

FTC Regulation of Mobile Health Apps

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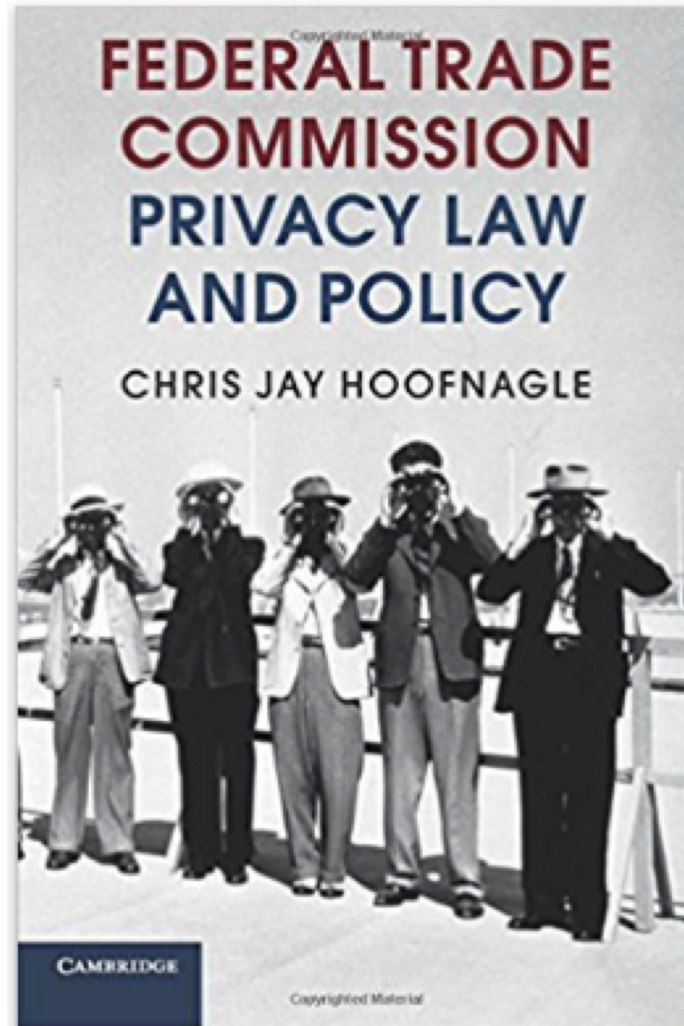
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- **I have relevant financial interests.**
 - My ELSI research is funded in part by NHGRI Grant No. R00HG006446 and in part by Geisinger.
 - I have a private law practice.
 - Unrelated to this presentation and my research, I have significant financial interests in KTFG Real Estate.

Recommended Reading



Overview

- FTC History
- FTC Structure
- FTC Key Features
- FTC Regulatory Scope & Powers
- Theories for FTC enforcement actions
- Recent FTC Reports
- FTC Mobile Health App Enforcement Actions
- Recommendations for ELSI Research

Relevant History

1914	Federal Trade Commission Act
1938	Wheeler-Lea Amendments
1972	FTC v. Sperry & Hutchinson
1973	Trans-Alaska Pipeline Act
1975	Magnuson-Moss Warranty – Federal Trade Commission Improvements Act
1976	Hart-Scott-Rodino Antitrust Improvements Act of 1976
1976	Spiegel v. FTC
1980	Federal Trade Commission Improvements Act of 1980
1995	First FTC workshop on internet consumer protection
2006	Division of Privacy & Identity (DPIP) launched in BCP
2012	Mobile Technology Unit (MTU) launched
2015	Office of Technology Research and Investigation (OTech) launched

FTC Structure

Overseen by Senate & House

- Commerce Committees
- Appropriations Committees
- Judiciary Committees



8 Divisions:

- Advertising Practices
- Consumer & Business Education
- Consumer Response & Operations
- Enforcement
- Financial Practices
- Litigation Technology & Analysis
- Marketing Practices
- Privacy & Identity Protection

FTC Structure

FTC Commissioners

Edith
Ramirez

Julie
Brill

Maureen
Ohlhausen

Terrell
McSweeney

Joshua
Wright

- Serve staggered 7-year terms
- Presidential appointment and Senate confirmation
- Can only be removed for cause
- Packing is forbidden (maximum of 3 per political party)

