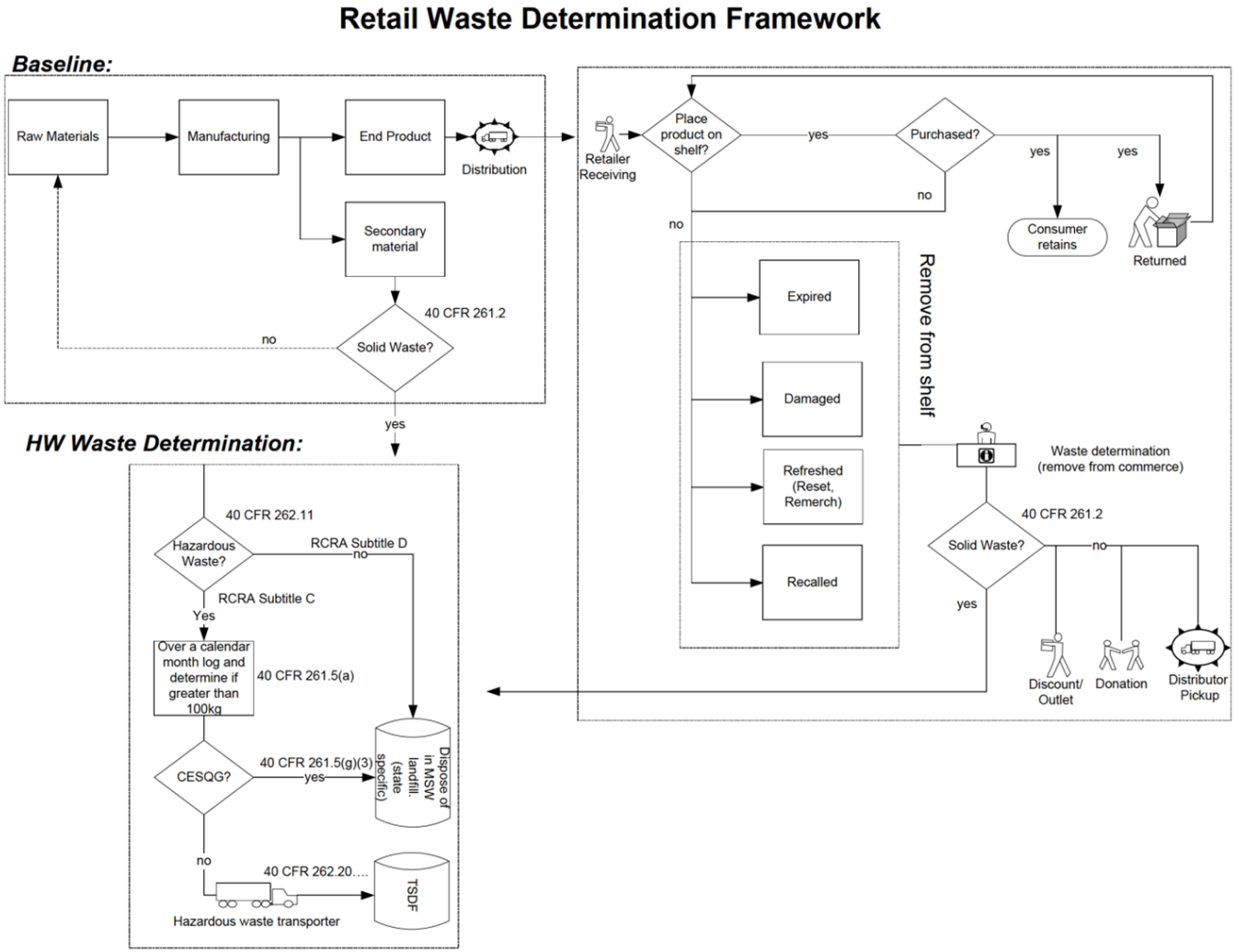
Emerging Regulations

- Pharmaceutical Hazardous Waste Rule (EPA)
- Hazardous Waste Generator Improvements Rule (EPA)
- Reverse Logistics Rule (DOT)

