

# Breaking Down the Barriers to Functional Foods

**FDA Public Meeting  
December 6, 2006**

**George A. Burdock, Ph.D.**

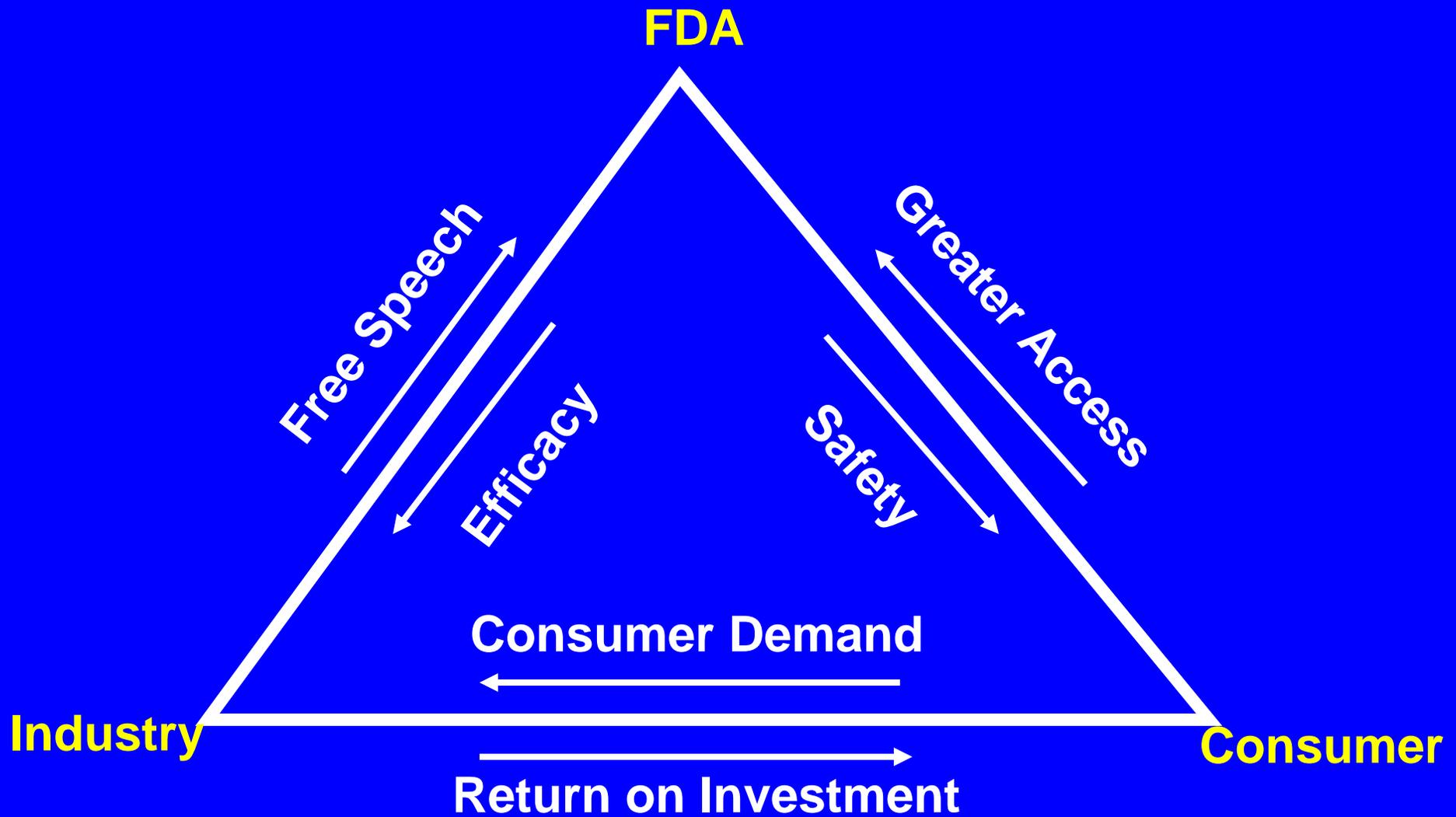
*Diplomate, American Board of Toxicology*

*Fellow, American College of Nutrition*

# Calls for Functional Food Claims Cannot be Ignored

- Strong consumer driving forces
  - Quality of life issues
  - Lionizing of natural remedies
  - Reaction to high cost of drugs
  - Conspiracy theories *re* big pharma
- Strong consumer market
  - Encourages enterprise
  - Encourages competition
  - Encourages investment

# Functional Food Players and the Tension



# Functional Foods Must Be Addressed by the Agency

**Functional Food Restrictions**

**Beyond Consumer's Reach**

**Underground/Unregulated Products**

**Loss of FDA Credibility**

- **Spurious Claims**
- **Unsafe Products**

# The Players and the Tension

FDA is the key player

FDA the *Engine for Resolution*

## Four things FDA must do before losing the confidence of the public

1. Create a new category of functional claims
  1. Disconnect health-disease conundrum
  2. Allow claims based on changes in biomarkers
  3. Allow claims for specific population subsets
  4. Most of all *be flexible*
2. Promote the use of Independent Expert determinations
3. Initiate a notification system
4. Provide a term of exclusivity for manufacturers

