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Marketing Meets Law: Your Guide to Compliance and Creativity

Presented by: Christine Au-Yeung, Aaron Hendelman, Brandon Leahy, and Alyssa Worsham | Wilson Sonsini; and Noah Drake | Roblox

June 18, 2025

Agenda

- **12:30 – 1:00 p.m.** Registration, Lunch, and Introductions
- **1:00 – 1:45 p.m.** Navigating Telemarketing Practices and Compliance Under the TCPA
- **1:45 – 2:00 p.m.** Break
- **2:00 – 2:45 p.m.** Strategies for Global Brand Expansion and Enforcement on Any Budget
- **2:45 – 3:00 p.m.** Break
- **3:00 – 3:45 p.m.** Navigating Contests and Sweepstakes with Your Marketing Team: An In-House View
- **3:45 – 4:00 p.m.** Break
- **4:00 – 4:45 p.m.** Advertising Review and Substantiation: Best Practices for Marketing Teams
- **4:45 – 5:00 p.m.** Break
- **5:00 – 6:00 p.m.** Reception

Today's Presenters



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Navigating Telemarketing Practices and Compliance Under the TCPA

Christine Au-Yeung, Wilson Sonsini

Alyssa Worsham, Wilson Sonsini

The Telephone Consumer Protection Act, 47 USC 227 ("TCPA") Overview

Enacted in 1991 to address abusive telemarketing practices

Separate provisions for:

- Calls to residential lines
- Calls to wireless lines
- Prerecorded voice message calls
- Faxed ads
- Calls to numbers on the federal DNC list
 - FCC regulations and numerous (often inconsistent!) declaratory rulings
 - Strict liability statute
 - Private right of action with statutory damages of \$500-\$1,500 per violation
 - Many huge settlements



Why Strict Compliance Matters

- As of April 2025: 691 TCPA class actions have been filed in 2025 (compared to 331 TCPA class actions filed in same period in 2024)
- April 2025 alone: 235 TCPA lawsuits filed – 78% were class actions

Fine

- Dish Network - \$280 Million Fine

Case Settlements

- JP Morgan Chase Bank - \$3.75 Million
- Frontier Communications Corp. - \$11 Million
- Orange Cab Co. - \$5.3 Million
- American Eagle Outfitters - \$14.5 Million

Other Considerations

- Lots of legal fees
- Insurance coverage often limited for TCPA liabilities



**Mandatory Arbitration Provision with
class action waiver is best protection**



Calls to Wireless Numbers

- Wireless calls/texts are the hottest area for TCPA litigation
 - Some form of consent required for all calls to wireless numbers
 - Most courts say the defendant has the burden of showing consent
- Applies to Text Messages
 - FCC and courts say a text is a “call”
 - Push notifications – generally not considered text b/c controlled by app user
- Covers calls to wireless numbers placed using an “automatic telephone dialing system” or “artificial or prerecorded voice”



Calls to Wireless Numbers, Including Texts

FCC's TCPA Regulation

■ No person or entity may:

- Except as provided in [paragraph \(a\)\(2\)](#) of this section, **initiate any telephone call** (other than a call made for emergency purposes or is made with the **prior express consent of the called party**) **using an automatic telephone dialing system or an artificial or prerecorded voice**;
 - To any emergency telephone line, including any 911 line and any emergency line of a hospital, medical physician or service office, health care facility, poison control center, or fire protection or law enforcement agency;
 - To the telephone line of any guest room or patient room of a hospital, health care facility, elderly home, or similar establishment; or
 - To any telephone number assigned to a paging service, cellular telephone service, specialized mobile radio service, or other radio [common carrier](#) service, or any service for which the called party is charged for the call.

Calls to Wireless Numbers, Including Texts (Cont'd)

FCC's TCPA Regulation

- Initiate, or cause to be initiated, any telephone call that includes **or introduces an advertisement or constitutes telemarketing**, using an automatic telephone dialing system or an artificial or prerecorded voice, to any of the lines or telephone numbers described in paragraphs (a)(1)(i) through (iii) of this section, **other than a call made with the prior express written consent of the called party or the prior express consent of the called party when the call is made by or on behalf of a tax-exempt nonprofit organization, or a call that delivers a “health care” message made by, or on behalf of, a “covered entity” or its “business associate,” as those terms are defined in the HIPAA Privacy Rule, [45 CFR 160.103](#).**

What Is an Automatic Telephone Dialing System?

Statutory Definition of ATDS

- The term automatic telephone dialing system means equipment **which has the capacity to—**
 - Store or produce telephone numbers to be called, **using a random or sequential number generator**; and
 - Dial such numbers.