Proposed Pharmaceutical Hazardous Waste Rule

- Retailers across the country have paid more than $150M in fines for hazardous waste handling and disposal violations (EPA and States).
- EPA rule intended to create nationwide consistency—it expressly mentions enforcement activity by regulators in California, Connecticut, and other jurisdictions in discussing the need to provide clarity and promote compliance.
- Focus is on reduction of illegal diversion and eliminating drain disposal of hazardous pharmaceuticals.
- Would preempt any state-specific requirements that are considered “less-stringent.” EPA has expressly stated that it believes the proposed rule is more stringent than all current state-specific requirements.
- May indicate a pendulum swing in regulation, but likely will have business repercussions throughout the supply chain.

Proposed Pharmaceutical Hazardous Waste Rule (cont'd)



Adapted from Council on Safe Transportation of Hazardous Articles, Inc.

Proposed Pharmaceutical Hazardous Waste Rule (cont'd)

- The United States Environmental Protection Agency ("EPA") has proposed adding a new "Subpart P" under 40 C.F.R. Part 266 to RCRA
  - Regulates healthcare facilities that manage hazardous waste ("HW") pharmaceuticals
    - Healthcare facilities—any person who sells or dispenses OTC or prescription pharmaceuticals, including over the internet, through the mail, or otherwise, and is intended to include pharmacies, hospitals, clinics, and long-term care facilities, among others
    - Pharmaceutical—any chemical or biological product intended for use in the diagnosis, cure, mitigation, care, treatment, or prevention of disease or injury of a human or other animal; or any chemical or biological product that is intended to affect the structure or function of the body of a human or other animal, a purposefully broad (or, as some retailers have commented, overbroad) definition
    - Hazardous Waste Pharmaceutical—any pharmaceutical that meets the definition of hazardous waste (i.e., either is listed or exhibits characteristics of hazardous waste)
  - Would define hazardous waste pharmaceuticals broadly to include prescription drugs, OTC drugs, and any other HW items with a "drug facts" label, as well as certain dietary supplements and personal care and beauty products

Proposed Pharmaceutical Hazardous Waste Rule (cont'd)

- Intends to address the compliance concern of pharmaceutical products mishandling and unnecessary hazardous waste costs by proposing two new management standards for HW pharmaceuticals
  - "Potentially creditable" HW pharmaceuticals could be managed by sending to a reverse distributor via common carrier, subject to certain tracking requirements
  - "Non-creditable" HW pharmaceuticals could be managed in a manner generally similar to current small quantity generator ("SQG") management standards for HW (e.g., pharmaceutical could be sent for disposal/destruction using a modified hazardous waste manifest)

Proposed Pharmaceutical Hazardous Waste Rule (cont'd)

- Would subject reverse distributors to potentially burdensome requirements
  - "Reverse distributor" includes any person, "including forward distributors and pharmaceutical manufacturers," that processes pharmaceuticals for the facilitation or verification of manufacturer's credit. This broad definition might include vendors/manufacturers who accept returns.
  - Reverse distributors would be required to notify EPA of their status as a reverse distributor, prepare a HW contingency plan, implement emergency procedures, and, if disposing of any HW pharmaceuticals, comply with the requirements of RCRA with respect to such waste items.