# 1. Health to Functional Claims

***Provides health a benefit beyond basic nutrition.***

*We have found the easy ones*

- *Vitamin C – scurvy*
- *Thiamine (B1) – beri beri*
- *Niacin (B3) – pellegra*
- *Cyanocobalamin (B12) – pernicious anemia*
  - *Iodine – goiter*
  - *Calcium - rickets*

# 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*

- *Calcium and osteoporosis – 101.72*
- *Sodium and hypertension – 101.74*
- *Dietary fiber and cancer – 101.76*

# 1. Health to Functional Claims

***Provides health a benefit beyond basic nutrition.***

*We have “damned those with faint praise”  
for which absolute certainty was not  
evident.*

- *Tomatoes and cancer*
- *Green tea and cancer*
- *Chromium picolinate and diabetes*

# 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

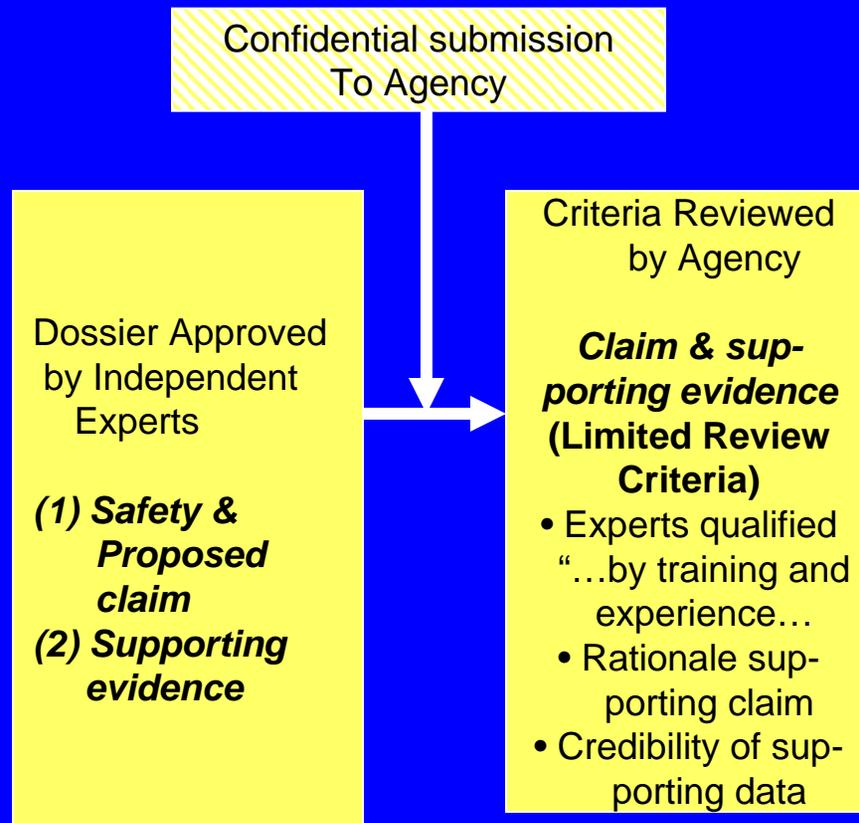
- Examples
  - GRAS Notification
  - NDIN
- Advantages
  - Public information and safety
  - Assured vendors

