



The views expressed are those of the speaker and not necessarily those of the FTC or any individual Commissioner.

**Defending Claims  
for Your Device**  
**Jon Miller Steiger**  
**Regional Director,**  
**FTC**



# Brief Overview - What is the FTC?

Nation's broad consumer protection agency

Headquarters – Washington, DC

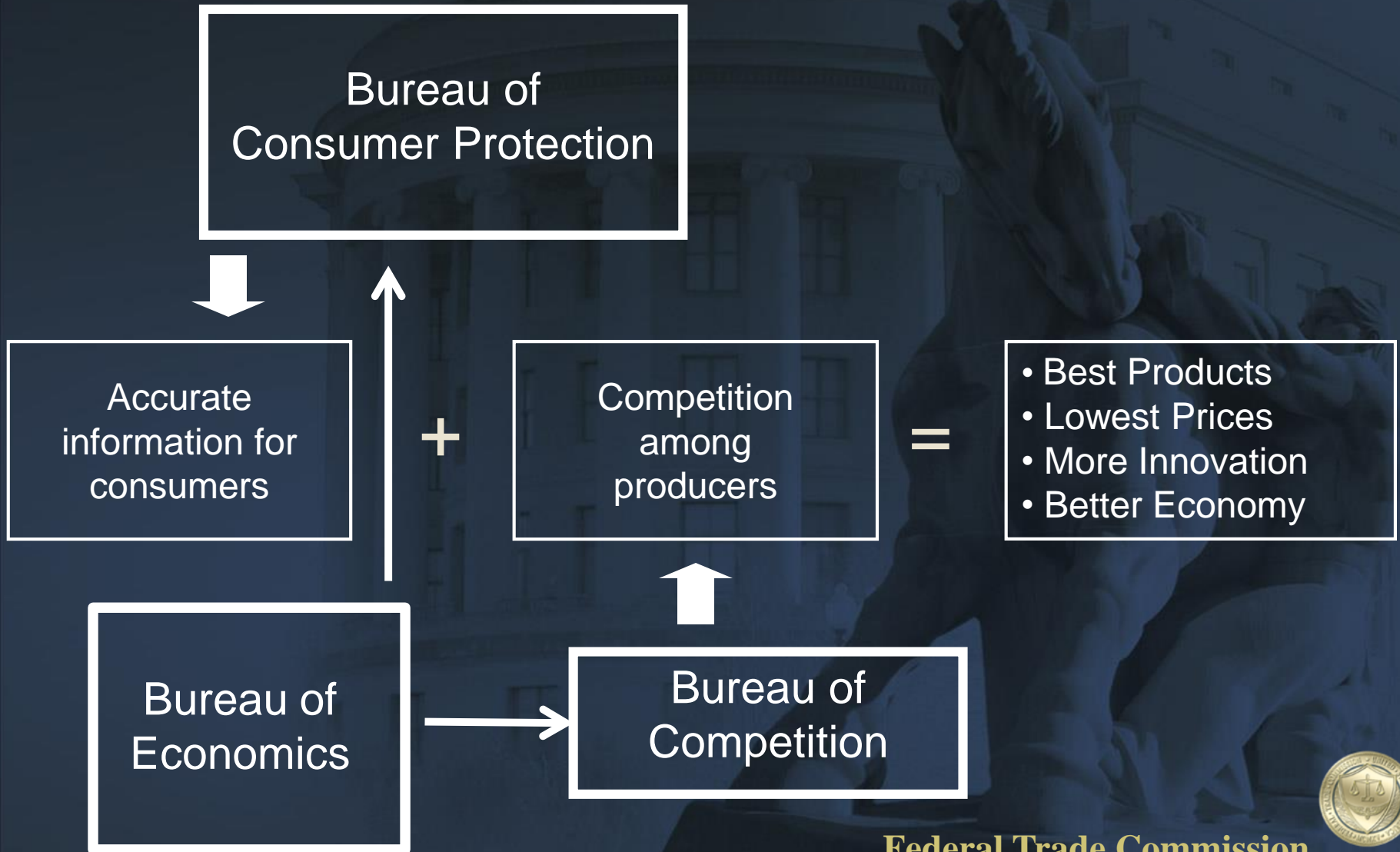
Eight Regional Offices, including Cleveland

