

Mobile Medical/Health Applications Navigating the Legal Maze

Presented to *Health TechNet* by:

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February 17, 2012

Overview of Mobile Medical/Health Apps

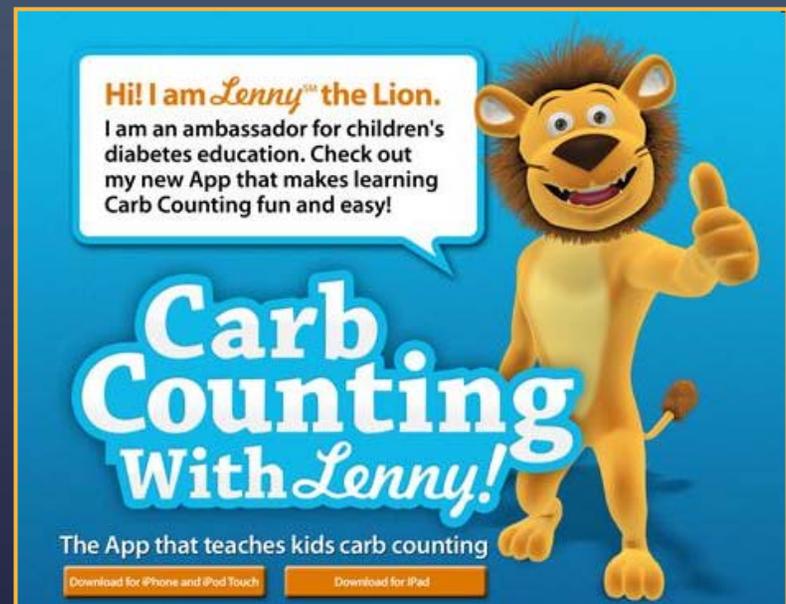
- Trends/Examples
- Overview of Regulatory Environment
- Sample Legal Issues

Mobile Medical Apps and Games are Exploding

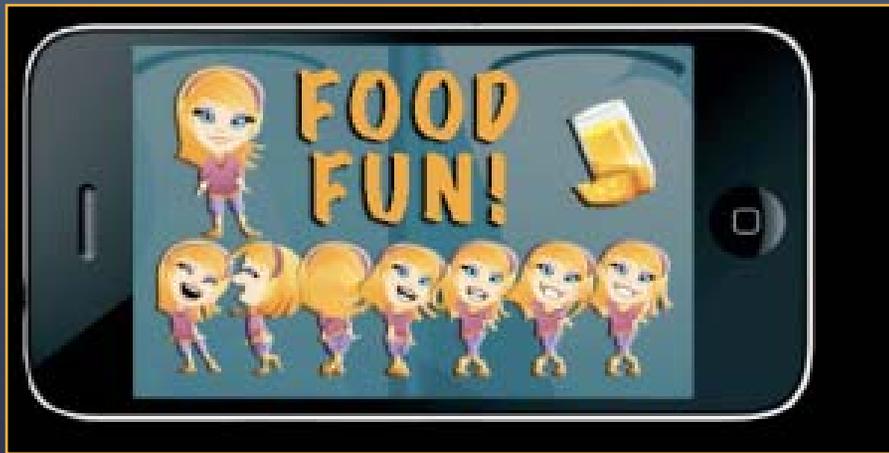
More than 13,000 health apps intended for use by consumers will be available for download in Apple's AppStore by next year

<http://mobihealthnews.com/research/consumer-health-apps-for-apples-iphone/>

By 2015, it is estimated that 500 million smartphone users will count on some kind of health care application on their device