# 2 & 3 Independent Expert Review & FDA Notification

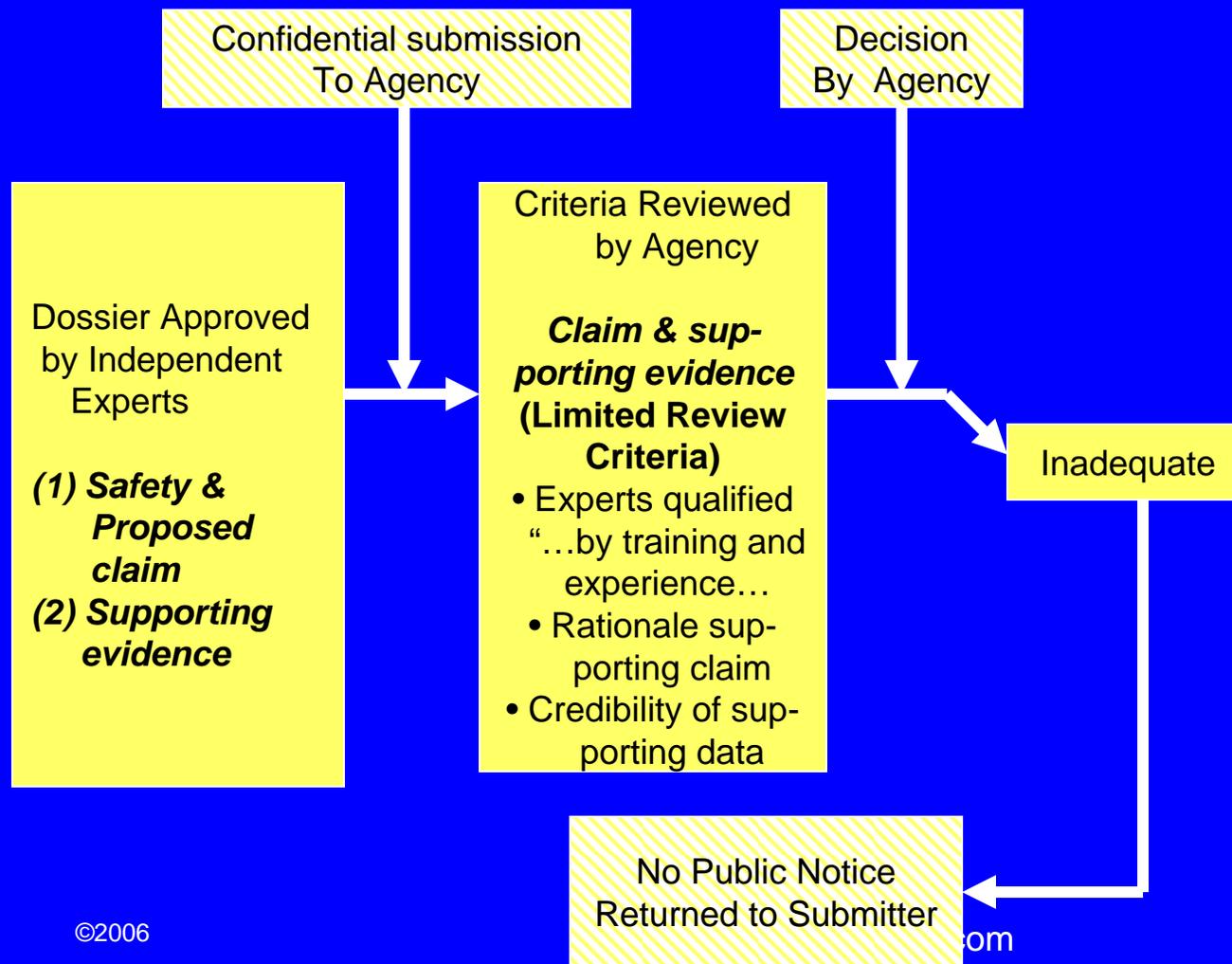
Dossier Approved  
by Independent  
Experts

- (1) Safety &  
Proposed  
claim**
- (2) Supporting  
evidence**

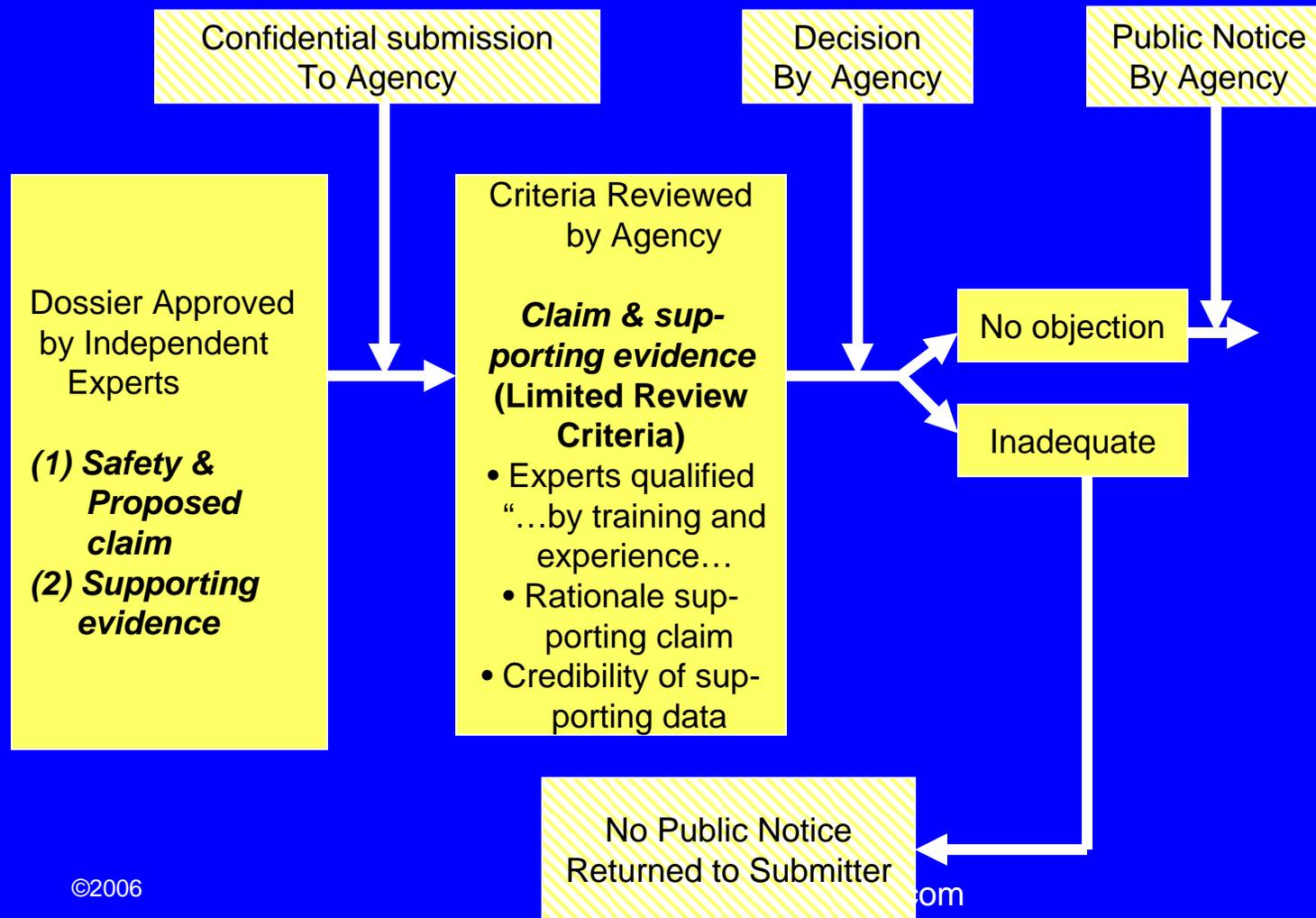
# 2 & 3 Independent Expert Review & FDA Notification