2021 *Facebook v. Duguid* Ruling from SCOTUS

- A device must have the capacity either 1) to store a telephone number using a random or sequential number generator, or 2) to produce a telephone number using a random or sequential number generator.
- Calls and text messages from systems that do not include a random or sequential number generator are outside the scope of the TCPA
- “Footnote 7 theory”: “[A]utodialer might use a random number generator to determine the order in which to pick phone numbers from a preproduced list.” What does this mean?
 - 9th Circuit: Rejected claim based on isolated reading of this FN
- BUT: State laws = mini TCPAs with more stringent regulations

Use of AI Technologies Under TCPA

■ “We confirm that the TCPA’s restrictions on the use of “artificial or prerecorded voice” **encompass current AI technologies that resemble human voices and/or generate call content using a prerecorded voice.**” *In the Matter of Implications of Artificial Intelligence Technologies on Protecting Consumers from Unwanted Robocalls and Robotexts*

■ FCC issued Notice of Proposed Rulemaking targeting use of AI-related technologies:

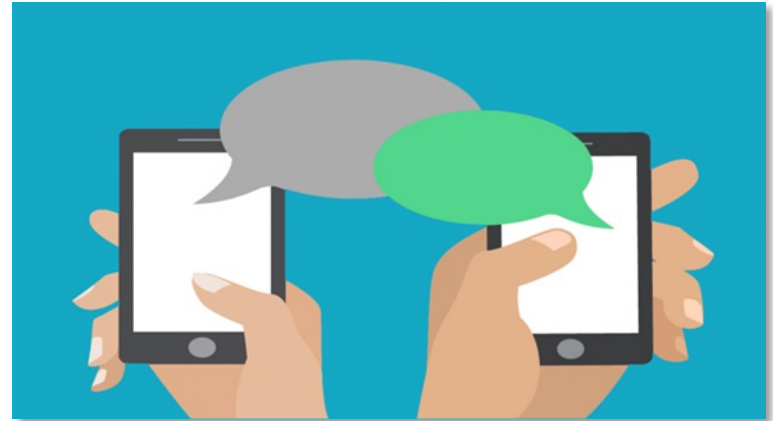
- Disclosures required when seeking prior express written consent and prior express consent
- Disclosures required when using AI-generated invoices



State Text Messaging Laws Are on the Rise

States with laws governing text messaging include:

- | | |
|---------------|----------------|
| ■ Arizona | ■ New Jersey |
| ■ New York | ■ North Dakota |
| ■ California | ■ Oklahoma |
| ■ Colorado | ■ Rhode Island |
| ■ Connecticut | ■ Utah |
| ■ Florida | ■ Washington |
| ■ Indiana | ■ Wisconsin |



TCPA Consent

Requirements for “prior express consent” differ based on type of text message.

■ **If purely informational**, consent can be verbal or based on provision of a cell phone number to the party sending the text in a context where the consumer would expect such calls/texts

- Ninth Circuit — plaintiff expressly consented to informational text messages to an existing customer when he provided cell number to company. (*Roberts v. Paypal, Inc.*, No. 4:12-cv-00622, Oct. 29, 2015)
 - Appointment reminders
 - School closings
 - Package delivery
- **BEST PRACTICE:** get affirmative opt-in consent

■ **If includes an ad or amounts to telemarketing**, then “prior express written consent” required

- Telemarketing = “Any call that advertises the commercial availability or quality of any property, goods, or services, or is made for the purpose of encouraging the purchase or rental of, or investment in, property, goods, or services”
- Advertisement = “Any material advertising the commercial availability or quality of any property, goods, or services”
 - Promotions
 - Download the app
 - Dual purpose
 - Seeking consent for marketing texts
 - INTENT of text (rather than specific language used)

TCPA Consent (Cont'd)

Prior express written consent regulatory definition:

- 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 advertisement or telemarketing messages to be delivered.
- **The written agreement shall include a clear and conspicuous disclosure informing the person signing that:**
 - By executing the agreement, such person authorizes the seller to deliver or cause to be delivered to the signatory **telemarketing calls** using an **automatic telephone dialing system or an artificial or prerecorded voice**; and
 - The person is **not required to** sign the agreement (directly or indirectly), or **agree** to enter into such an agreement **as a condition of purchasing** any property, goods, or services.
- The term “signature” shall include an electronic or digital form of signature, to the extent that such form of signature is recognized as a valid signature under applicable federal law or state contract law.

Methods of Obtaining TCPA Express Written Consent

- **Gold standard:** Opt-in check box with prominent disclosure language on page where phone number is provided.
- **Pretty good but can be challenged:** prominent acknowledgement language proximate to button that user must click on page where phone number is provided.
- **Likely sufficient:** recorded consent on incoming call following reading of disclosure.
- **Likely sufficient:** via text response in connection with “call to action” or in response to agreement to continue conversation via text.
 - [NAME OF COMPANY/PROGRAM]: Rply Y to [confirm agreement to receive texts/complete signup and agree to receive texts]. May be sent by autodialer and include promotional content. Agmt not condition of any purchase. Rply STOP to opt out, HELP for help. Msg & Data Rates May Apply.

