

Dietary Supplements Public Meeting

November 15, 2004

George A. Burdock, Ph.D.

Diplomate, American Board of Toxicology

Fellow, American College of Nutrition

A Conservative Response by the Agency

Legitimate dietary supplements



Out of reach of the consumer



Underground/unregulated products

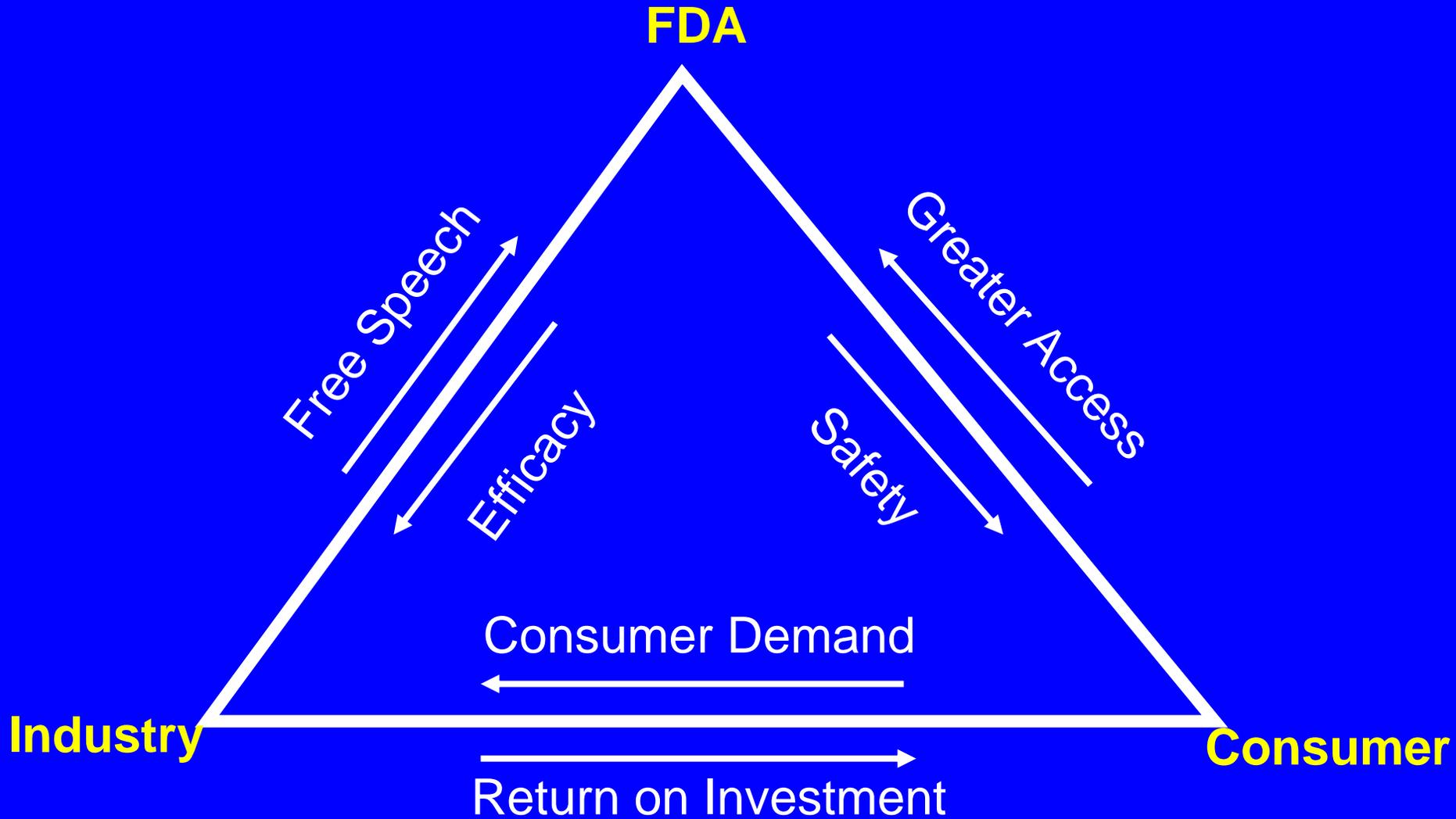
- Spurious claims
- Unsafe products

Dietary Supplement Market

- Strong consumer market & driving forces
 - Quality of life issues
 - Lionizing of natural remedies
 - Reaction to high cost of drugs
- Strong consumer market
 - Encourages enterprise
 - Encourages competition