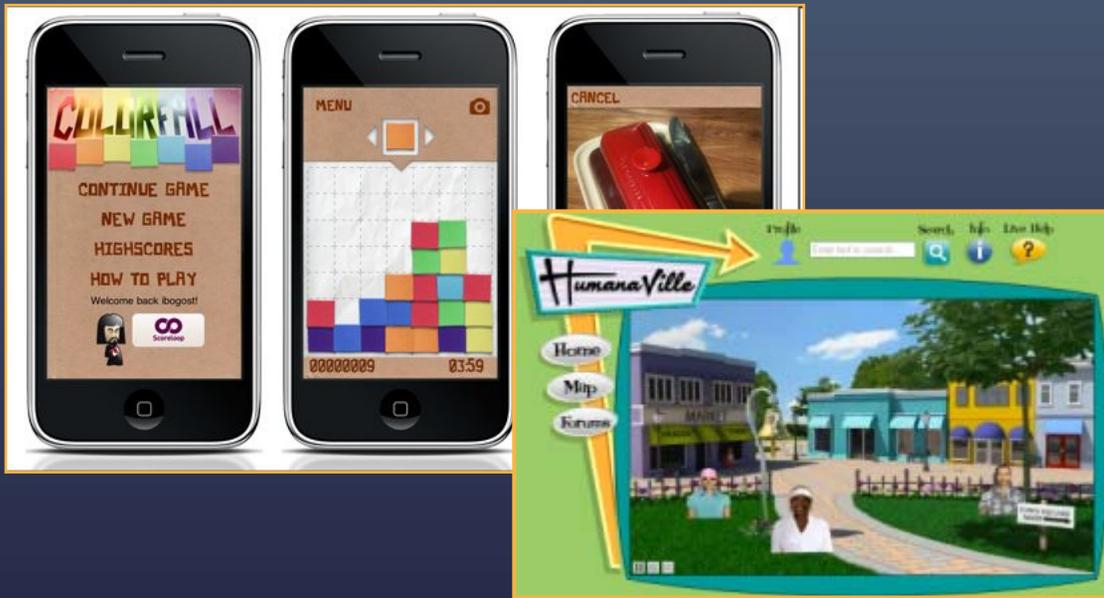
Health-Focused Games are Receiving Broad Support



Health-focused video games, including those for mobile platforms, now deserve “serious attention.”
The Journal of the American Medical Association

Insurers are Embracing Apps

Humana launched several iPhone games to help people engage in healthy activities.



"We're excited to be the first health insurance company to offer people fun, healthy mobile games that challenge their minds and bodies while encouraging healthy behaviors," **Paul Puopolo, director of consumer innovation at Humana**

Players of this fast-paced puzzle game have to arrange cascading tokens in the order of the colors of the rainbow. Part of the game play requires that players get up, move around, and use the phone's camera to take photos of real-world objects.

App Interoperability with Other Devices/Data

- Bringing gaming elements to the forefront of health devices to encourage patients to use them
- Hopes its standards will provide a way for people to interact with multiple data sources so consumer's Nike+ running shoes will tie in data to the person's Wii Fit workouts
- Bridging the gap between the numerous mobile and home-based gaming platforms and myriad mobile health devices
- Finding ways to store that data so it's easily accessible — like in a cloud-based online service



Sample Elements of Mobile Health Apps

- Mobile application
- Location aware
- Collect User Data
- Social network
- SMS/Text Messaging
- Advertising
- User generated Content
- Gamification
- Incentives/Rewards
- Contest-based/prizes
- In-app purchases/virtual currency

Location Based Apps - Integrating Games and Real Life Experiences

- A mobile app that turns outdoor recreational activities into real-life video games
- User generated
- Location-based
- Can be branded
- Contests/Prizes
- Social Networked