Prior Express Written Consent Examples

- I hereby [] consent [] do not consent to receive autodialed SMS text messages from or on behalf of [COMPANY AND ANY OTHERS WITH WHOM NUMBER IS PROVIDED] in connection with the services described herein at the following cell phone number: _____. I also agree and understand that in addition to purely informational texts, these texts also may include promotional material related to [COMPANY'S] products and services, that they may be sent using an autodialer or other automated technology, and that I am not required to provide my consent to marketing texts as a condition of any purchase. Reply STOP to any text or email [email address] to opt out at any time.
- By providing my phone number above and clicking the “SUBMIT” button I agree to receive calls [and/or text messages] at the number provided above from []. We're required to inform you that these calls[and/or text messages] may be considered marketing under applicable law, they may be made using an autodialer, and your consent is not a condition of purchase.
- [] I want to receive texts from [] at the number provided above. I understand and agree that these texts may include promotional content, they may be sent using an automatic telephone dialing system, and my agreement is not a condition of purchase.

Exceptions to Express Written Consent Requirement

- Texts by or on behalf of tax-exempt non-profit organizations
- Texts that deliver a “health care” message made by, or on behalf of, a “covered entity” or its “business associate,” as those terms are defined in the HIPAA Privacy Rule, 45 C.F.R. 160.103 [45 CFR 160.103](#).
 - Check with digital health experts
- Texts to collect a government debt **no longer** exempted
 - Check with financial services experts (Consumer Financial Protection Bureau)

One Time “On Demand” Text Messages

One-time text message sent immediately after a consumer’s request for a text does not violate the TCPA:

- Texts sent in response to a consumer’s request are not telemarketing but rather fulfillment of the request
- Conditions:

- Requested by the consumer
- Only one text in response (not signing up for a series of texts)
- Text sent immediately in response
- Contains only the information requested by the consumer with no other marketing or advertising



Other Exceptions

- **Clinical trials?** Calls made to residential landlines for the **sole purpose** of identifying participants for pharmaceutical clinical trials exempt from prior express written consent as long as no more than 3 of such calls made within any consecutive 30-day period and opt-out mechanism. *In re Matter of Acurian, Inc.*, Petition for Declaratory Ruling (F.C.C. Jan 15, 2021).
 - Applicable to wireless calls and texts?
- **Reviews on services already performed:** Texts sent for the **sole purpose** of requesting reviews on services already performed may be exempt from prior express written consent because they do not advertise commercial availability or quality of any product/service
- **Emergency purpose exception:** “Speed the dissemination of information” to the public regarding hazardous conditions
 - School callers may lawfully make robocalls and automated texts to student family members
 - Utility companies may make robocalls and automated texts on matters closely related to utility service (e.g., service outage, potential service interruptions)

Summary of General Requirements for Calls/Texts to Wireless Numbers

■ Questions for calls/texts to wireless:

- Using an Automatic Telephone Dialing System (ATDS)?
- Using Artificial or Pre-Recorded Voice Messages?
- If either is true, need prior express consent from the recipient
- Purely informational messages (e.g., fraud alerts, appointment reminders) = prior express consent
- Telemarketing messages = prior express written consent

■ No business relationship/inquiry exception in this context!

■ Cannot text recipient for the purpose of obtaining prior express written consent

Revocation of Consent

Revocation:

- “Until revocation occurs the caller may rely on the previous consent” [except for reassigned numbers]
- Revocation can be made via any “reasonable means that clearly expresses his or her desire not to receive further calls”

Standard Opt Out Keywords for Texts:

- STOP, QUIT, CANCEL, END, UNSUBSCRIBE
- Importance of telling recipient of command—don't have to, but you should!
- Check Mobile Marketing Association and CTIA for other best practices
- Companies should regularly audit blacklisting functionality

A single confirmation of opt out text is permitted:

- Confirmatory text should be made within 5 minutes of receipt of the opt-out request. If it is made within 5 minutes, it is presumed to fall within the consumer's prior express consent. If it takes longer to send the confirmatory text, then the sender has to show that its delay was reasonable

Revocation of Consent (Cont'd)

A single confirmation of opt out text is permitted

- The confirmatory text should be made within five minutes of receipt of the opt-out request. See FCC's Soundbite Ruling. If it is made within five minutes, it is presumed to fall within the consumer's prior express consent. *Id.* If it takes longer to send the confirmatory text, then the sender has to show that its delay was reasonable.