FTC Structure



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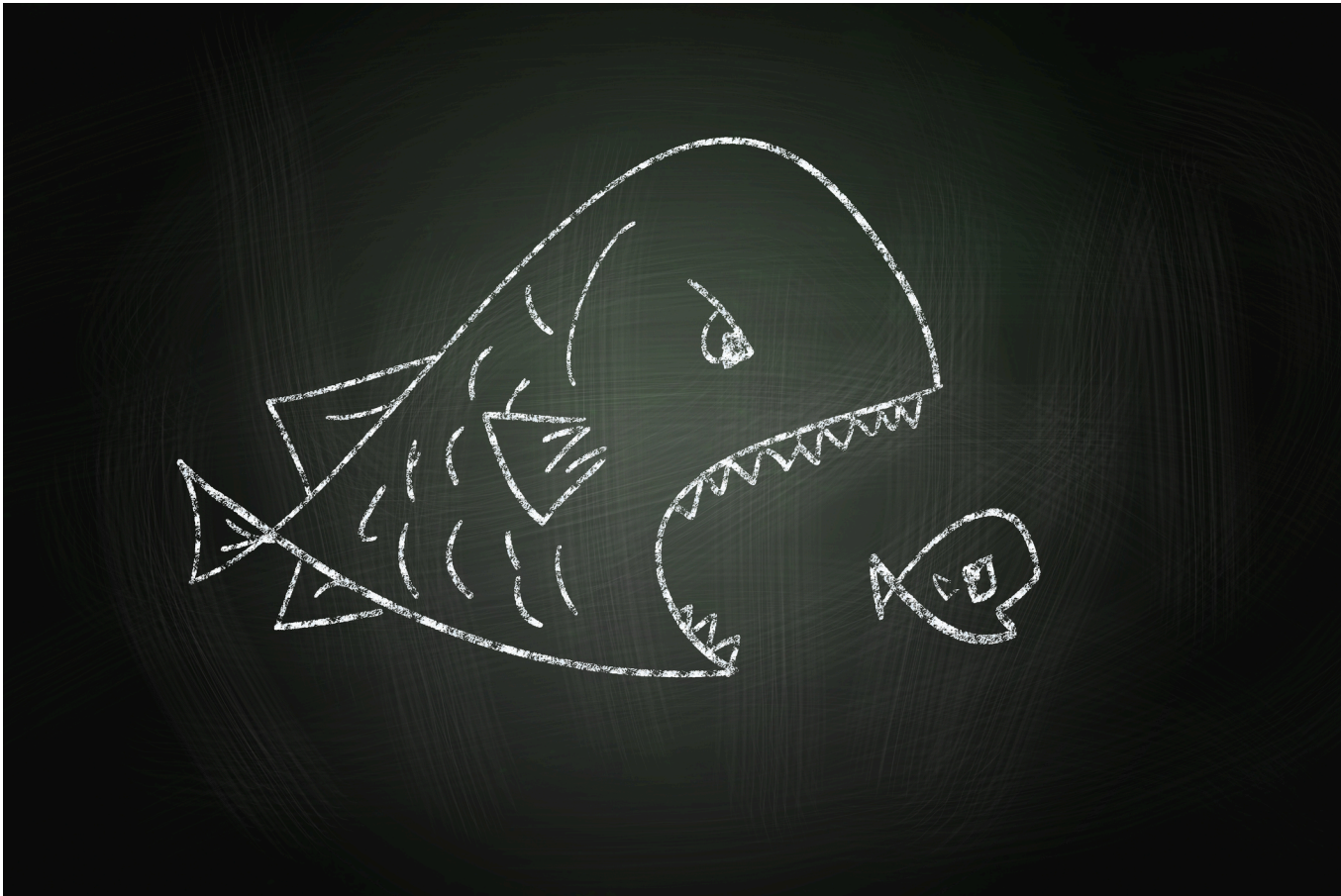
FTC Key Features

- According to Hoofnagle, these needs make FTC uniquely suited to regulate privacy:
 - Expertise
 - Certainty
 - Flexibility
 - Quick, Preventative Action
 - Compromise
- Because mission is preventative
 - Neither actual harm nor specific intent to defraud is required by §5
 - Selective enforcement is possible
 - May take action against acts legal under a state's law
 - Lack “aiding & abetting” authority and generally lack civil penalty authority.

