

Breaking Down the Barriers to Functional Foods

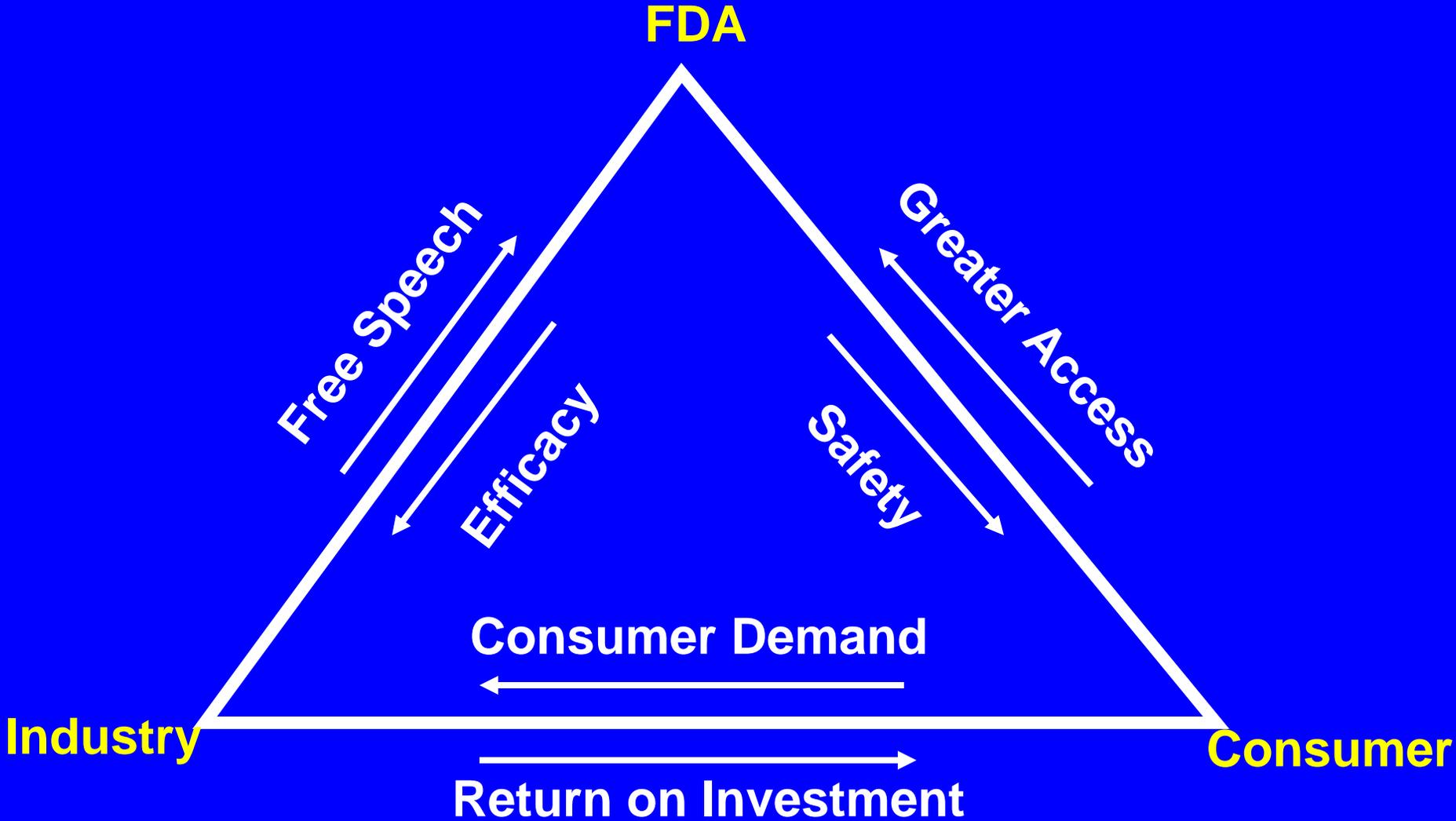
**FDA Public Meeting
December 6, 2006**

George A. Burdock, Ph.D.