Proposed Pharmaceutical Hazardous Waste Rule (cont'd)

- In general, the proposed rule has the potential to fundamentally alter business relationships among healthcare facilities, suppliers, manufacturers, and reverse distributors, among others
  - Healthcare facilities and reverse distributors may seek to alter vendor and manufacturer supply contracts:
    - To take into account new obligations that would exist under the proposed rule, particularly issues regarding liability, compliance with law, indemnities, and insurance
    - To remove freshness dates from certain products, to the extent permissible, to expand the period of time during which such products could be returned for credit
    - To ensure that credit is available in connection with the return of as many HW pharmaceutical products as possible to maximize the potential of such items being considered potentially creditable HW pharmaceuticals that can be sent back into reverse distribution
  - It is unknown how the proposed new requirements will ultimately affect the market, the reverse distribution and/or hazardous waste disposal business model, or the costs passed on to healthcare facilities and suppliers

Proposed Pharmaceutical Hazardous Waste Rule (cont'd)

- The final rule is scheduled to become effective on or about October 2016, but comments by EPA suggest additional delays are likely.
- Note that EPA continues to seek industry comment on whether and how to define "pharmaceutical" as well as how to address what might be "hazardous." These issues are likely to emerge in a separate rulemaking, under a new administration.
- We are encouraging regulated entities to reach out to business partners and environmental compliance professionals sooner rather than later.

- Background of Resource Conservation and Recovery Act
- "Characteristic" hazardous waste—an Rx (or other regulated item) that has the characteristic of corrosivity, reactivity, ignitability, and/or toxicity
  - Ignitability and toxicity are particularly relevant for Rx items, but also for front of store
  - Ignitable/Flammable: a liquid item with 24% or more alcohol may be ignitable (e.g., anbesol); other items with flammable components (e.g., certain aerosol sprays, inhalers, wart removal compounds, rubbing alcohol, hand sanitizers, hair spray, nail polish remover)
  - Toxic: some items are toxic to function (e.g., selenium) or contain toxic preservatives (e.g., pesticides, antifreeze, OTC medicines)
  - Corrosive and Reactive: These characteristics may be found in items such a lime remover, drain openers, cleaners/degreasers, soaps, batteries
- "Listed" hazardous waste—an Rx or other item that is listed or contains a sole active ingredient that is listed at 40 C.F.R. § 261.33 (includes epinephrine, nicotine, acetone, phenols, and others)

Proposed Hazardous Waste Generator Improvements Rule (cont'd)

- The Scope:

Generator Status	Number of Facilities	Total Hazardous Waste Generated (tons)	Percent of Total Hazardous Waste Generated
CESQGs	293,000–470,000	59,000–144,000	<1%
SQGs	46,000–60,000	70,000–152,000	<1%
LQGs	14,300	34.5 million	99%
Total	353,300–544,300	34.7–34.8 million	**100%**

Source: U.S. EPA estimates.

Proposed Hazardous Waste Generator Improvements Rule (cont'd)

- HW Generator Improvements proposed rule intends to:
  - Reorganize the regulations to make them more user-friendly and thus enable improved compliance by the regulated community
  - Provide greater flexibility for hazardous waste generators to manage waste in a cost-effective manner
  - Strengthen environmental protection by addressing identified gaps in the regulations
  - Clarify certain components of the hazardous waste generator program to address ambiguities and foster improved compliance
  - Notably, the "improved" rule would tailor increasing regulation to increasing volume of hazardous waste

Proposed Hazardous Waste Generator Improvements Rule (cont'd)

- Episodic Generation
  - A one-month increase in volume of HW could cause a CESQG or SQG to be considered a LQG for that month and on a going-forward basis even if typical waste volumes do not warrant it
    - E.g., a one-time disposal of expired nicotine-containing smoking-cessation products (which are considered "acutely hazardous" waste and thus limited to 2.2 pounds/month)
    - Or, hazardous waste generated by recertification of "clean room" or general plant clean-up of greater than 1000 kgs (approx. five 55-gallon drums of liquid waste)
    - Under the current program, that temporary LQG status entails increased hazardous waste management and disposal obligations
  - The proposed rule would provide HW generators a one-time-per-year, 45-day window to accommodate the increased volume of HW without needing to comply with more stringent LQG requirements

Proposed Hazardous Waste Generator Improvements Rule (cont'd)