Capital One Services, LLC FCC Petition – still pending (Filed November 1, 2019)

- Seeking declaratory ruling that a text message in response to a customer's opt-out request that seeks to clarify the scope of their request would not constitute a violation of the TCPA. The text message would confirm whether customer seeks to cancel one part of a broader automatic text-messaging program rather than the entire service.

Platform/App Liability for Texting

Who is liable for “making” the call (or sending the text)?

- 2015 FCC Ruling provided some relief for app/platform providers that facilitate texts

For apps and texting/calling platforms that can be used by others to send texts, the FCC says it will look to the **“totality of the facts and circumstances”** to determine:

- Who took the steps necessary to physically place the call; and
- Whether the app or platform provider was so involved in placing the call to be deemed to have initiated it "considering the goals and purposes of the TCPA."



Platform/App Liability for Texting

FACTORS:

- Who decides whether the texts are sent?
- Who selects the cell phone numbers to which the texts were sent?
- Who supplies the content of the messages?
- Can the user be deemed to have “programmed” the app/platform to send the texts?
- Did the app/platform knowingly allow its users to use the app or platform for unlawful purposes?

KEY IS USER CONTROL EVEN IF SOME INVOLVEMENT BY APP/PLATFORM

Additional considerations:

- Did the app/platform willfully enable spoofing?
- Did the app/platform willfully enable caller ID blocking
- Did the app/platform knowingly allow its users to use the app or platform for unlawful purposes?

FCC SEEMS MORE CONCERNED WITH **LEVEL OF INVOLVMENT VS. TECHNICAL INITIATION**



Peer to Peer Communications

- One-on-one individual communications
- Seeing more often in customer service
- FCC issued declaratory ruling directly addressing that P2P click-to-text platforms are NOT autodialers
 - “The fact that a calling platform or other equipment is used to make calls or texts to a large volume of telephone numbers is not determinative of whether that equipment constitutes an autodialer under the TCPA”
 - “If a calling platform is not capable of dialing such numbers without a person actively and affirmatively manually dialing each one, that platform is not an autodialer and calls made using it are not subject to the TCPA’s restrictions”

ALSO

- If only responding, you might fall under one-time text exception



Wrong Number/Reassigned Number Calls

- No liability for calls made with “the prior express consent of the called party.” ***But who is the called party?***
- 7th Cir. said “called party” refers to “the person subscribing to the called number at the time the call is made”
- FCC Order established nationwide reassigned numbers database with information provided by telephone companies that callers can use to avoid calling reassigned numbers
- Provides for very narrow safe harbor to protect callers from liability for any calls to reassigned numbers caused by database error (caller bears burden of proof and persuasion).

Best Practice: Third-party Solutions

- For now, risk best mitigated with third party solutions





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Strategies for Global Brand Expansion and Enforcement on Any Budget

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Scaling a Global Brand on a Budget: Make The Money Count

- Costly to implement strategy for every single product name, feature name, brand variation, tagline, logo, etc.
- What is the business' "house mark"?
 - Company name
 - House logo
- How will the business *primarily* use its mark?
 - Consumer products?
 - Life sciences or medical device?
 - Software as a service?
- How important is the brand to the company and its offering?
- Consider whether the logo or stylization will evolve overtime—with new funding comes more marketing budget.
- When to consider not filing
 - Descriptive marks can help educate



Scaling a Global Brand on a Budget: Preliminary Clearance

- Arguably one of the most important steps in brand protection process
- Determine protectability and risk of brand
 - Is the mark “descriptive”
 - Is the mark a common or trendy word?
 - Do you see other marketplace use for similar (if not the same) offerings?
- Perform high-level cursory searches on:
 - Google
 - Social media handles
 - USPTO database
- Engage outside counsel for more detailed searches, but only after some internal research to save \$\$
- Domain availability or availability on corporate register are not dispositive

Know When to Go Big with Formal Clearance

- It is always critical to properly assess availability and protectability across markets, but some industries are less forgiving
 - Increased risk examples: Consumer goods, pharma, new brand campaigns by public companies, expensive products
 - Conduct initial high-level diligence directly or via branding agency
 - Identify the nature of the intended uses and the target markets
 - Engage counsel for a full formal clearance process
 - Counsel should review a range of sources – trademark databases, business names, domain names, web hits, pharmaceutical databases
 - Consider engaging foreign counsel in mission-critical jurisdictions
- Better late than never
 - Even if a name is already in use, a search can provide valuable information to mitigate risk
 - Filing is not always the best policy

Scaling a Global Brand on Any Budget: Broad Considerations

■ Is the brand in use yet?