Diplomate, American Board of Toxicology

Fellow, American College of Nutrition

Functional Food Players and the Impasse



Four things FDA must do to resolve the impasse

1. Create a new category of functional claims
2. Promote the use of Independent Expert determinations
3. Initiate a notification system
4. Provide a term of exclusivity and ROI for manufacturers

1. Health to Functional Claims

Provides health a benefit beyond basic nutrition.

We have found the “no brainers” and those for whom cost was no object

- *Vitamin C – scurvy*
- *Thiamine (B1) – beri beri*
 - *Iodine – goiter*
 - *Calcium - rickets*
- *Calcium and osteoporosis – 101.72*
- *Sodium and hypertension – 101.74*
- *Dietary fiber and cancer – 101.76*

1. Health to Functional Claims

To move forward FDA must

- a. Disconnect health-disease conundrum
- b. Allow claims based on changes in biomarkers
- c. Allow claims for specific population subsets
- d. Most of all *be flexible*

1. Health to Functional Claims

Time now for the tough choices

- May include a substance *unrecognized* by “mainstream” science (e.g. folate)
- *Unrecognized* as the result of the objections of political interests
 - Pharmaceutical lobby
 - Insurance (& Medicare) limitations
 - Research foundations and grant recipients

1. Health to Functional Claims

Time now for the tough choices

- Nutrigenomics options
 - Proteomics
 - Metabolomics
- Special subpopulations with special needs

Because the ingredients are in food - all ingredients must be safe for any consumer

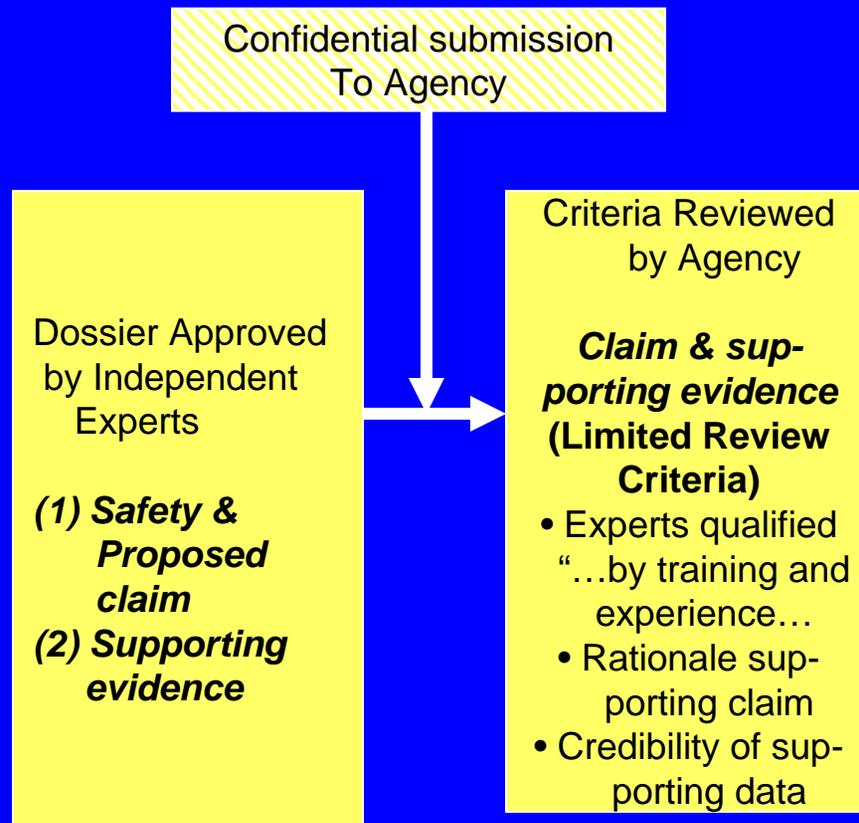
2. Independent Experts

- Precedent
 - GRAS for food ingredients
 - GRASE (...*safe and effective*) for drugs
 - FDA Advisory Committees
- Fact Sheet – Strategy for Dietary Supp.
 - Third party review cited