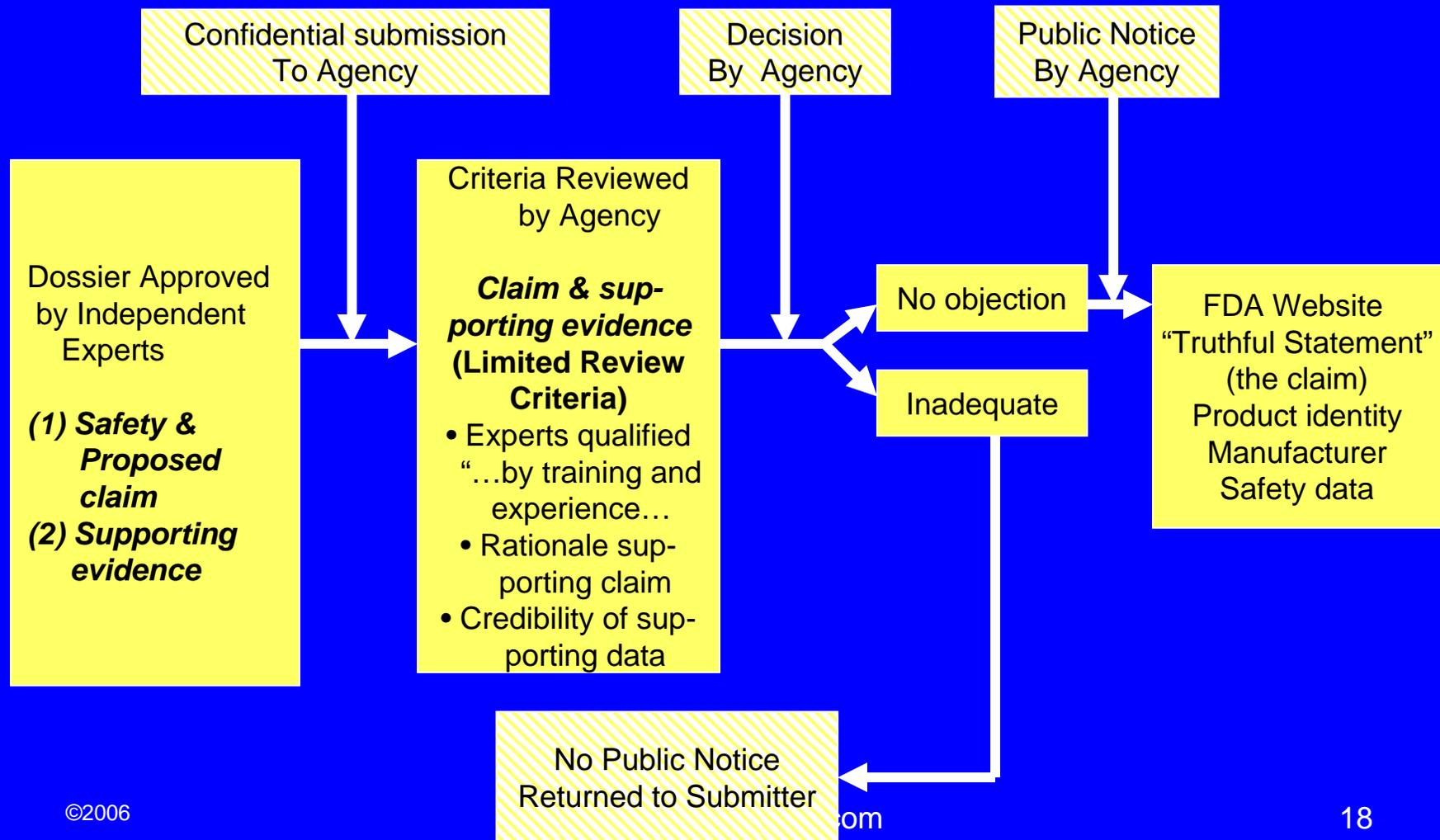
# 2& 3 Independent Expert Review & FDA Notification