FTC Scope & Powers

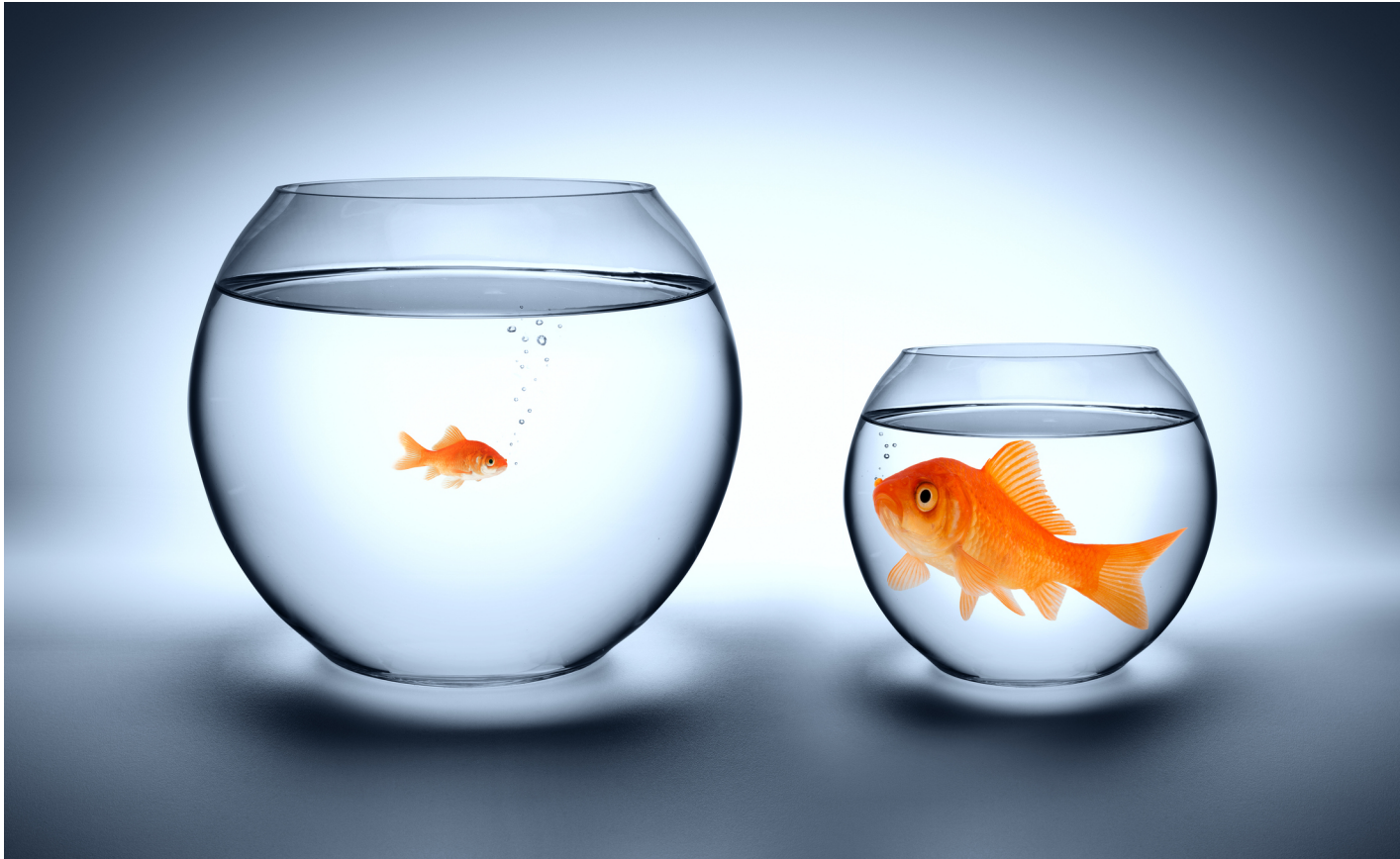
- More than 70 statutes
 - Federal Trade Commission Act
 - Clayton Act
 - COPPA
 - HITECH Act
- “A shape-shifting agency” (Hoofnagle)
 - Adjudications
 - Rulemaking
 - Investigations
 - Prosecutions
- Under the FTC Act
 - “prevent unfair methods of competition and unfair or deceptive acts or practices in or affecting commerce”
 - “seek monetary redress and other relief for conduct injurious to consumers”
 - “prescribe rules defining with specificity acts or practices that are unfair or deceptive, and establishing requirements designed to prevent such acts or practices”
 - “gather and compile information and conduct investigations relating to the organization, business, practices, and management of entities engaged in commerce”
 - “make reports and legislative recommendations to Congress and the public.”

Competition



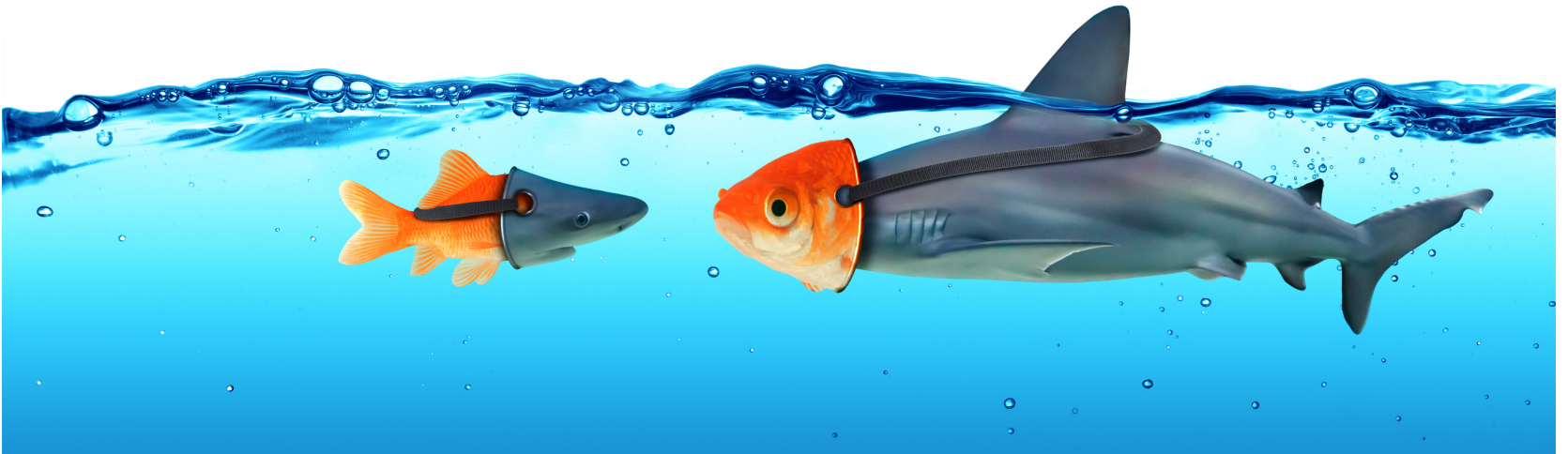
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Unfairness