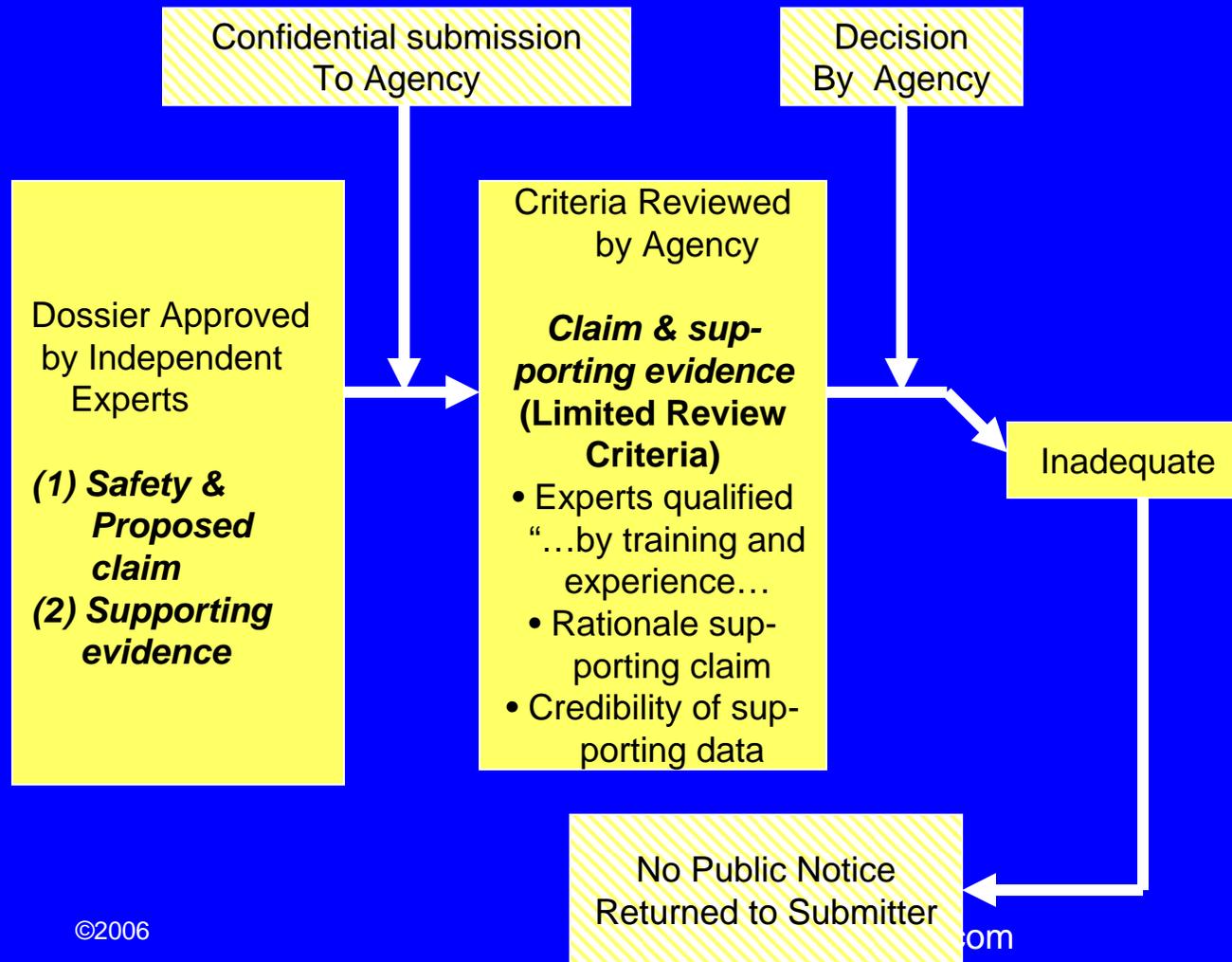
3. Notification Program

- Examples
 - GRAS Notification
 - NDIN
 - Qualified Health Claims
- Advantages
 - Public information and safety
 - Assured vendors