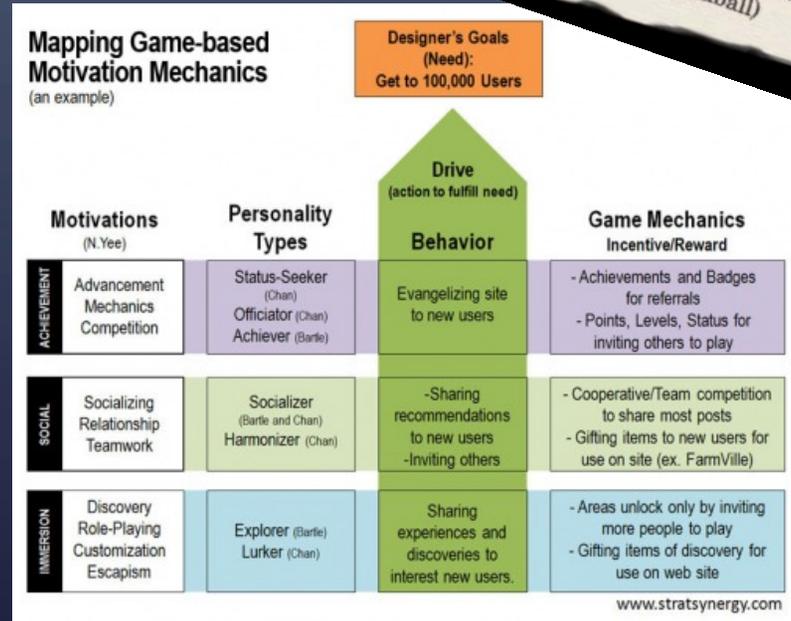


Gamification

Use of game mechanics for non-game purposes

- Leader boards
- Points/Rewards
- Levels
- Badges
- Exclusives
- **Status (expert)**

*ga•mi•fi•ca•tion [gay-muh-fi-kay-shuhn]
integrating game dynamics into your site,
service, community, content or campaign,
in order to drive participation.
(see Bunchball)*



Health Gamification



"We launched the S2H CHALLENGE in the summer of 2011 with a few hundred of our partners (employees); and four months later still have more than 80% participation and have logged more than 41 million steps! The S2H CHALLENGE (using the S2H STEP pedometer) has proved to be an effective program to help engage employees in health and wellness."

Virgil Jones III, Director of Partner Services at Starbucks

S2H.COM

Get Rewards from businesses that want to Reward you for your healthy physical activity.

I'm being rewarded
for my activity
by my favorite local business...

The screenshot shows a woman in a red tank top playing tennis on a court. Below the main image are three smaller icons: a crowd of people with arms raised, a bar chart with an upward arrow, and a red heart with a gold coin featuring a dollar sign.



FitBit –Tracking and Gamifying Health

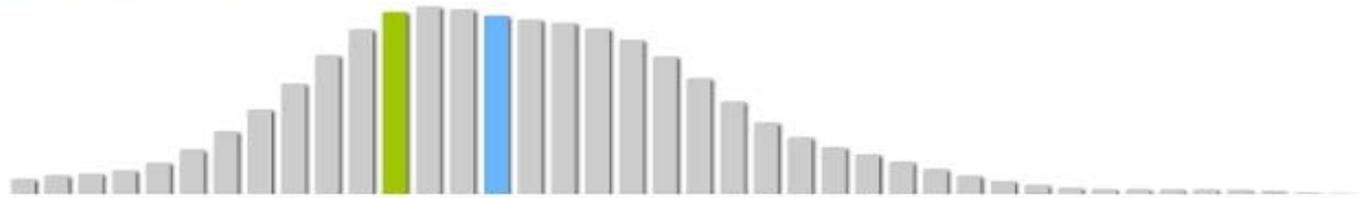


How do you compare to your peers?

Daily Steps

Single Demographic All Demographics

Typical You



This week you walked

5652 steps

that's **17%** less than the median for men and women 35 to 44 yrs who are overweight