- Consolidation of CESQG Sites into LQG Facilities
  - HW generators with multiple locations that are currently CESQGs (such as many pharmacies) may not have the staff or infrastructure to efficiently manage their HW
  - For these generators, consolidating HWs from multiple CESQGs into a single LQG location (such as a distribution center) may have environmental and economic advantages, but current rules prohibit this practice
  - The proposed rule would permit CESQGs to consolidate HW at a single LQG location owned by the same person, subject to certain administrative requirements
  - For example, a retail store might be able to send hazardous wastes (including pharmaceuticals and personal care products) to a LQG Distribution Center—or a manufacturer/vendor—for processing, handling, and disposal

Proposed Hazardous Waste Generator Improvements Rule (cont'd)

- Planning and Documentation
  - Clarifies biennial HW reporting obligations
  - Creates obligation to include an executive summary in contingency plans
  - Requires documentation of arrangements with local emergency responders
  - Requires documentation of hazardous waste determinations

Proposed Hazardous Waste Generator Improvements Rule (cont'd)

- Likely will provide greater flexibility for actual day-to-day waste handling, but:
  - Regulatory burden may actually increase, and
  - Potential adverse implications for the industry if Pharmacy and Generator rules are not enacted in tandem.
- Life Sciences manufacturers need to pay close attention to EPA published rulemaking, expected on or about October 2016
- New rule, at best, may require a total reset of corporate EHS policies and, specifically, hazardous waste operations

Reverse Logistics Rule

- Became effective March 31, 2016
- Department of Transportation Pipeline and Hazardous Materials Safety Administration ("PHMSA") amendments limited to "reverse logistics" of non-saleable hazardous materials transported via highway from retail stores to a manufacturer, supplier, or distribution facility
  - Hazardous material—a substance or material capable of posing an unreasonable risk to health, safety, and property when transported in commerce, including hazardous substances and hazardous wastes
- The RL rule creates a new section (§ 173.157) in the Hazardous Materials Regulations (49 C.F.R.)
- Requirements include specialized packaging, labeling, etc. for hazardous items being sent into reverse logistics for return and/or credit

Reverse Logistics Rule (cont'd)

- Reverse logistics rule contemplates that suppliers, manufacturers, and/or distributors will provide retailers with instructions to "properly classify, package, mark, offer, and transport" hazardous materials being sent into reverse logistics
  - Precise extent of such obligations is not well defined
  - Entities subject to the reverse logistics rule may seek to incorporate such obligations into vendor contracts

Conclusions

- This is merely a sampling of current and emerging environmental regulations
- Impacts day-to-day operations and long-term environmental compliance as well as business planning
- Unclear what next administration will pursue (or who next administration will be)

WEARABLES, DEVICES AND CYBERSECURITY

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Medical Device and Electronic Health Record Cybersecurity

- Vulnerability of Health Information
- Wearables and Mobile Apps
- Connected Medical Devices
- Recent Regulatory Attention
- Legislative Prospects
- Potential Liability Issues

- Particular Vulnerability of Healthcare Information
  - 23% of all data breaches occur in healthcare industry (May 2016 Brookings Report)
  - Nearly 90 percent of healthcare organizations had a data breach between 2013 and 2015
  - These breaches cost the industry a total of $6.2 billion
- Why is healthcare data so vulnerable?
  - Valuable identifying information
    - SS no., date of birth, home address
    - Information that cannot be changed (unlike a credit card number)
  - Increasingly shared
  - Kept for many years

Health Information Security

- Existing legal mandates
  - HIPAA
  - ONC Health Information Technology Certification Program
  - FDA premarket review / approval
- Non-Mandatory Regulatory Guidance, including:
  - wearables
  - mobile apps
  - connected medical devices

- Recent government actions:
  - OCR's release of **mHealth Developer Portal**, a community-based portal for developers to post HIPAA-related questions (October 2015)
  - OCR (February 2016) published informal guidance clarifying when mobile apps are subject to HIPAA
  - FTC released web-based interactive tools to help app developers navigate current laws and regulations (April 5, 2016)
- Key issue:
  - When and how does HIPAA apply to mobile apps?
  - For example, is an app that lets patients communicate with their healthcare provider covered by HIPAA if the provider didn't recommend or develop the app?

