

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**



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

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



What mattered?

- ' **Strong theory that true marketing claims benefit consumers**
- ' **Empirical studies**
- ' **Stronger 1st Amendment law for commercial speech; challengers**