



PROTECTING THE TELEHEALTH CONSUMER: FTC AND STATE- BASED CONSIDERATIONS

Brian Boyle, Partner
Jiayan Chen, Partner
Matthew Cin, Associate

**McDermott
Will & Emery**

mwe.com



SPEAKERS



BRIAN BOYLE

McDermott Will & Emery
Partner | Washington, D.C.

bboyle@mwe.com



JIAYAN CHEN

McDermott Will & Emery
Partner | Washington, D.C.

jychen@mwe.com



MATTHEW CIN

McDermott Will & Emery
Associate | Chicago

mcin@mwe.com

TELEHEALTH LEGAL CONSIDERATIONS

Technology
Development

Privacy and
Security

IP/Data Strategies

Care Delivery
Considerations

FDA/Regulatory

Reimbursement /
Payment Strategy

Commercialization
Strategy

Investment &
M&A

Licensing and
Collaborations

AGENDA

- Beyond HIPAA: FTC & State Privacy Considerations
- Advertising Telehealth
- Social Media
- Online Reviews
- Engaging with Users in the Digital Environment

FTC & STATE PRIVACY CONSIDERATIONS

Going beyond HIPAA



FTC REGULATION OF PRIVACY & SECURITY

- No general purpose federal privacy law
- FTC Act used as flexible tool
 - Poor security as a deceptive practice
 - Misrepresenting data privacy or security
- Additional FTC considerations
 - Children's Online Privacy Protection Act
 - Gramm-Leach-Bliley Act
- Statutes enforced by other agencies

FTC EXPECTATIONS FOR DIGITAL HEALTH

Minimize Data

Limit Access
and
Permissions

Keep
Authentication
in Mind

Consider the
Mobile
Ecosystem

Implement
Security by
Design

Follow Best
Practices

Communicate
Effectively with
Consumers

Remember
Other Laws

LESSONS FROM RECENT ENFORCEMENT

- Flo Health Inc. Case (January 2021)
 - Allegedly shared the health information of users with outside data analytics providers after promising that such information would be kept private
 - Violated FTC Act
 - Democratic commissioners urged application of **Health Breach Notification Rule**

DATA BREACH CONSIDERATIONS

- Notice is a key part of data breach response
- **State laws** typically tell you what information you must, or must not, provide in breach notices
- FTC has articulated its own expectations
- **Health-related breaches** may trigger special obligations
 - HIPAA Breach Notification Rule
 - FTC's **Health Breach Notification Rule**

HEALTH BREACH NOTIFICATION RULE

Who

- Affected individuals
- FTC
- Media
- Clients

When

- Depends on size of breach
- As little as 10 days
- “without unreasonable delay”

How

- Plan in advance
- E-Mail
- First Class Mail
- Webpage
- Media

What

- What happened
- What data
- Steps for individuals
- What you’re doing
- Contact information

ADDITIONAL STATE CONSIDERATIONS

- State privacy laws are proliferating
 - Know the laws in your states
- California Consumer Privacy Act (CCPA)
 - Organization's **status under HIPAA**, and the **purpose** for which the organization collects data, may affect exemptions
 - Information other than HIPAA PHI may be covered
- Need to carefully evaluate applicability of state laws to your data

ADVERTISING TELEHEALTH

FTC Considerations



ADVERTISING BASICS

- Advertising must be **truthful and not misleading**
- If an ad can be reasonably **interpreted in multiple ways**, each reasonable interpretation must be true
- **Claims** (express, implied, comparative) must be **substantiated** before they are made
- The **net impression** of the ad must be true
- Cannot be **deceptive** (must disclose “material” facts and can’t present facts in a false or deceptive light)

WHAT IS REQUIRED FOR “CLAIM SUBSTANTIATION”?