Works for consumers by:

- Stopping fraudulent, deceptive, and unfair business practices, and
- Providing information to help spot, stop, and avoid those practices



# Brief Overview - What does it do?



# Federal Trade Commission Act

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“The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations ... from using unfair or deceptive acts or practices in or affecting commerce”

“Unfair methods of competition”

- Deceptive acts or practices
  - Representation, omission, or practice likely to mislead consumers
  - acting reasonably under the circumstances
  - material to consumers

*Cliffdale Deception Policy Statement*





# Federal Trade Commission Act

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## Means and Instrumentalities:

A company cannot knowingly provide others with support that could be used to deceive or harm consumers.

However, services that are not inherently deceptive (like payment processing or lead lists), are usually not liable under this theory.

## Case Examples:

- Distributing deceptive marketing materials as part of a pyramid scheme
- Providing customers with marketing tools to sell products advertised with false or unsubstantiated environmental claims



## "I Went From Flabby To Fabulous in Under 4 Weeks, Here's How...."



Jane Clark  
Health and Fitness writer

### It sounds impossible right?

That's what I thought. So we at News 6 Reports decided to investigate. This report details our findings.

Before we get into the actual investigation results I want to tell you how we decided to test these miracle supplements.

To get started, I volunteered to be the guinea pig.

I poured over research for Acai Berry supplements.

Studied 175 different suppliers. Only one supplier was honest, pure and brilliantly trustworthy enough for us to use in the test. Their bottle of [Acai Ultra Lean](#) has the **most concentrated** and **purest Acai** out of all the products we researched.

(And judging by reviews, they have the ultimate Acai product on the market).

Luckily they had a Free Trial Option. I quickly took advantage of the free trial and



Maria pictured above followed the same diet as Jane and contributes her incredible 30lb weight loss to the [Acai](#) and [Colon Cleanse](#) diet.

# Case Example: Falsity

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Express advertising claims

*Or*

Implied advertising claims



Federal Trade Commission



# Case Example: Falsity

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Defendants have represented that:

- a. Defendants' websites are objective news reports (*implied*)
- b. Objective news reporters have performed independent tests demonstrating the effectiveness of the products (*express*)

In truth and in fact:

- a. Defendants' websites are advertisements made to appear as objective news reports
- b. Objective news reporters have not performed independent tests demonstrating the effectiveness of the products





# Deception: Need for Substantiation

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Whether or not false, advertising requires a “reasonable basis”

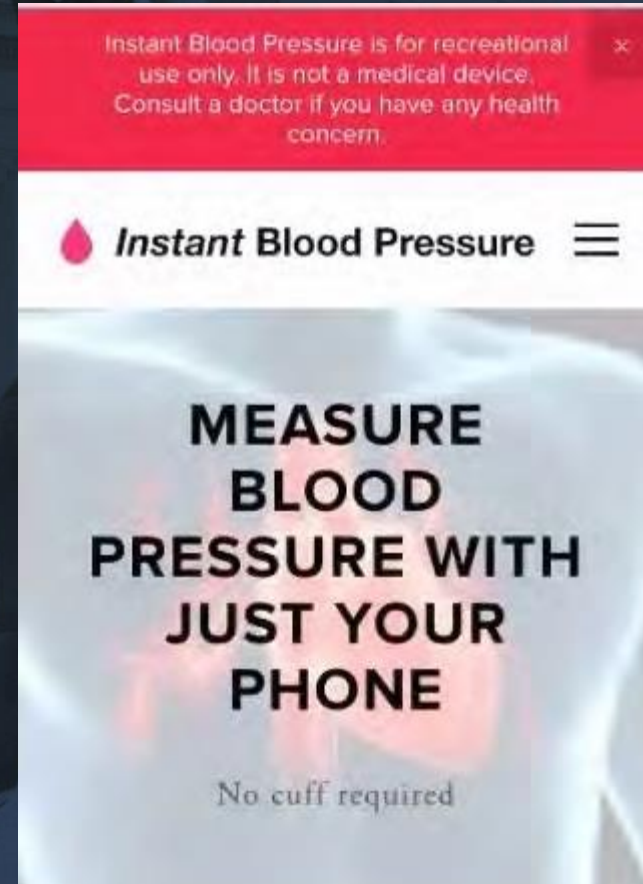
- Type of product and claim
- Consequences of a false claim and benefits of a truthful claim
- Cost of developing substantiation
- What experts in the field would require