- If not, consider ITU application in US and national applications in critical markets
- If yes, where? Consider common law protection to date.
- If US mark is registered, consider leveraging both nationals and Madrid for gap-filling

■ What are your key geographies now and in the next few years?

- If the company is a consumer product, consider import/export issues and counterfeiting
- If the company has already received a lot of PR (or it's expected to) consider defensive filings even if no market plans

■ What are your key brands?

- Focus on core word mark
- Stylized filings can help if word mark presents challenges
- Slogans can be unprotectable in certain geos (EU) or fleeting in marketing departments

Scaling a Global Brand on a Budget: Key Geographies

- Trademark rights are territorial
- If budget is tight, lock in US registration and go from there when you can
- Expensive to implement full-blown strategy in every country around the world, even for larger companies
- Focus on your most important business territories over the next 3-5 years + defensive considerations
- Usual suspects:
 - US, EU, UK, Canada
 - New Zealand, Australia, Japan, Korea and HK
 - China, Turkey, Russia, India, Brazil



Scaling a Global Brand on a Budget: Trademark Filings

■ File strategically in geographies that matter

■ Cost-effective considerations:

- Paris Convention filing window
 - **Pro:** Allows companies to stagger / push costs over six months; broad protection
 - **Con:** Can be expensive with national applications
- Madrid Protocol / WIPO
 - **Pro:** Allows companies to file a single International Registration (IR) at the World IP Office (WIPO) and extend to multiple territories
 - **Con:** Limited protection; all filings/extensions are tied together
- EUTM Filing
 - Single application covers 27 member countries

Scaling a Global Brand on a Budget: Enforcement

- Enforcement is key to maintaining brand value
- Responsible for taking *reasonable* effort to police third-party brands
 - Not necessary or efficient to take action against every single minor issue out there
- Geographies of interest and flagrant infringement are most important
- Watch notices
 - Allow companies to be notified early re: third-party issues, which can save money in the long run
 - Have counsel review and send for in-house buy-in before taking action to save money, or perform in-house review and flag hits for outside counsel





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Navigating Contests and Sweepstakes with Your Marketing Team: An In-House View

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Advertising Review and Substantiation: Best Practices for Marketing Teams

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Claim Substantiation and Comparative Advertising

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Who Are the Advertising "Police"?

■ Food and Drug Administration (FDA)

- Primary responsibility for ensuring the safety of foods, cosmetics, dietary supplements, drugs, biologics, and medical devices
- FDA has primary enforcement authority re **labeling** of FDA-regulated devices



■ Federal Trade Commission (FTC)

- Primary jurisdiction to regulate the truth or falsity of advertising across industries.
- FTC has primary enforcement authority re **advertising** of most FDA-regulated devices
- Publishes endorsement guides



■ National Advertising Division of BBB (NAD)

- Self-regulating dispute resolution forum that reviews factual claims for truthfulness and accuracy. Streamlined process, with written decision within 60-90 days (or faster for single-issue claims).
- Accepts cases involving product performance claims, superiority claims against competitive products, and scientific and technical claims.
- Compliance with findings is voluntary, but declination results in referral to FTC



■ State AGs and Private Rights of Action

Principles Behind Claim Substantiation

FTC focus: whether **material** claims for a product are **truthful, non-misleading** and **substantiated by “competent and reliable” scientific evidence**

- Substantiate claims before disseminating
- Advertiser responsible for all reasonable interpretations
- Advertiser responsible for third-party claims
- Supportive material must be timely and current
- Supportive materials can include peer-reviewed studies and expert testimony
 - NOT newspaper articles, sales materials, anecdotes
- Advertisers must possess at least the level of substantiation claimed in marketing
- Rules apply to third-party testimonials, endorsements



Puffery: No Substantiation Needed

Generalized, exaggerated, or vague statements that a reasonable person would not rely on as a factual claim do not require substantiation. “Puffery” statements are often hyperbolic. But court decisions are notoriously inconsistent, so make sure to evaluate the overall net impression – any ambiguities can be held against the advertiser.

Puffing

- “Best in the universe”
- “Exceptional care”
- “Excellent prices”

Not Puffing – Substantiation Needed

- “Most reliable test available”
- “Lowest price test”
- “Tested on over 400k patients”



Context can determine whether the same statement is puffery or an objective claim.



Substantiation Must Closely Tie to Specific Claim

Competent and reliable scientific evidence is required to substantiate all claims, and the evidence must be **relevant**. If relying on a study, the endpoints must match the claim.

■ **Claim:** Effective at eliminating 99.99999% of COVID-19

- Support: University of Minnesota study
- SARS-COV-2 was not used in the actual study

■ **Result:** NuWave compelled to modify claims:
“OxyPure is Calculated to Remove 99.9999% of Coronavirus Surrogate from the Air in Areas up to 1200 Square feet in 6 Hours!”