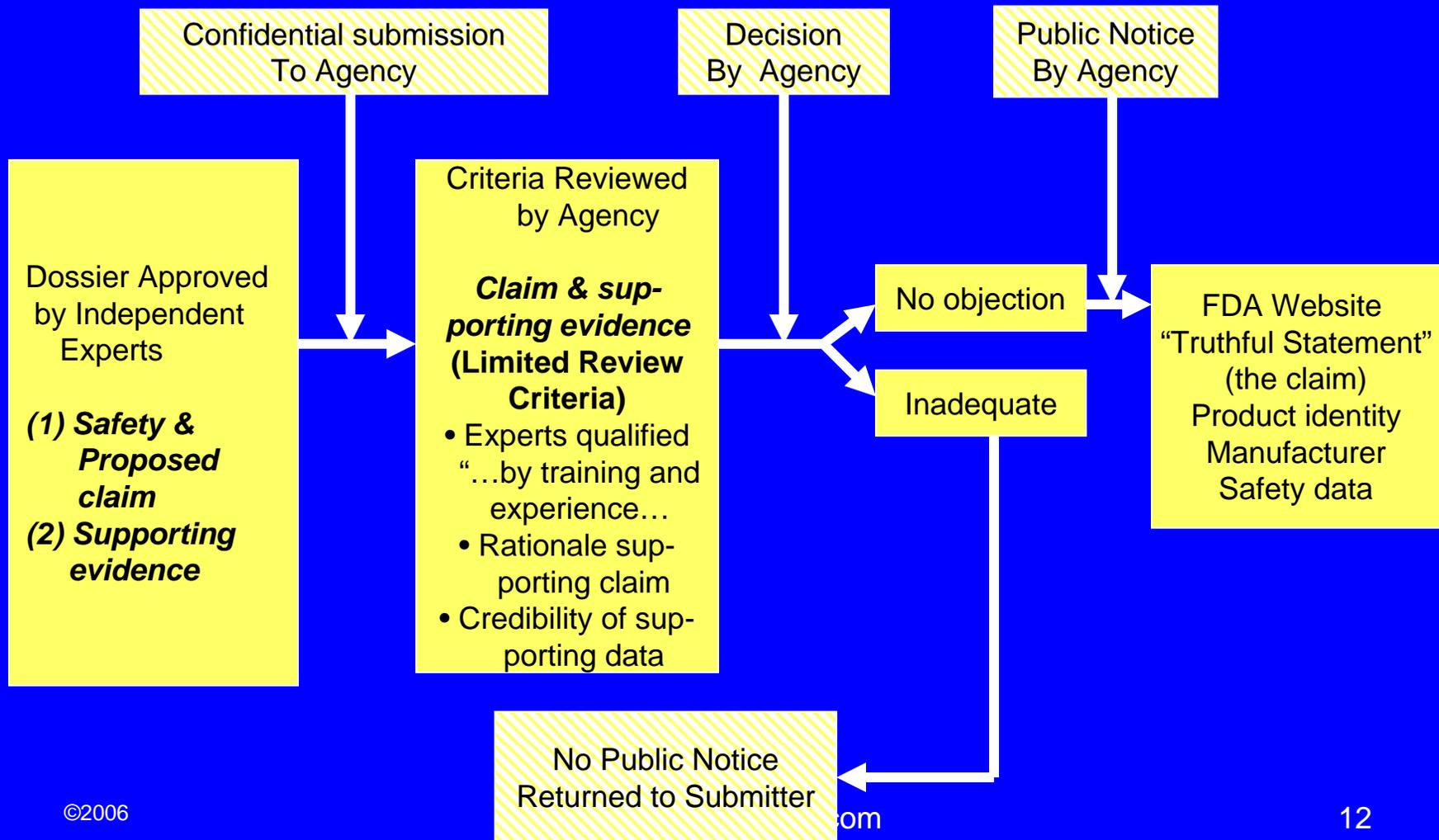
2 & 3 Independent Expert Review & FDA Notification



2& 3 Independent Expert Review & FDA Notification



2 & 3 Independent Expert Review & FDA Notification – How it works



2 & 3 Independent Expert Review & FDA Notification

- Relieve the logjam of petitions
- Respond to claims of free speech
- Benefit from the knowledge of independent experts
- Respond to consumer demands for empowerment

4. A term of Exclusive Marketing Rights

- Precedent
 - Food additive master files
 - Drug master files
- Will drive investment
 - Fund safety studies
 - Fund efficacy studies
- Return on investment required