- Connected Medical Devices
  - Medical devices that transmit information to and from the Internet, hospital IT systems, or each other
  - E.g., heart monitor that connects to EHR or infusion pump with remote dosage controls
  - EHRs are certified, but other types of medical software products are not
  - HIPAA applies to all PHI, regardless of where stored
    - Potential implications / pitfalls:
      - Product updates may be continually necessary to protect security
      - When medical devices are disposed of, they need to be wiped or destroyed to eliminate possibility of disclosure of PHI

Connected Medical Devices – Recent Regulatory Attention

- Health and Safety Vulnerabilities
  - Lessons from Dick Cheney and Hollywood
  - Mayo Clinic standards resulting from 2013 “white hat” hackers study
  - In 2014, Department of Homeland Security’s Industrial Control Systems Cyber Emergency Response Team (ICS-CERT) investigation
    - Investigated potential vulnerabilities in implantable cardiac monitors, pacemakers, infusion pumps, medical imaging systems and hospital networks
  - In July 2015, following warnings from ICS-CERT, FDA issued “stop use” recommendation of particular computerized infusion pump
    - Risk of unauthorized access and control of dosage delivery

Connected Medical Devices – Recent Regulatory Attention

- Non-binding guidance, recommendations, and tools
  - FDA guidance on connected devices
    - Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (October 2014)
    - (Proposed) Postmarket Management of Cybersecurity in Medical Devices (January 2016)
    - Encouraged participation in information exchange through National Health Information Sharing & Analysis Center, Inc. (NH-ISAC)
  - The Crosswalk: Technical guidance developed by OCR in collaboration with ONC and the National Institute of Standards and Technology (NIST) (February 2016)
  - HHS launches Healthcare Industry Cybersecurity Task Force (March 2016)

Congressional Prospects

- Is Congress poised to act?
  - **TRUST IT.** Transparent Ratings on Usability and Security to Transform Information Technology
    - Part of 21st Century Cures legislation, passed by the House in 2015
    - Senator Bill Cassidy (R-La.) pushing for stand-alone bill
  - **Boxer Letter.** Senator Boxer (D-Calif.) open letter to leading medical device companies (Feb. 2016)
    - "serious concerns that the cybersecurity vulnerabilities in medical devices are putting the health and safety of patients in California and across the country at risk"
    - Describe "the steps your companies are taking, or plan to take, to address the growing threat of medical device cybersecurity vulnerabilities."
  - **HHS Data Protection Act.** Bi-partisan sponsors (April 26, 2016)
    - Creates a separate office for the HHS Chief Information Security Officer (CISO)
  - **Cybersecurity Disclosure Act.**
    - SEC disclosures regarding presence of cybersecurity experts on boards of directors
  - **Brookings Institution**

ADVERTISING AND MARKETING: COMMUNICATING WITH CONSUMERS

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TCPA – Overview and Purpose

- Enacted in 1991 primarily to address:
  - Consumer privacy
    - Pre-recorded telemarketing ("robo") calls to residences
    - Calls to mobile phones
- The TCPA:
  - Authorized the establishment of a federal Do Not Call list
  - Established rules regarding the types of consent required to make certain calls
  - Established a private right of action (not generally available under the FTC's Telemarketing Sales Rule)
- TCPA: 47 U.S.C. § 227
- FCC Regulations: 47 CFR § 64.1200 *et seq.*

Damages under the TCPA

- Statutory Damages: $500 per call or text or actual damages, whichever is greater.
- Up to $1,500 per call for willful or knowing violations.
- Potential for significant damages:
  - 1,000 x $500 = $500,000
  - 10,000 x $500 = $5 million
  - 50,000 x $500 = $25 million
  - 100,000 x $500 = $50 million
  - 500,000 x $500 = $250 million
- No cap on statutory damages.
- Settlements in multi-million dollar range not uncommon.