Establishment Claims

- Establishment claims assert that there is objective evidence that “establishes” the truth of the advertiser’s claim
 - “Tests prove . . .”
 - “Studies show . . .”
- Held to high standard of proof
- Performance benefit must be statistically and clinically significant
- For health-related claims, must be supported by **competent and reliable scientific evidence**
- Tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area, which have been conducted and evaluated in an objective manner by persons qualified to do so, using procedures generally accepted in the profession to yield accurate and reliable results
- Establishment claims are open to attack on the ground that the underlying test or study does not support or verify the claim

Establishment Claims: ZyCal Cyplexinol – FTC Case

ZyCal advertised pills containing Cyplexinol, a dietary supplement, under the brand Ostinol. The product was promoted as a bone and cartilage growth stimulant that could relieve joint pain.

Claims

- Clinically proven to “stimulate cells to grow bone tissue”
- “proven for 40 years and used clinically for 20 years to grow bone”

FTC Decision

- Claims were deceptive, false, and unsubstantiated. ZyCal was barred from making any similar claims about bone and cartilage growth unless backed by “competent and reliable scientific evidence, including randomized clinical trials.”
- “This settlement is an important reminder that health-related advertising claims require rigorous substantiation in the form of competent and reliable scientific evidence.”



510(k) Clearance May Provide Limited or No Support for Actual Claims

FDA 510(k) clearance for nerve and muscle stimulation to temporarily increase local blood circulation in healthy muscles

Example Express Claims

- “Clinically Tested”
- “No Risk”

Example Implied Claims

- Will cure various conditions (“Stop wasting time with endless appointments”; “Live a more active life”)
- “Safe” and without side effects

NAD Arbitration Decision

- Discontinue “clinically tested” claims because unreliable/dated study.
- Discontinue health-related claims outside 510(k) clearance



Comparative Advertising: Key Principles

- Comparative advertising that is truthful and not misleading is generally permissible.
- General claims of superiority over a comparative product that are vague or indeterminate are viewed as mere expressions of opinion. For example, “better than” claims are often merely puffery.
- Comparative/establishment claims can be vulnerable to attack – a plaintiff can simply assert that the underlying test does not support or verify the claim, placing the burden on the advertiser.
- Tests can be undermined as unreliable or not establishing the proposition for which they were cited (if, for example, they stand for some other proposition or are contradicted by other tests).
- Product comparisons should generally be apples-to-apples. If comparing Company A’s product to Company B’s product, ensure the products at issue (i) have the same function or intended purpose and (ii) are the most relevant/similar products for comparison of the respective companies.
- Product comparisons that are considered apples-to-oranges – where things that are non-comparable are portrayed as otherwise equivalent – are generally considered literally false. Such comparisons can be permissible, however, if all material differences are clearly disclosed and the advertisement does not imply that the competitor does not have a more similar product.

Comparative Advertising: Citracal Calcium Dispute (NAD Arbitration)

Claims

“Citracal is twice as well-absorbed as calcium carbonate.”

“Calcium citrate is better absorbed than calcium carbonate by about twenty-five percent.”

- **Challenger:** Claims are false. Well-conducted clinical studies prove that calcium citrate and calcium carbonate are equally well-absorbed when taken with food. Claims are also misleading because they imply that calcium citrate (Citracal) works better than calcium carbonate products, such as challenger’s product.
- **Advertiser:** Submitted two studies concluding that 500 mg of calcium citrate from Citracal was significantly better absorbed than 500 mg of a calcium carbonate supplement when both were taken with a meal

Decision

- Various studies comparing calcium citrate and calcium carbonate have reached different conclusions. One study is not definitive
- The advertiser here claims specific and quantifiable product use results – claims which by their specificity **require competent and very reliable (and directly applicable) scientific support**
- The evidence provided was insufficient to support the advertiser’s unqualified, specifically quantified, claims of calcium absorption

Comparative Advertising: Guardant Health v. Natera Litigation

- Guardant Health's Reveal product: a colorectal cancer diagnostic based on a blood draw
- Natera's Signatera product: a colorectal cancer diagnostic using tumor sampling and sequencing
- Natera claimed its Signatera product:
 - Had a lower “failure rate” than Reveal
 - Had superior “pre-surgical sensitivity”
 - Had superior “diagnostic lead time”
 - Had superior post-surgical predictive value