Term of Exclusivity

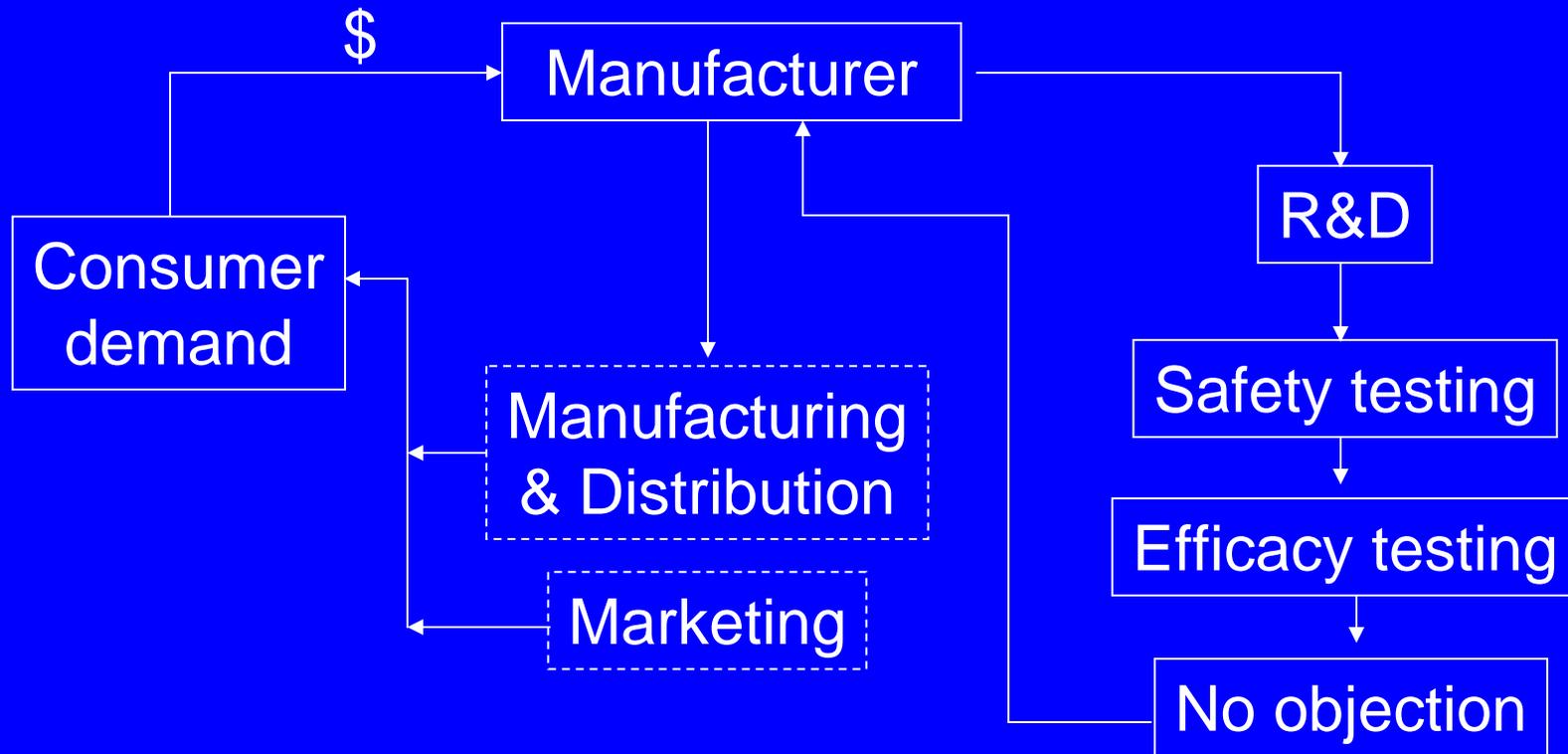
Public Release
(immediate)