Claims require reasonable basis before being made



# Case Example: Need for Substantiation

## Aura Labs, Inc. – Instant Blood Pressure App



# Case Example: Need for Substantiation

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23. Defendants have represented, directly or indirectly, expressly or by implication, that the Instant Blood Pressure App:

- A. Serves as a replacement for a traditional blood pressure cuff;
- and
- B. Measures blood pressure as accurately as a traditional blood pressure cuff.

24. The representations set forth in Paragraph 23 are false or misleading or were not substantiated at the time the representations were made.



# Deception: Need for Substantiation

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Establishment Claims – special type of advertising claim that a product’s “effectiveness or superiority has been scientifically established”

*POM Wonderful, LLC v. F.T.C.*, 777 F.3d 478, 490 (D.C. Cir. 2015)

The amount of substantiation needed will differ based on the claim.  
For example:

“Clinically proven” requires substantiation that would “satisfy the relevant scientific community”

But

“[T]he Journal of the AMA is quoting medical researchers now that say[] calcium reverses cancer” requires substantiation that studies referred to in JAMA show that calcium reverses cancer





# Case Example: False Establishment

# **1** INTERNATIONAL DOCTOR  
RECOMMENDED FORMULA



The **most respected medical research shows** that nothing beats the joint restoring power of Supple's® key ingredients to help you be more active and feel your best. Discover how Supple® can help you get your life back today.

**FEEL THE DIFFERENCE**

**Try Supple® risk free for 30 days**

Your satisfaction is 100% guaranteed.

The right ingredient. The right dosage. The best ingredient sources

Supple® Works!

Comfort · Repair · Protect

**Order Now**



# Case Example: False Establishment

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In addition to allegations that Supple's representations regarding its efficacy were false or misleading, or not substantiated...

“Defendants Apatow and Supple have represented, expressly or by implication, that Supple is clinically proven to eliminate joint pain.”

The FTC alleged that this representation was false, and pled a deceptive false establishment claim



# Unfairness

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## FTC Act Section 5:

“The Commission is hereby empowered and directed to prevent persons, partnerships, or corporations ... from using unfair or deceptive acts or practices in or affecting commerce” 15 U.S.C. 45

- Unfair acts or practices
  - substantial injury
  - not reasonably avoidable
  - not outweighed by benefits

*Int'l Harvester Policy Statement on Unfairness.*



# Case Example: Deception and Unfairness



“Transform your smartphone into a breathalyzer in seconds.”

“...it allows you to make more informed decisions...”

“Breathometer is a[n] FDA-registered device which boasts accuracy that compares favorably to other high-end breathalyzers.”





# Case Example: Deception and Unfairness

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## **Concurring Statement of Commissioner Maureen K. Ohlhausen In the Matter of Breathometer, Inc.**

Companies remain free to market their breathalyzer devices, provided their claims match their substantiation and do not mislead consumers.

Settlement required very specific forms of substantiation, which is not typical

Does not reflect industry-wide substantiation standards



# Working with FDA

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FTC and FDA work together under long-standing liaison agreement

FDA regulates product labeling, packaging, inserts, and promotional materials distributed at point of sale

FTC regulates claims in advertising, including print, broadcast, and online ads, infomercials, catalogs, telemarketing, and other direct marketing materials

FTC frequently consults with FDA when issues overlap and carefully considers their assessment of the science



# Working with FDA

## 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)



The Office of the National Coordinator for  
Health Information Technology

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
**OFFICE FOR CIVIL RIGHTS**



Flow chart on which agency covers your app:

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



# Questions?

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