- It is a deceptive practice to make **unsubstantiated claims** about a product or service
 - An advertiser must have a reasonable basis for all express and implied claims about the product or service before disseminating the claims
- If an advertiser makes an express or implied statement about the amount of support it has for a claim (e.g., “studies show”), it must have the **amount and type of substantiation claimed**
 - The exact amount and type of substantiation required depends on several factors, including the product or service, the claim being made, the consequences of a false or misleading claim (e.g., risks to users), the benefits of a truthful claim, the cost of substantiating the claim, and the substantiation that experts in the field would consider reasonable

HEALTH AND SAFETY CLAIMS

- Require a **high level** of substantiation
- Competent and reliable scientific evidence
 - Tests, studies, other scientific research
 - Based on expertise of professionals in field
 - Objectively conducted by qualified people
 - Using procedures accepted as accurate
- **NOT**: anecdotal evidence from patients



WHAT IS “FALSE OR MISLEADING”

- Claims may be false or misleading if they:
 - Do not include appropriate content and context of information
 - Suggest that non-clinical data has clinical significance when no such clinical significance has been demonstrated
 - Misrepresent literature, data, or quotes from other sources
 - Use headline, pictures, or graphic matter in a misleading manner
 - Suggest a procedure is safer or more effective than has been demonstrated

SOCIAL MEDIA



THIRD-PARTY TESTIMONIALS AND ENDORSEMENTS



kimkardashian

FOLLOWING

464k likes

1w

kimkardashian OMG. Have you heard about this? As you guys know my #morningsickness has been pretty bad. I tried changing things about my lifestyle, like my diet, but nothing helped, so I talked to my doctor. He prescribed me #Diclegis, I felt a lot better and most importantly, it's been studied and there was no increased risk to the baby. I'm so excited and happy with my results that I'm partnering with Duchesnay USA to raise awareness about treating morning sickness. If you have morning sickness, be safe and sure to ask your doctor about the pill with the pregnant woman on it and find out more www.diclegis.com; www.DiclegisImportantSafetyInfo.com

[view all 10,983 comments](#)

[imoumaima @youssefchorfi](#)

[flawlessfashionstore](#) ldk if shes getting

THIRD-PARTY CONTENT: FTC IMPLICATIONS

- Endorsements **cannot convey express or implied claims that would be deceptive** if advertiser made them directly
- Must have **adequate substantiation** for all claims (express or implicit) made through endorsements
- Endorsements must reflect the **honest opinions, findings, beliefs, or experience** of the endorser
- If the ad represents that the endorser used the product, they must have been a **bona fide user**
- Must **disclose material connections** with the endorser

DISCLOSING MATERIAL CONNECTIONS

- Material connections must be adequately disclosed on all endorsements, including statements in social media
 - Material Connection: any financial, employment, personal, or family relationship with a brand, including receiving free product or anything of value
 - Adequate Disclosure: clear and conspicuous, #ad before clicking more, displayed in the first 2-3 lines, standing alone
- Include appropriate provisions in agreements with influencers

ONLINE REVIEWS



CUSTOMER REVIEWS

- Section 5 of the FTC Act prohibits unfair and deceptive acts and practices. When it comes to reviews this means:
 - Negative reviews cannot be suppressed
 - Negative reviews cannot be hidden – reviews should be displayed by date, not star rating
 - Incentives for reviews must be disclosed – such as being entered in a sweepstakes
 - Material connections between the reviewer and the reviewed product must be disclosed – such as an employee or owner of the company, receipt of free product
 - Review gating is prohibited

CUSTOMER REVIEWS

- The Consumer Review Fairness Act makes it illegal for companies to include standardized provisions that threaten or penalize people for posting honest reviews
- The Act makes it illegal for a company to use a contract provision that:
 - bars or restricts the ability of a person who is a party to that contract to review a company's products, services, or conduct,
 - imposes a penalty or fee against someone who gives a review, or
 - requires people to give up their intellectual property rights in the content of their reviews
- The law doesn't apply to employment contracts, independent contractors

ENGAGING WITH USERS IN THE DIGITAL ENVIRONMENT



MASS COMMUNICATION CONSIDERATIONS

Automated or Prerecorded Calls and Text Messages

- Regulated by the Telephone Consumer Protection Act
 - Among other things, the TCPA regulates the use of an automated telephone dialing system (ATDS) and artificial / prerecorded voice (PRV) in certain telephone communications
 - Different levels of consent to make calls/texts
 - Penalties - \$500/\$1,500 per negligent/willful violation (per call/text)
 - Four relevant exemptions to the TCPA's consent requirements

TCPA CONSENT STANDARDS

Prior Express Consent – Informational

- FCC and many courts have interpreted the term to mean any written or oral consent to receive calls at a particular phone number
- “Implied Consent”
 - Some courts have concluded that when a consumer knowingly provides a phone number to a business, the consumer consents to receive informational calls or texts to the phone number
 - But scope of consent is critical