- Safety information
- Claim
- Product name & manufacturer

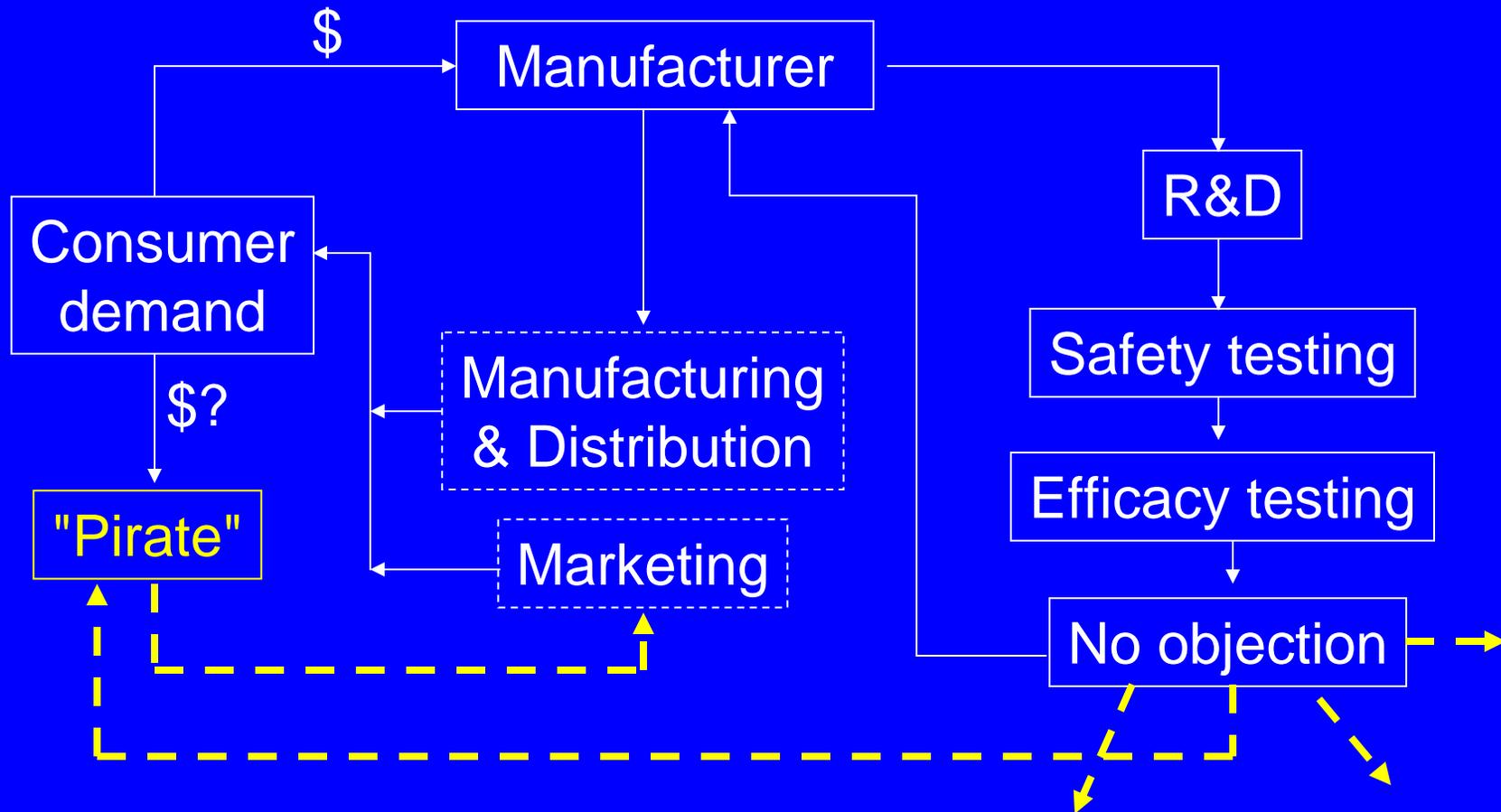
Sequestered Info.
(~5 years)