You are in the

33rd percentile

of all men and women 35 to 44 yrs who are overweight

Show my

As a daily average

Or weekly total

Compare me to

Men and women

Men

Women

All ages

Under 25 yrs

25 to 34 yrs

35 to 44 yrs

45 to 54 yrs

55 to 64 yrs

65 yrs and older

All body types

Normal or underweight

Overweight

Obese

Regulatory Overview and Environment

Regulatory Clarity

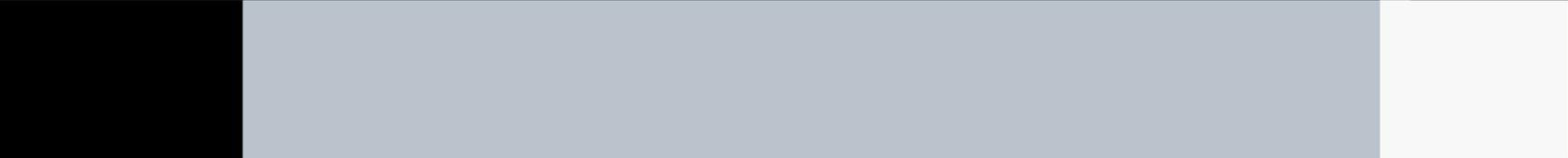
Ideal

Illegal

Legal



Reality



Overview of Legal Considerations

- Food and Drug Administration (FDA)
- Federal Trade Commission (FTC)
- Federal Communications Commission (FCC)
- Other Legal Issues

FDA, FTC, FCC

“We are developing draft guidance that will help clarify an appropriate policy and role for the FDA regarding the regulation of mobile applications, including those on smartphones,”

FDA spokesperson Dick Thompson

“We will soon be seeing some enforcement actions on [mobile] apps.”

FTC Commissioner Brill, ABA Annual Meeting, August 2011

“Some industries are new to *FDA regulation* and the affected companies are in danger of inadvertent regulatory violations”

FCC

Food and Drug Administration (FDA)

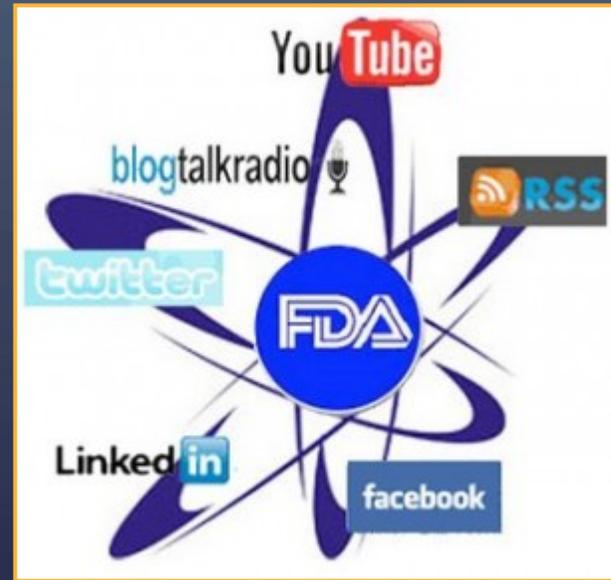
- July 21, 2011 - FDA issued "draft guidance" discussing how it intends to regulate "mobile medical apps."
- "Mobile medical apps" are defined as software applications that meet the statutory definition of a "device" under Section 201(h) of the Federal Food, Drug, and Cosmetic Act, and are either used as an accessory to a regulated medical device, or transform a mobile platform into a regulated medical device.
- The FDA plans to exercise regulatory oversight over those mobile medical apps that are associated with current device classifications.

FDA Regulatory Guidance

- The FDA outlines three types of apps that will be subject to regulatory oversight:
 - Apps that connect to or extend the functionality of other medical equipment
 - Apps that support external medical peripherals (like blood sugar monitors, heart rate monitors, etc)
 - Apps that diagnose problems, suggest treatment, or make clinical decisions based on user-supplied data.
 - In total, FDA's recent draft guidance lists 34 types of apps that the FDA views as "mobile medical apps"
- A mobile app that “Is used as an accessory to a regulated medical device” will be classified as a mobile medical application that is subject to future FDA review and approval.

FDA Social Media Guidelines

- Last December, the FDA issued draft social media and technology guidelines to pharmaceutical companies in which it set limits on how drugmakers can respond to consumer questions about off-label uses of prescription drugs.



Federal Trade Commission (FTC)

- **Section 5** of the FTC Act prohibits unfair or deceptive acts or practices
 - Applies to mobile applications
 - FTC using to address privacy, COPPA, false medical claims, more
- Has already acted against “medical” app

Recent FTC Cases – AcneApp and Acne Pwner



- Marketers advertised that their Smartphone applications could treat acne
- Agreed to stop making baseless claims in order to settle FTC charges.