TCPA Requirements

- Basically, need consumer consent before:
  - Using an autodialer to send texts or call mobile phones
    - Texts are calls under the TCPA
  - Placing pre-recorded marketing messages to landlines
- Level of consent determined by type of intended call/message
  - Commercial/telemarketing
  - Purely informational or transactional
- Some exemptions
  - Emergency notices
  - Carrier service messages
  - Healthcare messages under HIPAA

Automatic Telephone Dialing System

- Threshold question for mobile calls: Are you using an autodialer?
  - Statutory definition: "***capacity*** *to store or produce telephone numbers to be called, using a random or sequential number generator and to dial such numbers*"

Automatic Telephone Dialing System (cont'd)

- Issue: Whether the term "capacity," as used in the definition of ATDS, means a device's present or potential capacity.
- FCC July 10, 2015 Ruling: System may be an ATDS if it has the "potential capacity" even though it is not currently being used for autodialing
  - Rejects petitions seeking "present" capacity definition
  - Embraces broad definition for fear of rendering statutory definition meaningless
  - If system requires a mere software fix or unlocking a dormant ATDS function to perform autodialing functions, then it is an autodialer
  - BUT "mere theoretical capacity" is not sufficient
    - What is a "theoretical" capacity?
    - How easily could a system be modified for autodialing?
    - What is considered the system?

Not an autodialer!

What Are Informational Calls Under the TCPA?

- Examples of informational calls:
  - Debt collection calls
  - Calls for political purposes
  - Airline notification calls
  - Bank/credit card balance and fraud alerts
  - School and university notifications
  - Research or survey calls
  - Package deliveries
  - Wireless usage notifications
  - Payment reminders

Purely Informational or Transactional Calls/Messages

- Requires the recipient's "*prior express consent*"
  - 47 C.F.R. Part 64.1200(a)(1)
  - Term not defined in the TCPA or the FCC's TCPA rules
  - The FCC has ruled that this standard may be satisfied by the consumer providing her phone number to the intended caller

    [P]ersons who knowingly release their phone numbers have in effect given their invitation or permission to be called at the number which they have given, absent instructions to the contrary. Hence, telemarketers will not violate our rules by calling a number which was provided as one at which the called party wishes to be reached."
  - May be oral or written
  - But recent case law requires consideration of the context in which the number was provided

Kolinek v. Walgreen Co. (N.D. Ill.)

- Consumer provided mobile number to Walgreens at time of prescription pick up, relying on sales associate statement that the number would only be used to verify his identity for future refills.
- Walgreens sent text messages with refill reminders. Consumer filed TCPA class action.
- Court denied Walgreens' motion to dismiss because questions remained about the context in which the consumer provided his mobile number and his expectation of how the number would be used.
  - More of a "misrepresentation" issue
- Case settled for $11 million.
  - Class size: more than 9 million

What is a telemarketing call?

- A call that includes or introduces an "advertisement" or constitutes "telemarketing"
  - Broadly defined in TCPA Rules
    - Advertisement, 47 C.F.R. Part 64.1200(f)(1)
      - "Any material advertising the commercial availability or quality of any property, goods or services."
    - Telemarketing, 47 C.F.R. Part 64.1200(f)(12)
      - "the initiation of a telephone call or message for the purpose of encouraging the purchase or rental or investment in property, goods, or services, which is transmitted to any person."
- Requires higher level of consent – "*prior express written consent*"

Prior Express Written Consent

- Definition (47 C.F.R. Part 64.1200(f)(8)):