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Deceptive

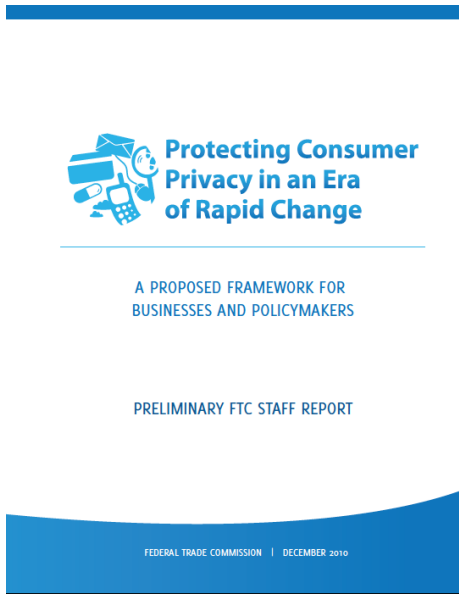


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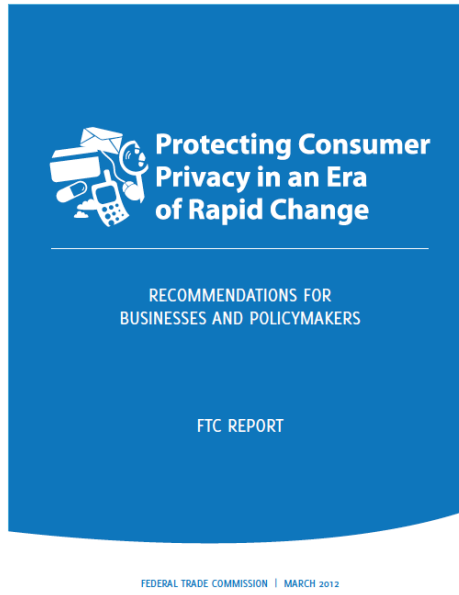
Substantiated



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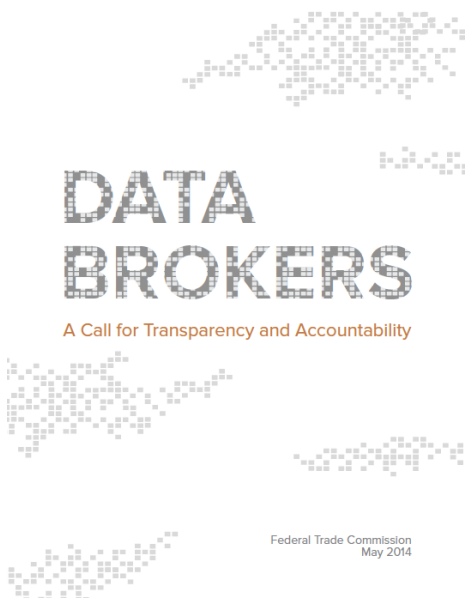
2010



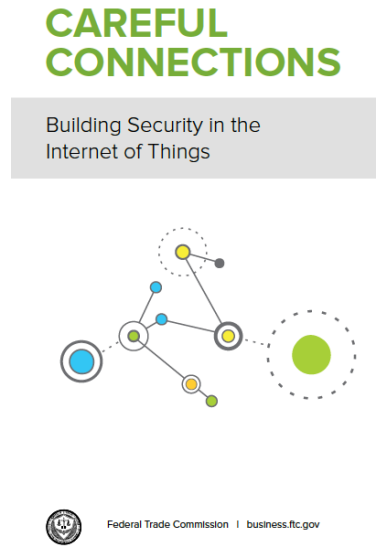
2012



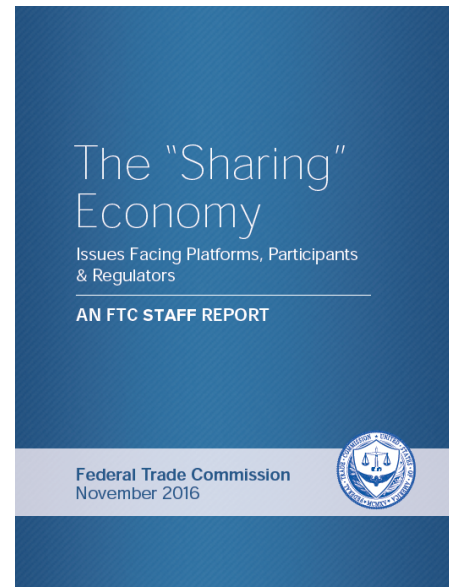
2013



2014



2015



2016



2016



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Office of Technology Research and Investigation