# 2 & 3 Independent Expert Review & FDA Notification



# 2 & 3 Independent Expert Review & FDA Notification



## 2 & 3 Independent Expert Review & FDA Notification

- Relieve the logjam of petitions
- 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

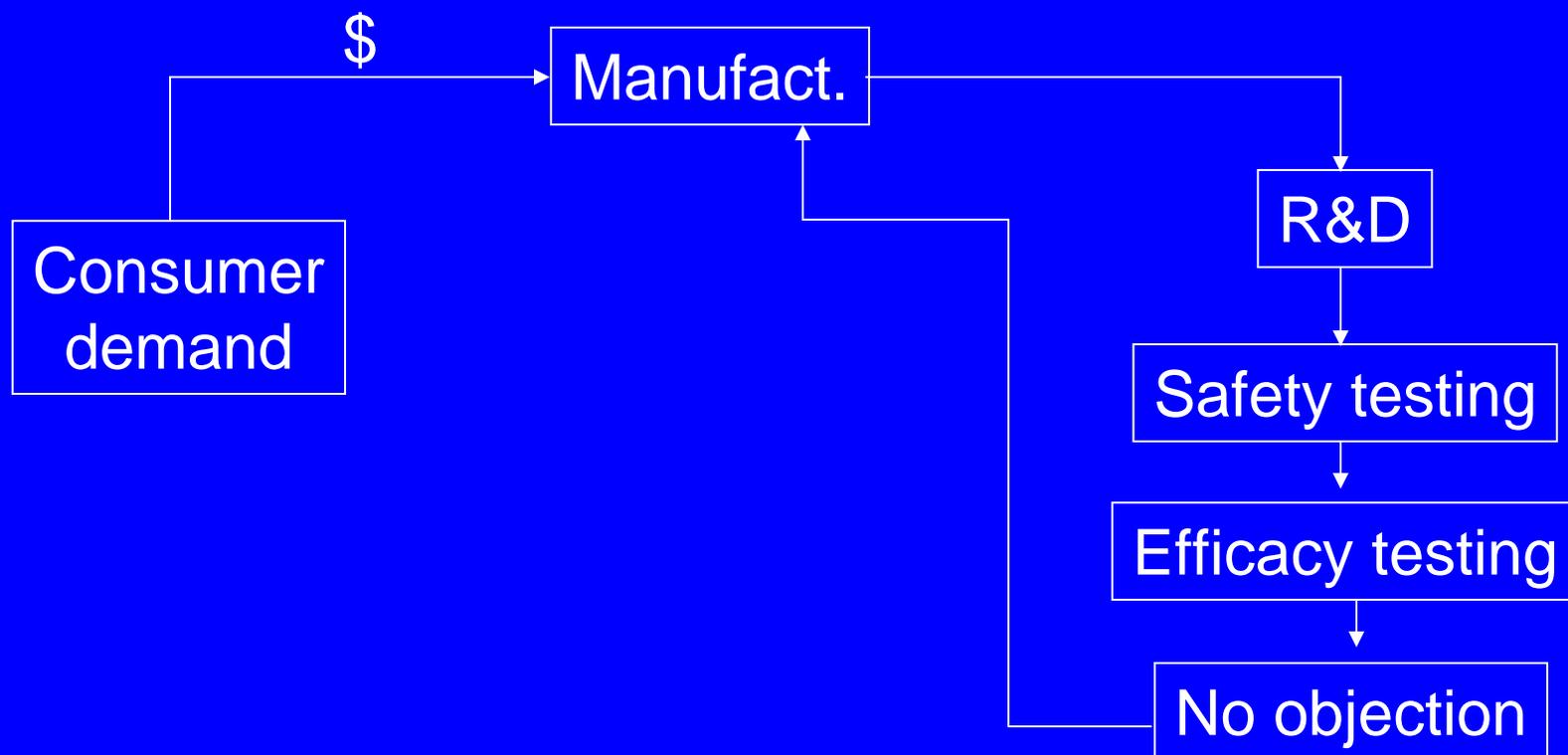
Sequestered Info.  
(~5 years)