  :"***an agreement, in writing***, *bearing the signature of the person called that clearly authorizes the seller to deliver or cause to be delivered to the person called advertisements or telemarketing messages using an automatic telephone dialing system or an artificial or prerecorded voice, and the telephone number to which the signatory authorizes such advertisements or telemarketing messages to be delivered."*

- Written agreement (can be electronic) shall include a clear and conspicuous disclosure:
  - Executing the agreement authorizes the seller to deliver telemarketing calls using an automatic telephone dialing system or an artificial prerecorded voice; and
  - The person is not required to sign the agreement or enter into the agreement as a condition of purchasing any property, goods or services.

Prior Express Written Consent (cont'd)

- Can be obtained in print, online, IVR
- Sample Agreement Language

  "By [signing] [clicking Yes below] [replying to this e-mail], I consent to receive phone calls from [Company Name], regarding [Company Name's] products and services, at the phone number(s) above, including my wireless number if provided. I understand these calls may be generated using an automated technology and that my consent is not required to make a purchase."
- Agreement must include the consumer's wireless number.
- Signature
  - Paper signature
  - Online & IVR
    - Must satisfy ESIGN Act
    - Click or pressing buttons
    - Must be recorded

"Dual Purpose" Messages

What if a call/text contains both informational and marketing content?

- Dual-Purpose Calls/Texts
  - Calls/texts that contain both informational and telemarketing content are considered by the FCC to be telemarketing for purposes of the TCPA.
  - July 3, 2003 Report and Order
  - Does not matter that a sale is not completed during the call.
- Examples addressed in FCC Report and Order:
  - Calls from mortgage brokers to their clients notifying them of lower interest rates
  - Calls from phone companies regarding new calling plans
  - Calls from credit card companies offering overdraft protection
- Questionable Messages
  - An informational text/call ending in "We value your business."
  - Including a company website URL in a text message.

Dual Purpose Cases

- *Pre-recorded message reminding customers to use their unused loyalty points (Chesbro v. Best Buy* (9th Cir. 2012))
  - Ninth Circuit upheld circuit court finding that prerecorded "courtesy" messages made by Best Buy to its Best Buy Reward Zone members regarding unused reward program certificates were not solely "informational," but rather, dual purpose telemarketing calls, as they encouraged consumers to make a purchase.

- A "Free" offer can trigger liability (*Bennett v. Boyd Biloxi, LLC* (S.D. Ala. May 6, 2015))
  - Court denied defendant's motion to dismiss, finding that prerecorded messages offering free concert tickets to visit a casino was found to be considered both advertising and telemarketing. Though message did not explicitly describe or attempt to other goods/services.

HIPAA & TCPA

The FCC's October 16, 2012 Ruling added two exemptions from the *prior written express consent* requirement:

- **Residential:** Artificial voice/prerecorded telemarketing calls to residential phones are *exempt* from PEWC requirement if the call delivers a "healthcare" message made by, or on behalf of, a "covered entity" or its "business associate," as defined by HIPAA Privacy Rule.
- **Mobile:** Similarly, exemption for calls to mobile phones. Only *prior express consent* required.

The 2012 HIPAA Exception

- **If "healthcare-related call"/"healthcare" message:**

  ⇨ HIPAA rules apply (including marketing rules)

- **If <u>not</u> "healthcare-related call"/"healthcare" message:**

  ⇨ TCPA rules apply

The 2012 HIPAA Exception (cont'd)

- What is a "healthcare-related call" or "healthcare" message?
  - Needs to be a "**healthcare**" message by a "**Covered Entity**" or "**Business Associate**," as those terms are defined by the HIPAA Privacy Rule.
  - **Healthcare** is "care, services, or supplies related to the health of an individual."
  - While "**healthcare**" is generally defined, it is not entirely clear what constitutes a "**healthcare**" message.
  - HIPAA Privacy Rule addresses the use and disclosure of "**protected health information**," not "**healthcare**" messages.