The Office of Technology Research and Investigation (OTech) is located at the intersection of consumer protection and new technologies. As a trusted source for research and information on technology's impact on consumers, the Office conducts independent studies, evaluates new marketing practices, and provides guidance to consumers, businesses and policy makers. It also assists the FTC's consumer protection investigators and attorneys by providing technical expertise, investigative assistance, and training. The Office is housed in the Bureau of Consumer Protection and its work supports all facets of the FTC's consumer protection mission, including issues related to privacy, data security, connected cars, smart homes, algorithmic transparency, emerging payment methods, fraud, big data, and the Internet of Things.

For additional technology-related content, please visit the [Tech@FTC](#) blog.

Help protect consumers through research. The FTC welcomes research. Please note that the FTC does not offer compensation of any kind. If your research reveals a security vulnerability or otherwise contains information that you wish to share with the FTC, please contact Dan Salsburg, Chief Counsel.

Home » [Tips & Advice](#) » [Business Center](#) » [Guidance](#) » Mobile Health Apps Interactive Tool

Mobile Health Apps Interactive Tool

Developing a mobile health app?
Find out which federal laws you need to follow.

Produced in cooperation with the U.S. Department of Health & Human Services (HHS); the Office of the National Coordinator for Health Information Technology (ONC), the Office for Civil Rights (OCR), and the Food and Drug Administration (FDA)



TAGS: [Advertising and Marketing](#) | [Health Claims](#) | [Privacy and Security](#) | [Consumer Privacy](#) | [Data Security](#) | [Tech](#) | [Health Care](#)

You're developing a health app for mobile devices and you want to know which federal laws apply. Check out this interactive tool.

- [What Are the Laws?](#)
- [Which Laws Apply to My Mobile Health App?](#)
- [Glossary](#)

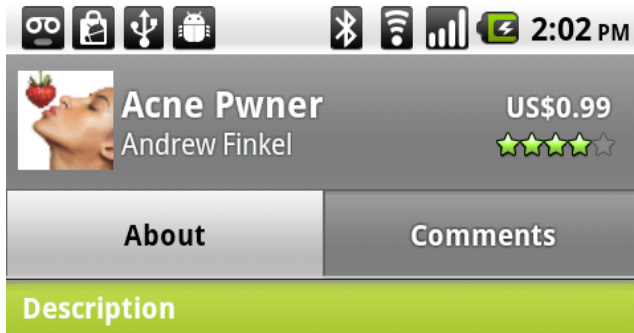
<https://www.ftc.gov/tips-advice/business-center/guidance/mobile-health-apps-interactive-tool>

FTC Mobile Health App Enforcement Actions

- 2011 – AcneApp and Acne Pwner (5-0)
- 2015 – Mole Detective and MelApp (4-1)
- 2016 – Lumosity (4-0)
- 2016 – Ultimeyes (4-0)
- 2016 – IBP App (Aura Labs) (3-0)
- 2017 – Breathometer (3-0)
- 2017 – Pact App (2-0)

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

Former FTC Chairman Jon Leibowitz
September 8, 2011

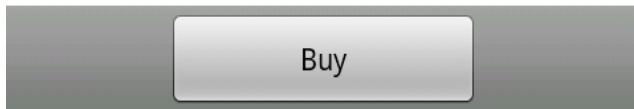


Kill ACNE with this simple, yet powerful tool!

"Light exposure has long been used as a short term treatment for acne. Recently, visible light has been successfully employed to treat mild to moderate acne."

Blue frequency (Bacteria)
 Red frequency (Healing)
 Amber frequency (Repair) !NEW!

