Advocacy at FDA

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* Speaking only for myself and not for the FTC.

Overlapping jurisdictions

- **Food, OTC Drugs, Supplements**   **Labels → FDA**
  Ads → FTC

- **Rx Drugs**   **Both → FDA**

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'Unavoidable Partnership'

Agencies Differ

- **Goals**
- **Cultures**
- **Constituents**
- **Statutes & Legal Tools**
- **Feedback / Checks**

FTC Goals & Culture

Economic / Reasonable Consumer Model

- Competition is important
- Incentives matter
- Advertising plays a key role in markets
- Consumers more rational than not
- Type I error as important as Type II error
- Lawyers and economists

FDA Goals & Culture

Public Health Model

- **Firms driven by profits – not public health**
- **Consumers don't have experts' knowledge**
- **Govt. & health authorities are best arbiters of health decisions**
- **First, do no harm → Type II error most important**
- **Chemists and nutritionists**

FDA / FTC Interaction

- **Staff to staff contact**
  - **Particular issues or cases**
  - **Policy**
- **Empirical research**
- **White papers**
- **Formal comments**

Why Formal Comments?

- **Frame the arguments carefully**
- **Put evidence on the record**
- **Impose discipline on the process**

Health Claims History

- **1974 FTC Staff proposes ban to match FDA ban**

- **1978 Presiding Officer recommends rule to allow**

- **1980 FTC tells staff to develop rule**

- **1982 FTC ends Food Rule; nondeceptive health claims allowed in ads; case by case**

- **1987 FDA proposes similar approach**

Health Claims History (Cont.)

- **1990 FDA rescinds '87 proposal; NLEA**

- **1993 FDA/NLEA rules strictly regulate HCs; FTC Harmonization Statement**

- **1999 Pearson v. Shalala challenges scientific requirement for health claims; 1st Amend.**

- **2004 FDA also allows qualified health claims, structure-function claims, dietary guidance, authoritative statements.**

What mattered?

- **Strong theory that true marketing claims benefit consumers**

- **Empirical studies**

- **Stronger 1ˢᵗ Amendment law for commercial speech; challengers**