The 2012 HIPAA Exception

- FCC Examples or exempted calls:
  - prescription refills
  - immunization reminders
  - post-hospital discharge follow-up
  - health screening reminders
  - medical supply renewal requests
  - generic drug migration recommendations

- No relevant court cases or FCC petitions pending at this time.

Marketing Under HIPAA

- Marketing is "a communication about a product or service that encourages recipients of the communication to purchase or use the product or service."
  - If marketing, must first obtain the individual's written "authorization"
- Not "marketing" under HIPAA if:
  - The communication imparts information about a product or service that is included in a healthcare benefits plan offered by the covered entity
  - Gives information concerning treatment
  - Describes goods or services for case management or care coordination

2015 FCC Ruling—Exigent Healthcare Message Exemption

- FCC exempts time-sensitive exigent healthcare messages from the TCPA consent requirement.
  - Broader than 2012 exemption
  - Messages are "expected and desired" by consumers
  - Examples provided:
    - appointment and exam confirmations and reminders
    - wellness checkups (surprising, given absence of urgency)
    - hospital preregistration instructions
    - preoperative instructions
    - lab results, post discharge follow-up intended to prevent readmission
    - prescription notifications
    - home healthcare instructions
- But, subject to conditions...

Exempt Healthcare Messages—Conditions

- "Free-to-end-user"
  - The calling party must ensure that consumers are not charged in any way for the communication (including counting towards plan limits)
- Only sent to the wireless telephone number that the customer provided to the calling party
  - *Prior express consent!*
- Required disclosures
- No telemarketing, cross-marketing, solicitation, debt collection or advertising content
- Must be short (one minute or less for voice calls and 160 characters or less for text messages)
- Provide an "easy" means to opt-out of receiving the communication (i.e., an interactive voice or key press-activated opt-out mechanism for voice calls)
- The calling party must immediately honor opt-out requests
- Only one message per day, maximum of three per week per sender

Exempt Healthcare Messages—Other Considerations

- Exemption not applicable to healthcare communications pertaining to:
  - Account communications
  - Payment notifications
  - Social Security disability eligibility
- Prior express consent can be given to a HIPAA-covered entity or Business Associate acting on the covered entity's behalf within the scope of the consent granted.
- Consent may also be provided by a third party in cases where a patient is medically incapacitated (as legally defined).

Net Impact of 2012 and 2015 Rulings

- 2012—Exempts "healthcare" messages from PEWC requirements for marketing calls
  - Broader universe of covered messages
  - FCC list of examples that aren't really marketing
  - Confusing interplay with HIPAA terminology
- 2015—Exigent Exemption
  - Narrow examples
    - None are marketing
  - Free-to-end user
    - *Not happening*
  - Additional content and message limitations
  - 2015 EXEMPTION IS EFFECTIVELY MEANINGLESS

Risk Analysis

- Are you using technology (ATDS) that triggers the consent requirements of the TCPA?
- What type of number is being dialed? Mobile or residential?
- Is it likely to be deemed “telemarketing” or an “advertisement” under the TCPA?
- If yes, does an exemption or exception apply such as the HIPAA exemption?
- If HIPAA applies, is the call likely to be considered marketing under the HIPAA Privacy Rule?
- Scrubbing numbers

Mitigating Risk

- How to avoid TCPA liability
  - Get and maintain appropriate level of consent
  - For residential phones, use live agents and avoid artificial voices or prerecorded voice messages
  - For mobile phones, have live agents make manually dialed calls
  - Have members identify type of phone number being provided. Hiring a vendor to scrub for phone type is still recommended
  - Scrub DNC, wireless and reassigned databases
- Ensure collection of consumer phone numbers is not limited
- How to get *prior express written consent*
  - Member applications
  - Account login
  - Customer service call/ inbound IVR
  - Online lead forms

Questions?

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