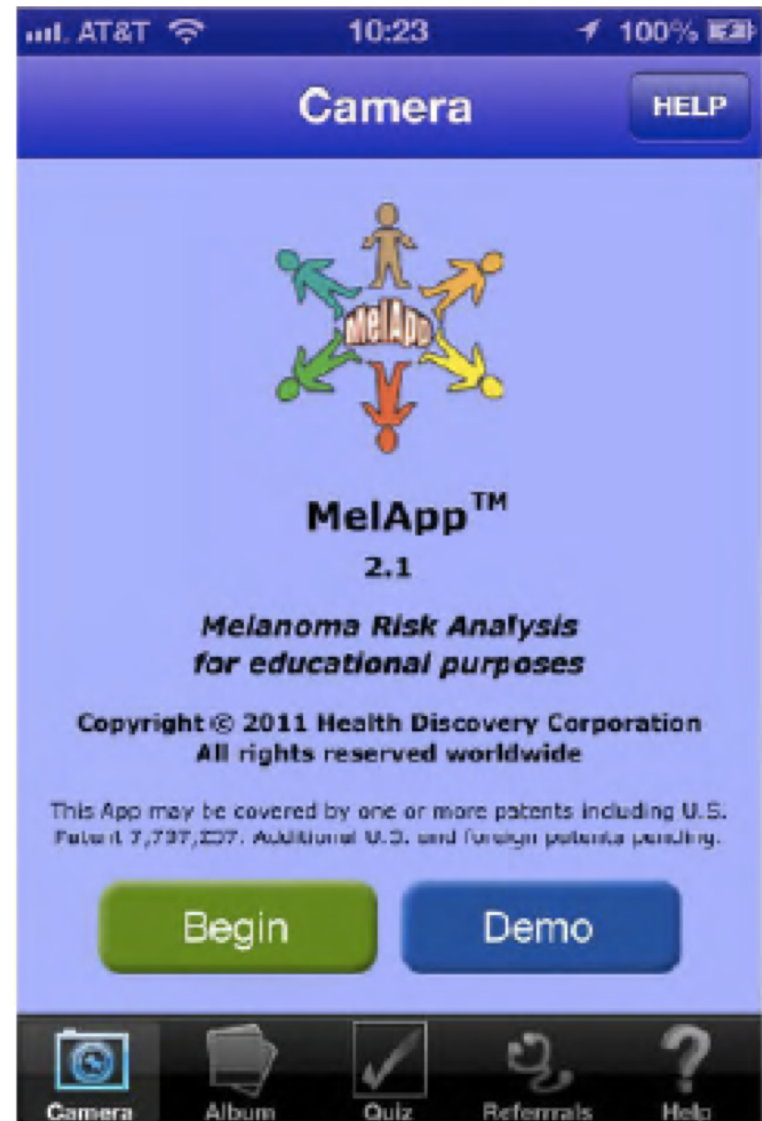
Keys:ZIT SKIN HEALTH SEX EASY FUN



“Truth in advertising laws apply in the mobile marketplace...

App developers and marketers must have scientific evidence to support any health or disease claims that they make for their apps.”

Jessica Rich, Director
FTC Bureau of Consumer Protection
February 23, 2015



Left Image: <https://www.pcworld.idg.com.au/article/581909/seller-melanoma-detection-apps-settles-ftc-complaint/>

Right image: https://www.ftc.gov/system/files/documents/cases/complaint_exhibits_a-c.pdf pg. 4 of 7

These matters are another example of the Commission using **an unduly expansive interpretation** of advertising claims to justify imposing **an inappropriately high substantiation requirement** on a **relatively safe product**...Because I fear this course of action will inhibit the development of beneficial products and chill the dissemination of useful health information to consumers, I dissent.

Commissioner Maureen K. Ohlhausen
Dissenting Statement, February 23, 2015

“Technologies such as health-related mobile apps have the potential to provide tremendous conveniences and benefits to consumers. However, **the same rules of the road apply to all media and technologies** – advertisers must have substantiation to back up their claims.”

Chairwoman Ramirez, Commissioner Brill, and
Commissioner McSweeney
February 23, 2015



“Lumosity preyed on consumers’ fears about age-related cognitive decline, suggesting their games could stave off memory loss, dementia, and even Alzheimer’s disease,” said Jessica Rich, Director of the FTC’s Bureau of Consumer Protection. “But Lumosity simply did not have the science to back up its ads.”

“...Section 5 of the FTC Act requires that advertisers have a reasonable basis to support their express and implied advertising claims before they are disseminated **to ensure** that such claims are **truthful and non-deceptive**. Advertisers must also have **rigorous, scientific support to substantiate claims** for products that purport to prevent or treat health or disease-related conditions. Because claims that indicate scientific support can easily imply to consumers greater health benefits than are actually the case, companies marketing brain training products should carefully evaluate their advertising to **make sure consumers do not take away a stronger efficacy message than scientific evidence supports.**”

Commissioner Brill, concurring
January 4, 2016

ULTIMEYES®

A simple-to-use interactive game **scientifically shown** to improve vision.

\$5.99 for a limited time

[Buy](#)

Available on Windows, Mac, iPad, iPhone and Android devices.

