Advocacy at FDA

Pauline M. Ippolito*
Bureau of Economics
FTC

* Speaking only for myself and not for the FTC.
Overlapping jurisdictions

- Food, OTC Drugs, Supplements → Labels → FDA
  - Ads → FTC
- Rx Drugs → Both → FDA
Overlapping jurisdictions

• Food, OTC Drugs, Supplements
  - Labels → FDA
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• Rx Drugs
  - Both → FDA

‘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
- 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