- Supporting evidence for claim

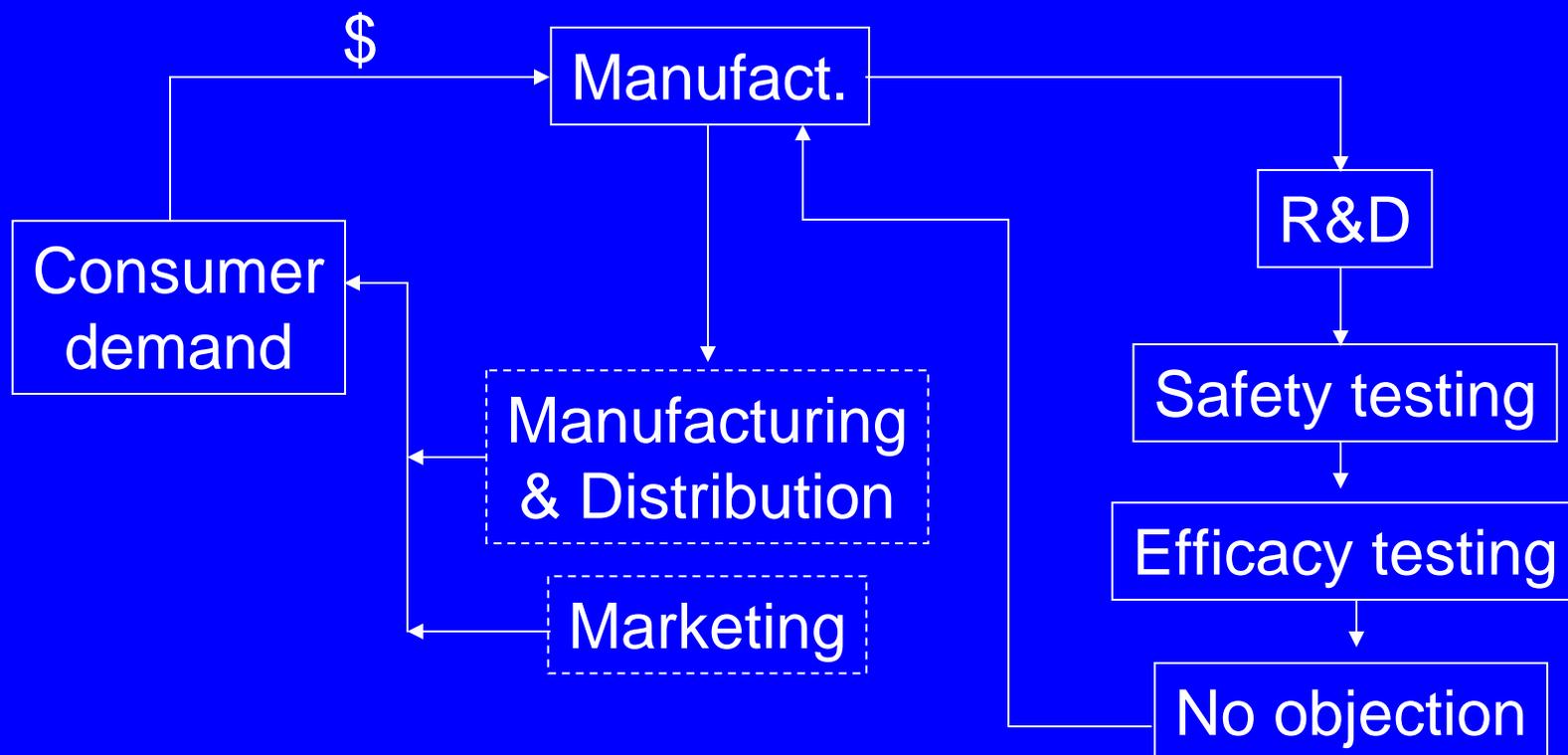
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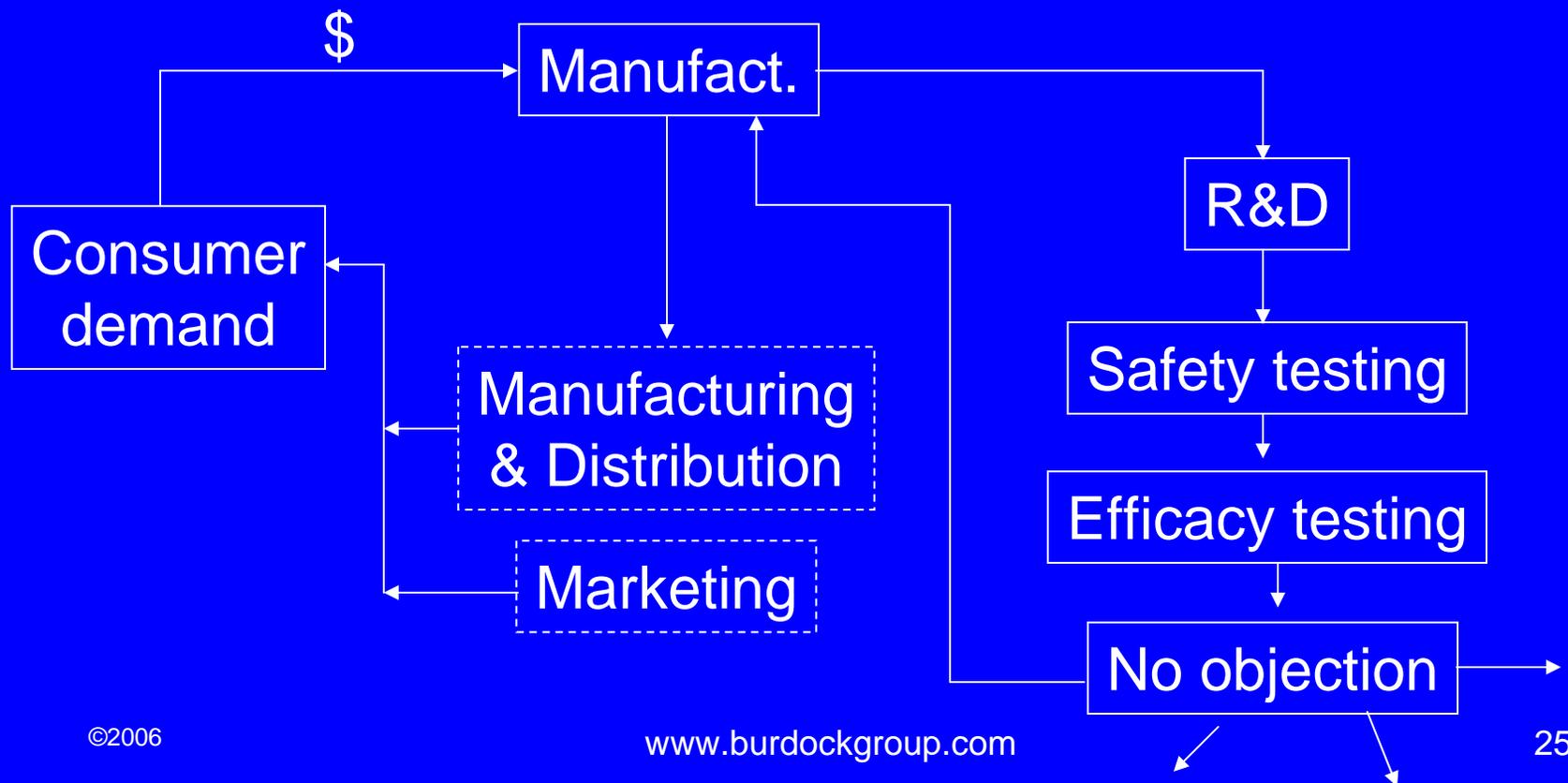
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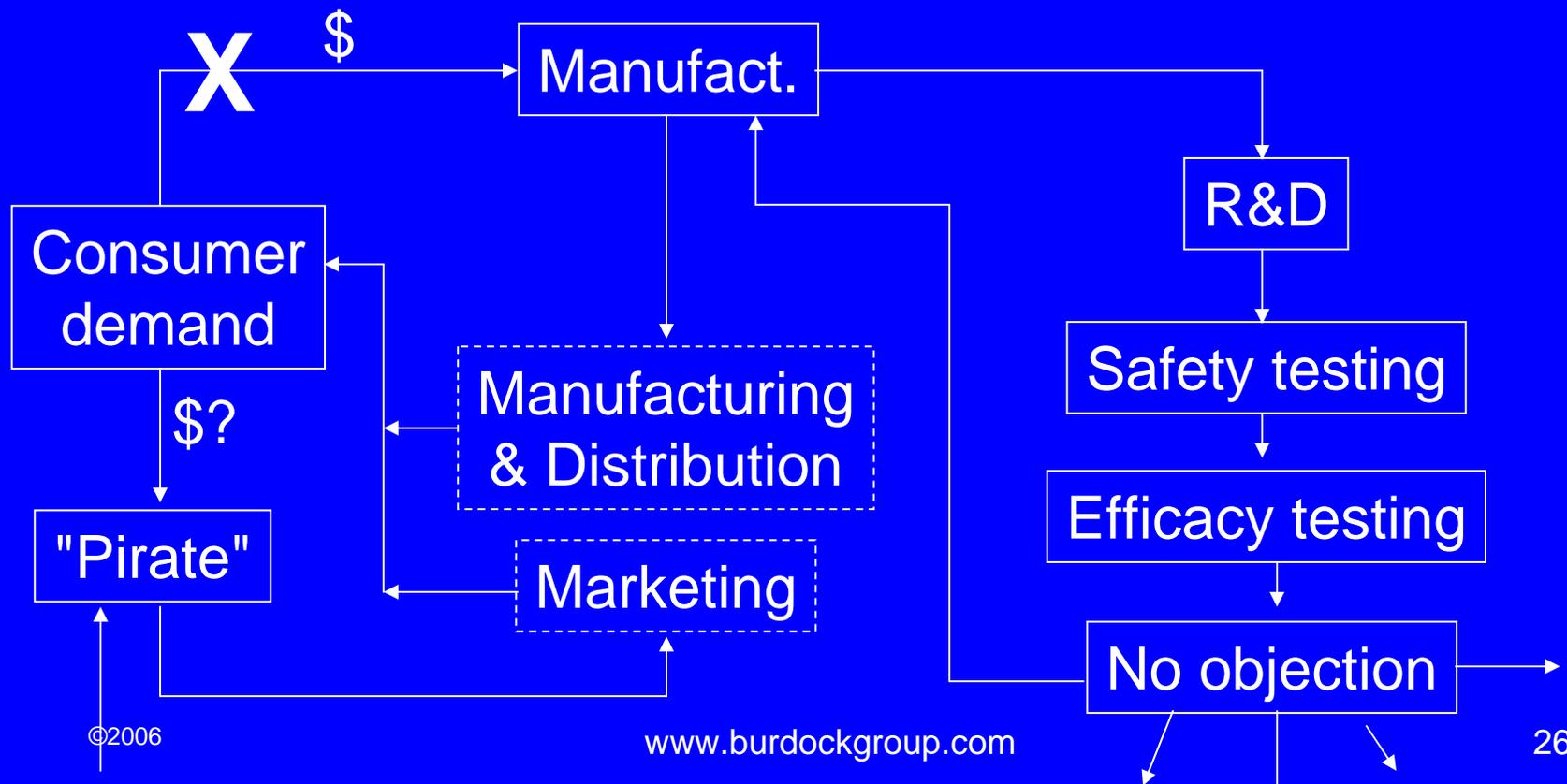