[Back](#)

ULTIMEYES 4+
Carrot Neurotechnology, Inc. >

★★★★☆ (39) \$9.99

[Details](#) [Reviews](#) [Related](#)

Description

ULTIMEYES® is not compatible with First Gen iPad or First Gen iPad Mini

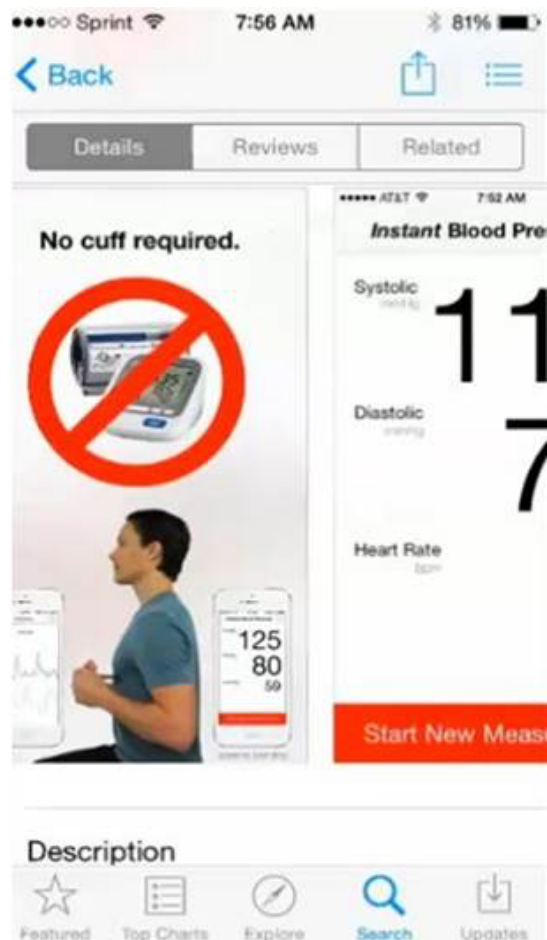
ULTIMEYES® is simple to use. The program requires you to follow the on-screen prompts and complete four 25-minute sessions per week for a total of eight weeks.

Since ULTIMEYES® does not expire you can use ULTIMEYES® whenever you'd like and as often as you'd like.

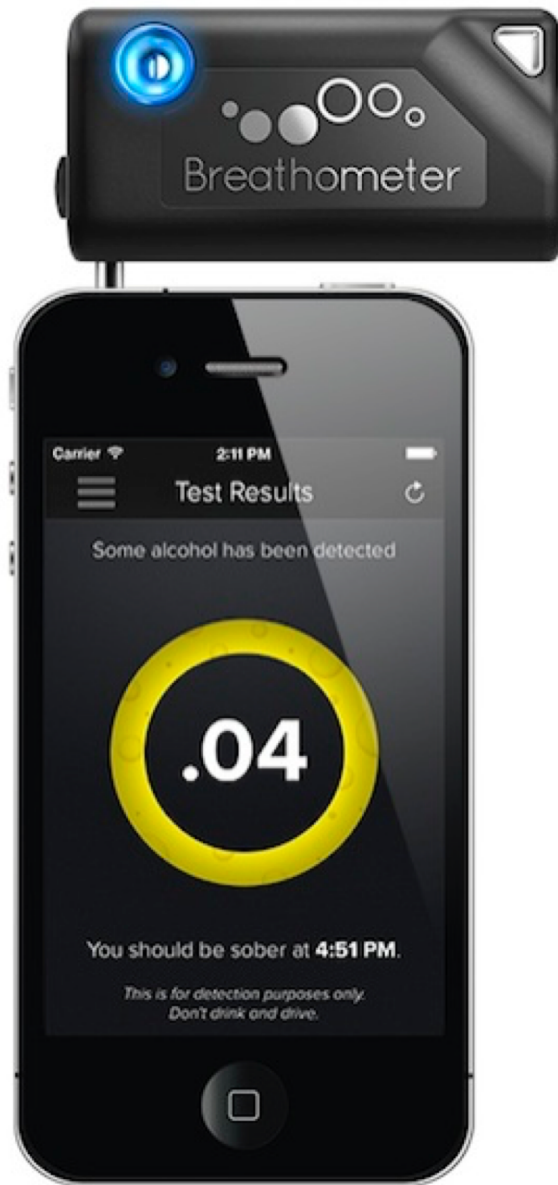
What's New
Apr 21, 2014
Updated Messaging

Information

Seller	Carrot Neurotechnology, Inc.
Category	Health & Fitness
Updated	Apr 21, 2014
Version	1.05
Size	25.2 MB



“While the Commission encourages the development of new technologies, health-related claims should not go beyond the scientific evidence available to support them.”