Prior Express Written Consent - Telemarketing

- Agreement in writing before call/text
- Signature, including electronic or digital signature or voice recording, of recipient
- Recipient clearly authorizes the call/text
- Clear and conspicuous notice that would be apparent to a reasonable consumer, separate and distinguishable from other disclosures
- Services cannot be conditioned on telemarketing consent

MASS COMMUNICATION CONSIDERATIONS CONT'D

Commercial Emails

- The Controlling the Assault of Non-Solicited Pornography And Marketing Act (the “CAN-SPAM Act”) - 15 U.S.C. §§ 7701–7713
 - A federal law that establishes requirements for commercial electronic mail message
 - Provides recipients with the right to opt-out of receiving such messages
 - The CAN-SPAM Act applies to any “electronic mail message the primary purpose of which is the commercial advertisement or promotion of a commercial product or service”
 - Note that the term “commercial electronic mail message does not include transactional or relationship messages

SUMMARY OF CAN-SPAM ACT REQUIREMENTS

- **Use accurate email header information:** The “From,” “To,” “Reply-To,” and routing information – including the originating domain name and email address – must be accurate and identify the entity initiating the email.
- **Use accurate email subject lines:** The subject line must accurately reflect the content of the message.
- **Identify the message as an advertisement:** The email must clearly and conspicuously disclose that the email is an advertisement.
- **Provide sender’s mailing address:** The email must provide recipients with the sender’s valid physical mailing address.
- **Instructions on how to opt-out of receiving future emails:** The email must include clear and conspicuous instructions on how to opt-out of future emails. The notice should be easy for an ordinary person to recognize, read, and understand. The email must also provide a return email address or another easy Internet-based way to allow people to opt-out.
- **Honor opt-out requests promptly:** Honor a recipient’s opt-out request promptly, but in no case later than 10 business days. Any opt-out mechanism must be able to process opt-out requests for at least 30 days after you send your message.
- **Monitor service providers:** You cannot contract away your legal responsibility to comply with the law. Both the company whose product is promoted in the email and the company that actually sends the email may be held legally responsible.

MASS COMMUNICATION CONSIDERATIONS CONT'D

Call Recording Laws

- State and federal wiretap laws require the consent of some/all parties to calls that are recorded
- One-party consent: Federal standard and over 35 states
 - Federal law permits recording of conversations with the consent of one party to the conversation (including the caller)
- Two-party consent: A small handful of states require the consent from all parties to a conversation
- In some states, it is sufficient if the other parties to the call know that the call is being recorded and proceed with the communication, even if there is not an explicit consent

CONTRACT CONSIDERATIONS

Contracting with Consumers

- How to bind users to Terms of Service?
 - Click-wrap vs browse-wrap mechanism
- Privacy Policy as a Contract
 - **Terms of Service** – User agreement governing access and use of a service
 - **Privacy Policy** – Compliance document setting forth information on how the business will collect, use and disclose user data
- Procedurally enforceable - readability is critical
- Substantively enforceable?
 - Arbitration and class action waiver provisions
 - Limitations of liability

CONTRACT CONSIDERATIONS CONT'D

Electronic Signatures

- With the passage of the ESIGN Act, electronic signatures became legal in every state and U.S. territory where federal law applies
- Where federal law does not apply, most U.S. states have adopted the Uniform Electronic Transactions Act (UETA)
- The main thrust of ESIGN and UETA is that a signature, record or contract may not be denied legal effect solely because it is in electronic form
- Both the ESIGN Act and UETA have general minimum requirements for the acceptance of e-signatures, as well as certain exceptions for which e-signatures are generally not acceptable

CONTRACT CONSIDERATIONS CONT'D

Auto-Renewal Laws

- Regulates recurring subscriptions and negative option contracts
- State and federal auto-renewal laws impose several requirements on businesses that charge a consumer's credit card automatically on a recurring basis
- These requirements include additional disclosures embedded throughout the user interface, including next to the various portions of the website that mention the subscription (or free trial) and in advertisements that promote the subscription offer
- There are a number of additional requirements to comply with such laws, including email acknowledgements, easy ability to cancel, among others

QUESTIONS?



THANK YOU

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