Natera Investor Presentation

Signatera vs. Reveal performance comparison

	Signatera	Reveal
Validation data published or presented (# patients analyzed)	> 2,000 ^{1,2}	< 150 ^{4,5}
Pre-surgical sensitivity in CRC	89-94% ^{1,3}	47% ⁴
Failure rate in CRC – tissue and plasma combined	< 3% ³	12-14% ⁴
Number of blood tubes required	2	4
Diagnostic lead time vs. radiographic recurrence in CRC (avg)	8.7 months ¹	~4 months ⁴
Post-surgical NPV/PPV in CRC (30 days post-surgery)	88% / 100% ^{1,1}	not reported ⁴
Serial longitudinal NPV in CRC	97% ¹	82% ⁴
Serial longitudinal Hazard Ratio in CRC	43.5 ¹	11.4 ⁴
Serial longitudinal sensitivity in CRC	88-94% ^{1,2}	69% ⁴
Quantitation of ctDNA burden for monitoring purposes	Tumor copies per mL	none

Comparative Advertising: Guardant Health v. Natera Litigation (Cont'd)

- Natera: Signatera's "test performance" is "unsurpassed," while tumor naïve tests (like Reveal) have "unknown" performance metrics
- Guardant: Natera's claims of superiority were false, misleading, and deceptive.
 - No head-to-head studies were performed
 - Natera relied on different studies, run in different countries, using different test protocols and methods, and examining different patient populations
 - Natera made misleading statements not supported by its own studies. For example, "pre-surgical sensitivity" metrics were irrelevant because neither product was used as a pre-surgical diagnostic

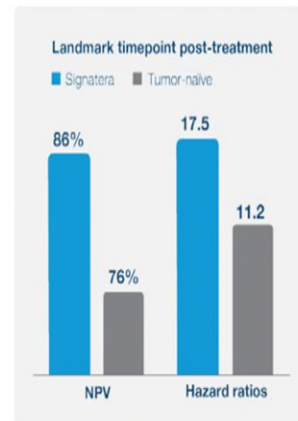
Natera Chart

Three time points matter for performance assessment in CRC

	Signatera HR ^{1,3}	Tumor-naïve HR ²
Single test 30 days post-surgery	7.2-14.0*	Unknown
Single test post-treatment	17.5	11.2
Serial testing in surveillance	43.5-47.5	Unknown

	Signatera NPV ¹	Tumor-naïve ²
Single test 30 days post-surgery	88% (74/84)	Unknown
Single test post-treatment	86% (44/51)	76% (37/49)
Serial testing in surveillance	97% (58/60)	Unknown

*3/32 post-surgical positive patients cleared cDNA with adjuvant chemotherapy and did not relapse, implying 75% PPV in patients who receive subsequent ACT



1. Havel T, Chen Y, Chen Y, et al. Analysis of plasma cell-free DNA by ultrashort sequencing in patients with stage IV colorectal cancer. *JAMA Oncol*. 2015;3(12):1524-1530.

2. Parkin A, et al. Minimal residual disease (MRD) detection in colorectal cancer (CRC) using a plasma-based integrated genomic and exogenous circulating tumor DNA (ctDNA) assay. *ESMO* 2022.

3. Havel T, Chen Y, Chen Y, et al. Circulating tumor DNA to detect minimal residual disease, response to adjuvant therapy and identify patients at high risk of recurrence in stage IV CRC. *ASCO* 2020.














Comparative Advertising: Guardant v. Natera Litigation

■ **Guardant:** Natera's use of "apples-to-oranges" comparison renders the ads literally false; the analysis could not legitimately be used to claim that one product is superior to the other

■ Court Instructions to Jury:

- Claims using an "apples-to-orange" comparison are literally false by necessary implication where things that are non-comparable are portrayed as otherwise equivalent
 - Claims based on peer-reviewed studies can still be literally false if the claims are not supported by the study
- **Jury:**
- Natera engaged in willful false advertising
 - Natera liable for \$292.5 million in damages (actual and punitive)

Third-party Market Analysis

	Tumor-Informed	Tumor-Naïve
Key Differentiators	<ul style="list-style-type: none">• Potential for high sensitivity due to personalized variant tracking• Potential to apply personalized approach across tumor types (presumed independently of cancer-specific optimization)• Strong synergies with tissue WES / CGP assay portfolios• Likely well-positioned for heterogeneous cancers where a generic panel may not sufficiently cover inter-patient variability	<ul style="list-style-type: none">• Faster turnaround time for initial blood result (particularly well-suited to late-stage monitoring and early-stage cases where adjuvant treatment may begin within 4 weeks)• Convenient sampling logistics, which are better suited for centralized and decentralized testing alike• Epigenomic signatures expected to increase technical performance without need for tissue• Likely well-positioned for homogenous cancers where a set of common mutations is applicable across patients and cancers where tissue is limited even in early stages
Competitors	 natera  INVITAE  FOUNDATION MEDICINE  EXACT SCIENCES  Inivata  Personalis  C2i Genomics  Predicine	 GUARDANT  GRAIL  CARIS LIFE SCIENCES  freemome  Predicine