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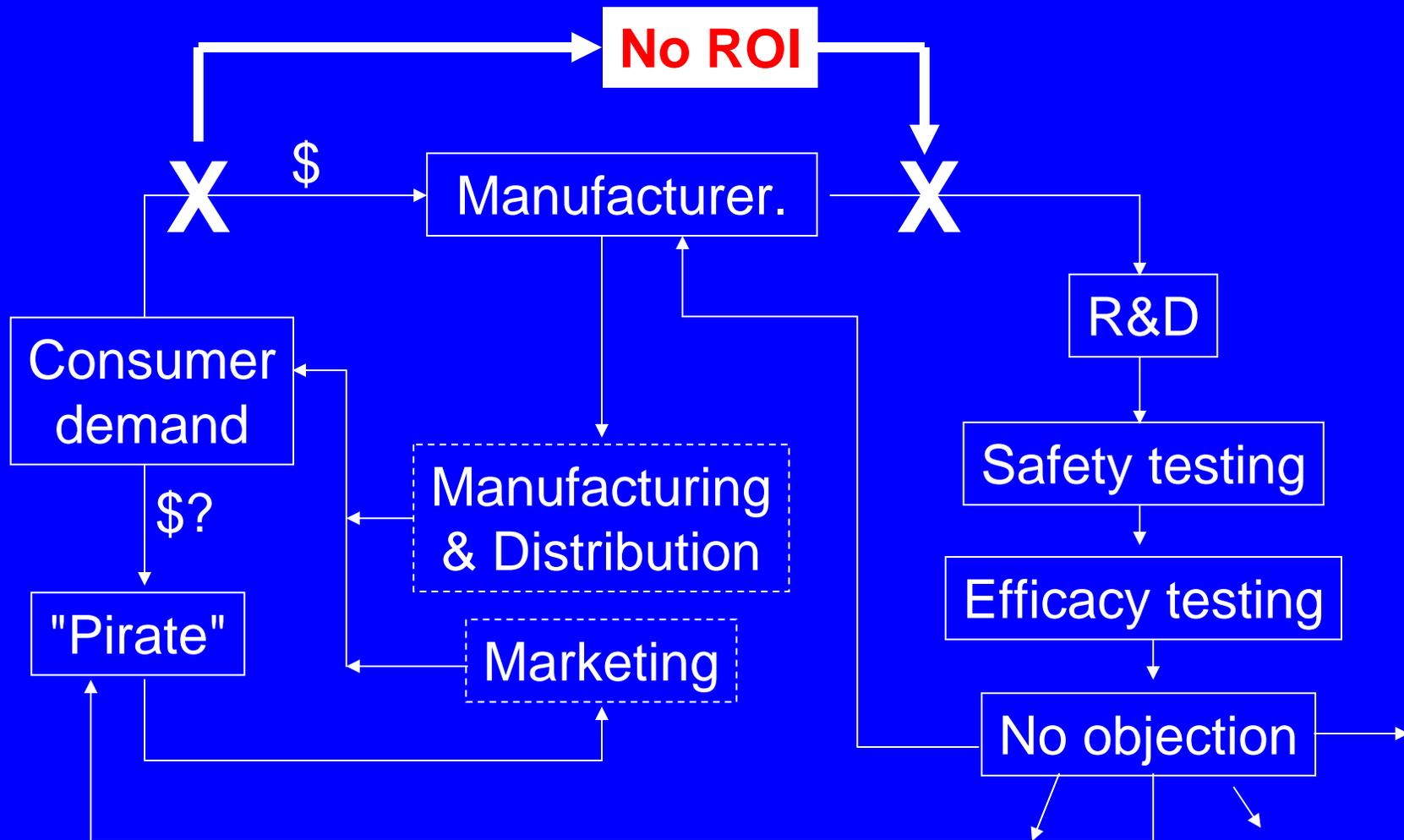
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# 4. Term of Exclusivity



# 4. Term of Exclusivity



# 4. Term of Exclusivity

## Ensure ROI

- Respond to consumer demands for a variety of products
- Ensure products are properly vetted
- Ensure competition in marketplace

# 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

# 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

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