- Supporting evidence for claim

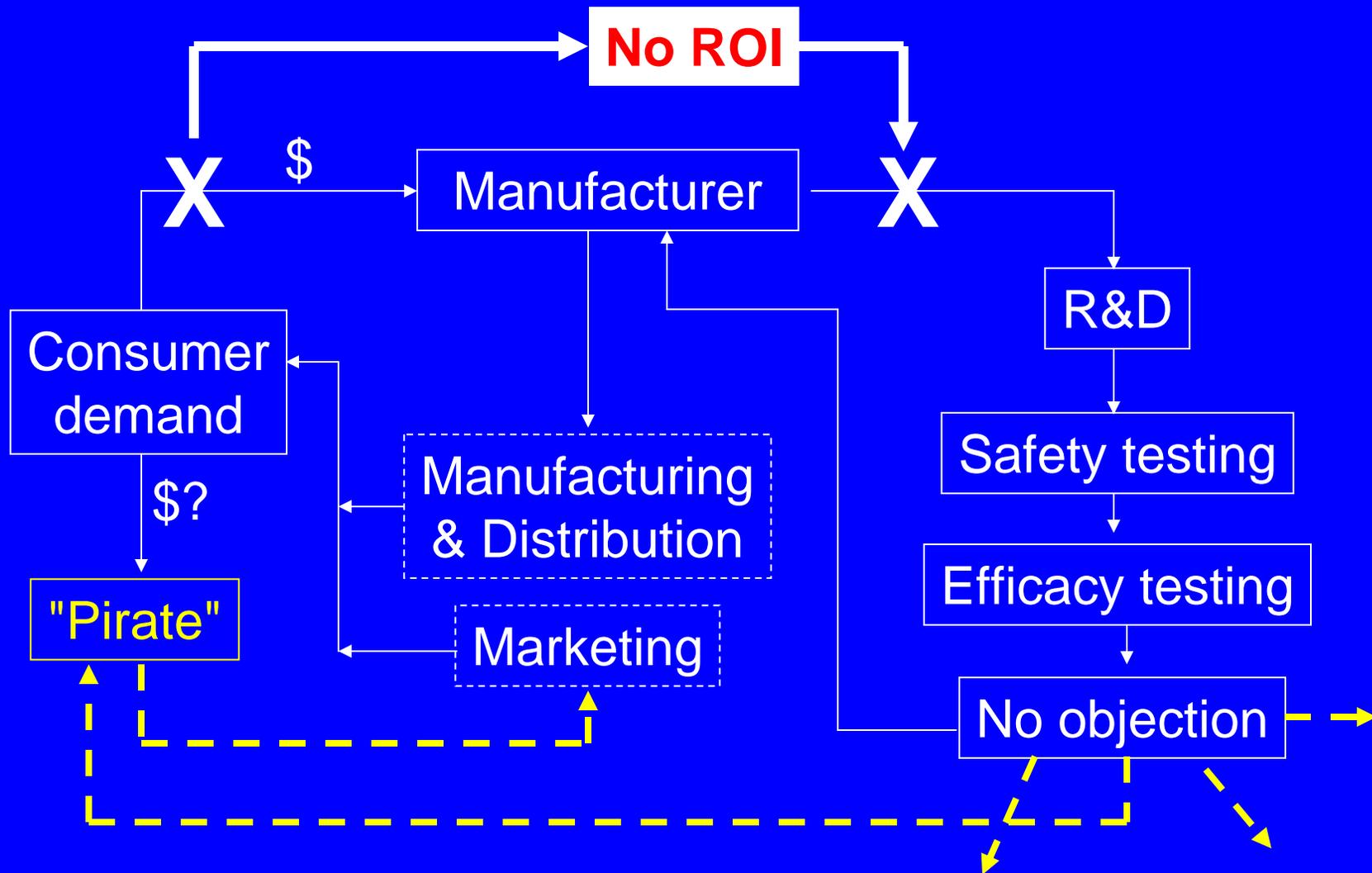
4. Term of Exclusivity



4. Term of Exclusivity



4. Term of Exclusivity



Four Steps Forward

1. Change from health claims to functional claims
2. Promote the use of Independent Experts
3. Initiate a Notification program
4. Permit a term of exclusivity for ROI

Resolution

- Consumers
 - Empowerment - greater access to new discoveries/enhancement of QoL
 - Drug cost savings
- Industry
 - Free speech assured
 - Return on investment
- FDA
 - Ensure consumer safety
 - Ensure efficacy (no mis-labeling)
 - Forestall increasing abuse of medical foods category

Breaking Down the Barriers to Functional Foods

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December 5, 2006**

George A. Burdock, Ph.D.

Diplomate, American Board of Toxicology

Fellow, American College of Nutrition