Practical Takeaways

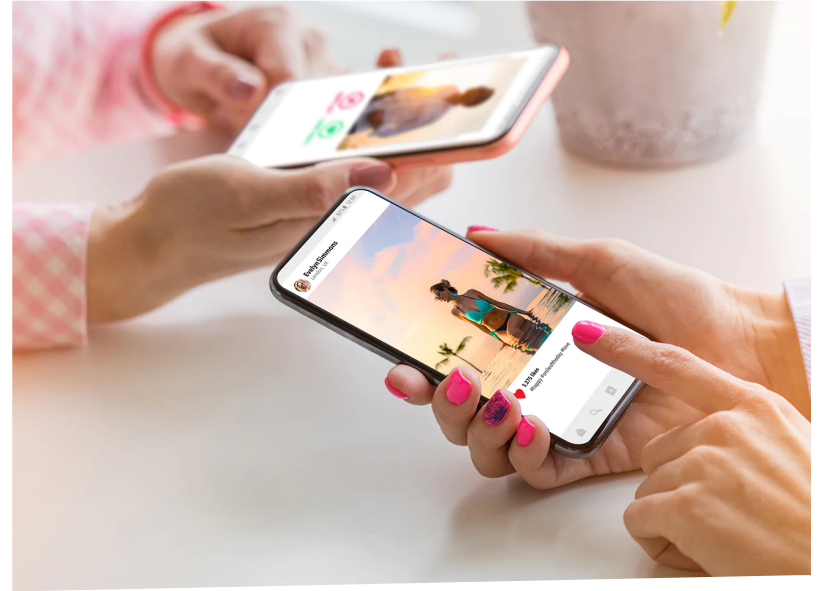
- Back-up your claims with reliable, competent, and directly applicable support
- Diligently maintain files with up-to-date backup
- Narrowly tailor claims backed by evidence
- Where backup is unavailable, avoid making factual statements, and make clear that any statements are expressions of opinion, not fact
- All medical device or diagnostics claims, particularly establishment claims, have a particularly high bar
- Qualifiers are unlikely to save the day
- Only make apples-to-apples comparisons
- Focus on comparing goods and services, rather than company-level comparisons
- Questionable advertising practices of competitors is not an excuse

Endorsements and Testimonials

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Endorsements and Testimonials

- An advertising message that consumers are likely to believe reflects an opinion of a party other than sponsoring advertiser
- Must reflect honest opinions of the endorser and cannot express something that would be deceptive if made directly by the advertiser
- Ad law substantiation requirements apply
- Endorsers must be bona fide users if their statements suggest so, and endorsers must have the expertise that they are represented as possessing



Is a Social Media Message “Sponsored”?

Is speaker acting independently or acting on behalf of advertiser or its agent?

■ Fact and circumstances dependent:

- Is speaker compensated by the advertiser or its agent?
- Was the product or service provided to the speaker for free by the advertiser?
- Was an opportunity to win something offered to speaker?
- What is the value of the items or services received?
- If sponsorship relationship, then...



Need to Disclose Material Connection

- Disclosure of ***material connection*** required when sponsorship relationship exists
- ***Endorser*** is the primary party responsible for disclosing the material connection
- Advertiser not off the hook for failure of endorser to disclose
- Employees will **always** have material connection
- As always, disclosure needs to be ***clear and conspicuous***



2023 Updates to FTC Guidelines re Influencers/Endorsers

■ Expanded definitions of “endorsement” and “endorsers”

- Now expressly includes fake reviews, tags in social media, virtual influencers and fictional characters

■ New “Clear and Conspicuous” Definition

- “Difficult to miss”; “unavoidable”
- Click through disclosure is avoidable

■ Monitoring Obligations Prohibit:

- Selling or obtaining fake consumers reviews and testimonials
- Providing compensation or other incentives in exchange for reviews that express a particular sentiment
- Suppressing reviews
- Facilitating “insider” reviews without disclosure
- Utilizing misleading websites that appear independent



Social Media Endorsement Issues

Clear Example of Non-Disclosure



Closer Questions

Is it OK for athletes, celebrities and social media personalities to post an Instagram Story without disclosure, to promote their sponsors?

Are “likes” or “retweets” equivalent to endorsements or are they merely opinions or updates?

Is a consumer “endorsing” a product when she comments on Instagram in exchange for a coupon or sweepstakes entry?

Can a person endorse a product on social media without even mentioning it?

Are employee postings about the company on their personal accounts/time endorsements?

Can we pay our customers as a courtesy for using their social media posts in our marketing?

Must we track all social media endorsements?

Thank You!



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