“Smartphones make our lives easier in countless ways, but unfortunately when it comes to curing acne, there’s no app for that,” said **FTC Chairman, Jon Leibowitz.**



CAN-SPAM Act – Facebook Post = EMAIL

- Covers all commercial messages - “any electronic mail message the primary purpose of which is the commercial advertisement or promotion of a commercial product or service,” including email that promotes content on commercial websites.
- The Act defines an "electronic mail message" as "a message that is sent to a unique electronic mail address," 15 U.S.C. § 7702(6)
- "electronic mail address" defined as "destination, commonly expressed as a string of characters, consisting of a unique user name or mailbox and a reference to an Internet domain (commonly referred to as a "domain part"), whether or not displayed, to which an electronic mail message can be sent or delivered." 15 U.S.C. § 7702(5).
- Facebook postings within the definition of "commercial electronic mail message" under the Facebook, Inc. v. MAXBOUNTY, Inc., Case No. CV-10-4712-JF (N.D. Cal. March 28, 2011).

FTC Endorsement Guidelines

- “material connections” (sometimes payments or free products) between advertisers and endorsers must be disclosed
- Covers consumer testimonials, such as reviews or recommendations endorsing a product or service on any social media site, not just blogs
- Need to disclose connection between endorser and advertiser – anything of value, including “points “
- *Need to advise the consumer giving the testimonial that this connection should be disclosed, and have procedures in place to try to monitor the consumer's postings for compliance*

<http://www.ftc.gov/multimedia/video/business/endorsement-guides.shtm>

FTC Endorsement Guidelines

- Another aspect relates to "expert" endorsements
- Whenever an advertisement represents, directly or by implication, that the endorser is an expert with respect to the endorsement message, then the endorser's qualifications must in fact give the endorser the expertise that he or she is represented as possessing with respect to the endorsement.
- May be relevant to status/levels



FTC Endorsement Enforcements

- March 2011 - guitar-lesson DVD seller agreed to \$250,000 fine to settle FTC charges that it deceptively advertised its products through online affiliate marketers who falsely posed as ordinary consumers or independent reviewers.
- According to the FTC's complaint, Legacy Learning advertised using an online affiliate program, through which it recruited "Review Ad" affiliates to promote its courses through endorsements in articles, blog posts, and other online editorial material, with the endorsements appearing close to hyperlinks to Legacy's website. Affiliates received substantial commissions on the sale of each product resulting from referrals. According to the FTC, such endorsements generated more than \$5 million in sales of Legacy's courses.

FTC Endorsement Enforcements

- August 2010 – Video game PR agency agreed to pay \$250,000 fine to settle FTC charges that it engaged in deceptive advertising by having employees pose as ordinary consumers posting game reviews at the online iTunes store, and not disclosing that the reviews came from paid employees working on behalf of the developers.
- The company also agreed to set up a monitoring program to ensure compliance going forward.