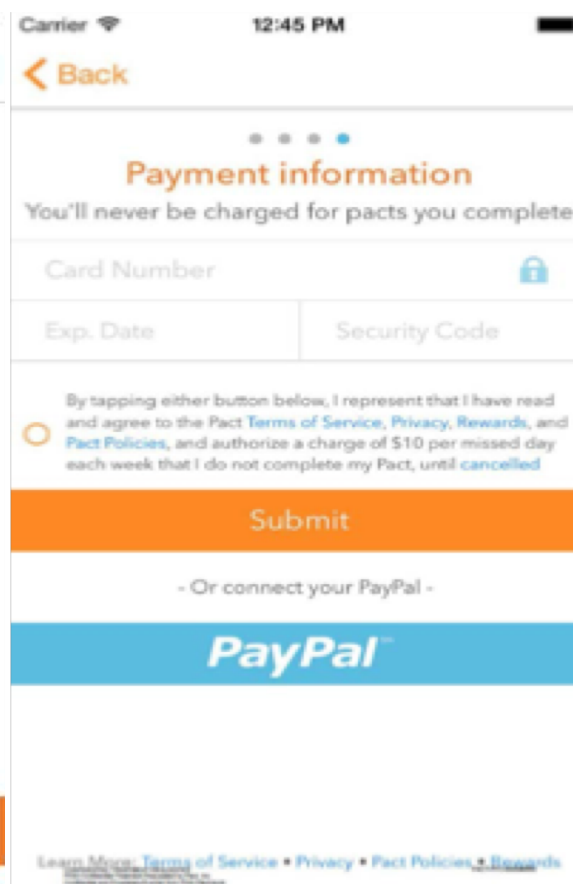
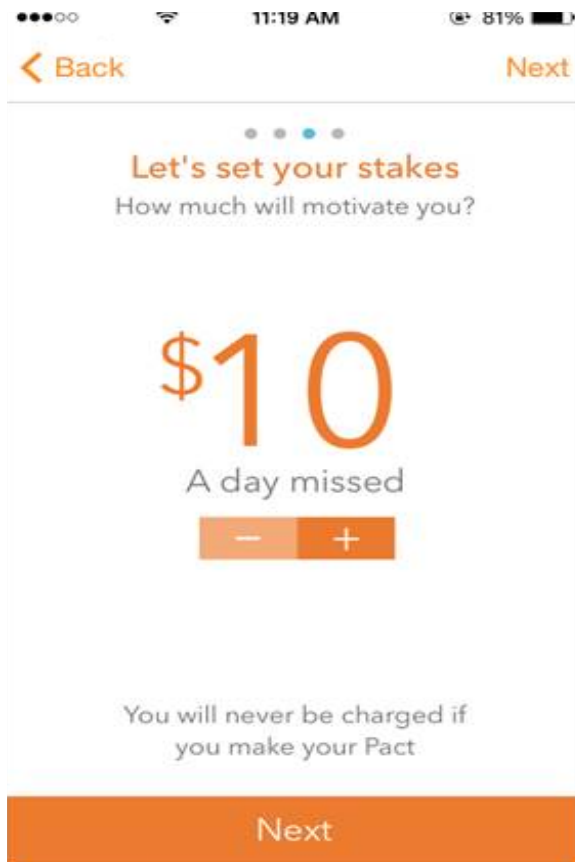


A. Exhibit A, Original Sell Sheet:

**Transform your smartphone
into a breathalyzer in seconds.**

*Breathometer™ gives you the power to make
smart decisions while you're drinking . . . and
assists you to make a more informed decision
about how or when to get home. Breathometer
[gives] you the ability to make informed
decisions about how and when you want to drink.
Choose Breathometer.*

Drink Smart. Be Safe.



Left image: <https://www.ftc.gov/news-events/press-releases/2017/09/mobile-app-settles-ftc-allegations-it-failed-deliver-promised>

Right image: <https://www.ftc.gov/system/files/documents/cases/1523010pactcomplaint.pdf> page 8

Unfairness and Data Privacy and Security

- FTC v Wyndham
 - “This settlement marks the end of a significant case in the FTC’s efforts to protect consumers from the harm caused by unreasonable data security,” said FTC Chairwoman Edith Ramirez. “Not only will it provide important protection to consumers, but the court rulings in the case have affirmed the vital role the FTC plays in this important area.”
 - Upheld in 799 F.3d 236 (3d Cir. 2015)
- In re LabMd

Respondent's Brief LabMD v. FTC

The Commission does not mandate data-security standards that companies must follow; technology and data-security threats continuously evolve, so what is appropriate today may not be tomorrow. Moreover, because companies vary widely in size and the type and volume of data they hold, a one-size-fits-all regime would be unworkable. Instead, the Commission has made clear that “[t]he touchstone of [its] approach to data security is reasonableness: a company’s data security measures must be reasonable and appropriate in light of the sensitivity and volume of consumer information it holds, the size and complexity of its business, and the cost of available tools to improve security and reduce vulnerabilities.”

Commission Statement Marking the FTC’s 50th Data Security Settlement (Jan. 31, 2014).⁴ The Commission “does not require perfect security,” but only “reasonable and appropriate security”; it recognizes that “the mere fact that a breach occurred

Recommendations for ELSI Research

- Support the FTC's ability to function in the areas in which it is most vulnerable to political attack (i.e., those of common law failures and market failures)
- Identify ways in which to optimize inter-agency memoranda of understanding (e.g., FDA, FCC)
- Contribute empirical scholarship that could be used by the FTC to assess an industry's ability to self-regulate
- Help the agency establish workable contours for fairness
- Articulate an appropriate privacy framework (e.g., privacy as control, contextual integrity, privacy as autonomy) and non-economic injuries that are "substantial"
- Illuminate the dynamics between extensive substantiation requirements and a desire for transparency/informed consumers in order to develop heuristics the FTC could apply.