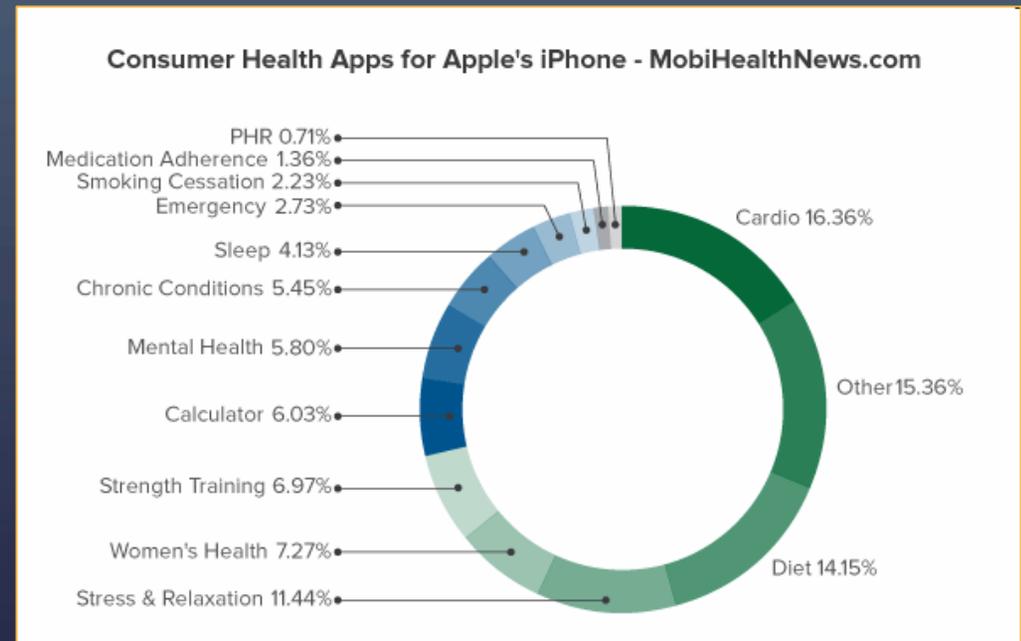
FTC Endorsement Enforcements

Other regulators have taken similar actions

- 2009 -- a cosmetic surgery company, paid \$300,000 fine to settle with the NY State over its attempts to fake positive consumer reviews on the Web regarding the results of face-lift procedures.

FCC, FDA to regulate mHealth

- Within the healthcare chapter of the FCC's National Broadband Plan the FCC recommended that it work together with the FDA to clarify regulatory requirements and the approval processes for converged communications and health care devices.



FCC -Telephone Consumer Protection Act

- “Do Not Call” law
- Originally directed to residential phones, fax and cell phone “calls”
- FCC – interpreted to cover text/SMS too
- **SMS/TEXT = CALL**
- Courts adopted that interpretation
- USDC for the Northern District of Illinois’ Eastern Division has found that a Twentieth Century Fox SMS campaign violated the TCPA by sending SMS marketing messages without the consumer’s consent
- A class action lawsuit has been filed against NASCAR alleging that the company sent unsolicited text messages.

Contests/Sweepstakes/Gambling



- Apps for Healthy Kids competition - \$60,000 in prizes to create innovative, fun and engaging software tools and games that encourage children directly or through their parents to make more nutritious food choices and be more physically active; part of First Lady Michelle Obama's *Let's Move!* campaign

- American Medical Association launches medical app contest for physicians and medical students



Contests/Sweepstakes/Gambling

- **Penn Medicine Contest - MyHeartMap Challenge Will Create Nation's First Crowdsourced Citywide Registry of Automated External Defibrillators - \$10,000 to Participant Who Locates Largest Number of Lifesaving Devices**
- **U.S. Department of Healthcare and Human Services - public data and cancer challenge asked contestants to create health IT applications that use public data and existing technology to help patients and health care professionals prevent, detect, diagnose and treat cancer**
- **The Office of the National Coordinator for Health IT (ONC) and Health 2.0 – launched 2 competitions to spur development and advancement of health IT applications that could ease patients' care transitions and facilitate the reporting of medical device-related adverse events.**

Contests/Sweepstakes/Gambling



- Text to Win cases
- Fox, NBC and other media companies will be barred from offering certain types of text-to-win sweepstakes as part of the settlement for a class action lawsuit in California.
- Similar suit in Georgia was decided favorably for companies
- At a minimum, each sweepstakes should include a free method of entry and consumers who pay premium fees should get something of value for those fees.

Contests/Sweepstakes/Gambling



- Prize + Chance + Consideration = legal issues!
- DOJ recently reversed itself on interpretation of the Wire Act
- State laws vary widely

Intellectual Property - Patents

- Incredible amount of Patent activity in mobile space
- Increase in patent filings
- Increase in patent litigation
- Increase in patent sales/acquisitions
- Interplay between patents and standards
- Patent Reform Act – most sweeping patent reform in decades
 - America Invents Act (AIA) Legal Analysis and Resources Page
<http://www.pillsburylaw.com/index.cfm?pageid=12&itemid=1925>

Intellectual Property - Copyright

- If you are hosting user generated content on your site – potential copyright infringement
- Digital Millennium Copyright Act can shield you from liability
- But must proactively take steps – it does not automatically apply

Thank you!



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