Dietary Supplements

The Players and the Tension



A Conservative Response by the Agency

May affirm some strongly held beliefs

- Conspiracy theories about “big pharma”
- We ignore the wisdom of our elders
- We ignore the beneficence of ‘mother earth’

DSHEA as a Safety Valve

- DSHEA was a safety valve in response to a conservative posture by FDA
- Locking the valve
 - Consumers will lose faith in the Agency
 - Will give rise to
 - Underground
 - Uncontrolled
 - Unsafe
 - Wild, wild west

The Players and the Tension

FDA is the key player

FDA the *Engine for Resolution*

Three Steps Forward

1. Promote the use of Independent Experts
2. Initiate a Notification program
3. Permit a term of exclusivity

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
- Future?
 - Health Independence Information Act - HR 4004

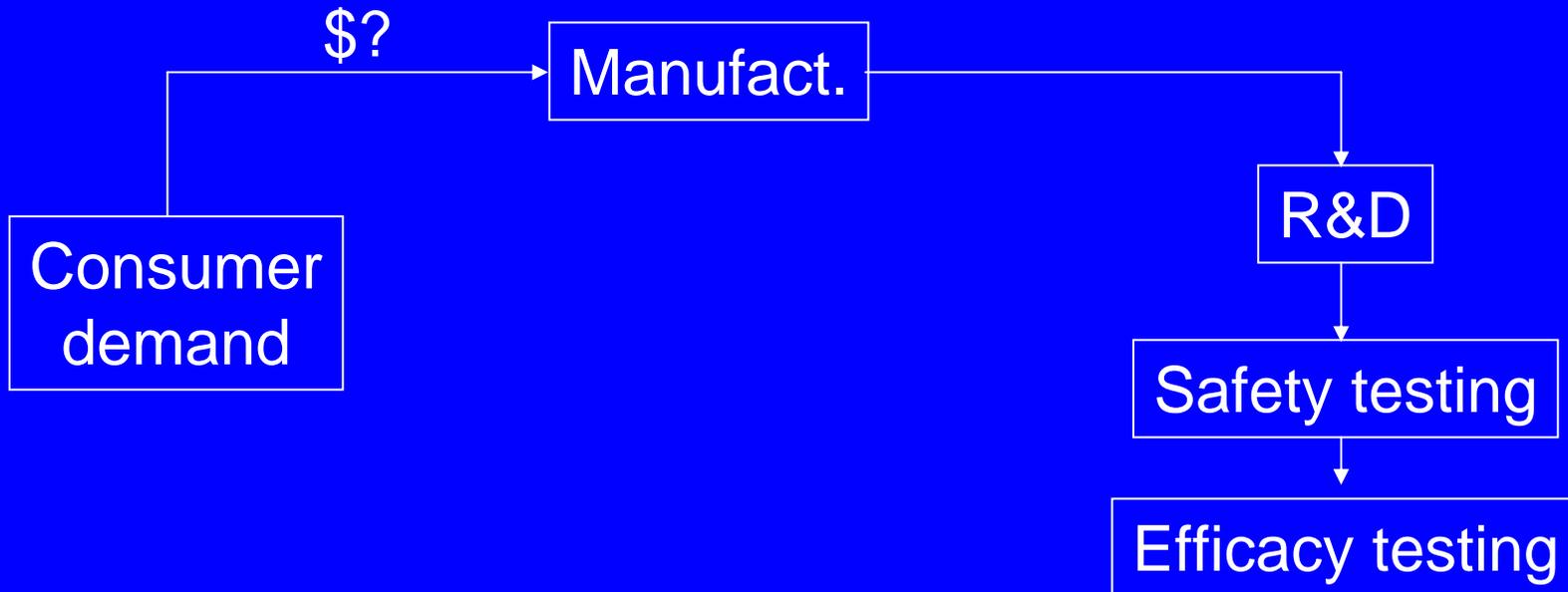
Notification Program

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

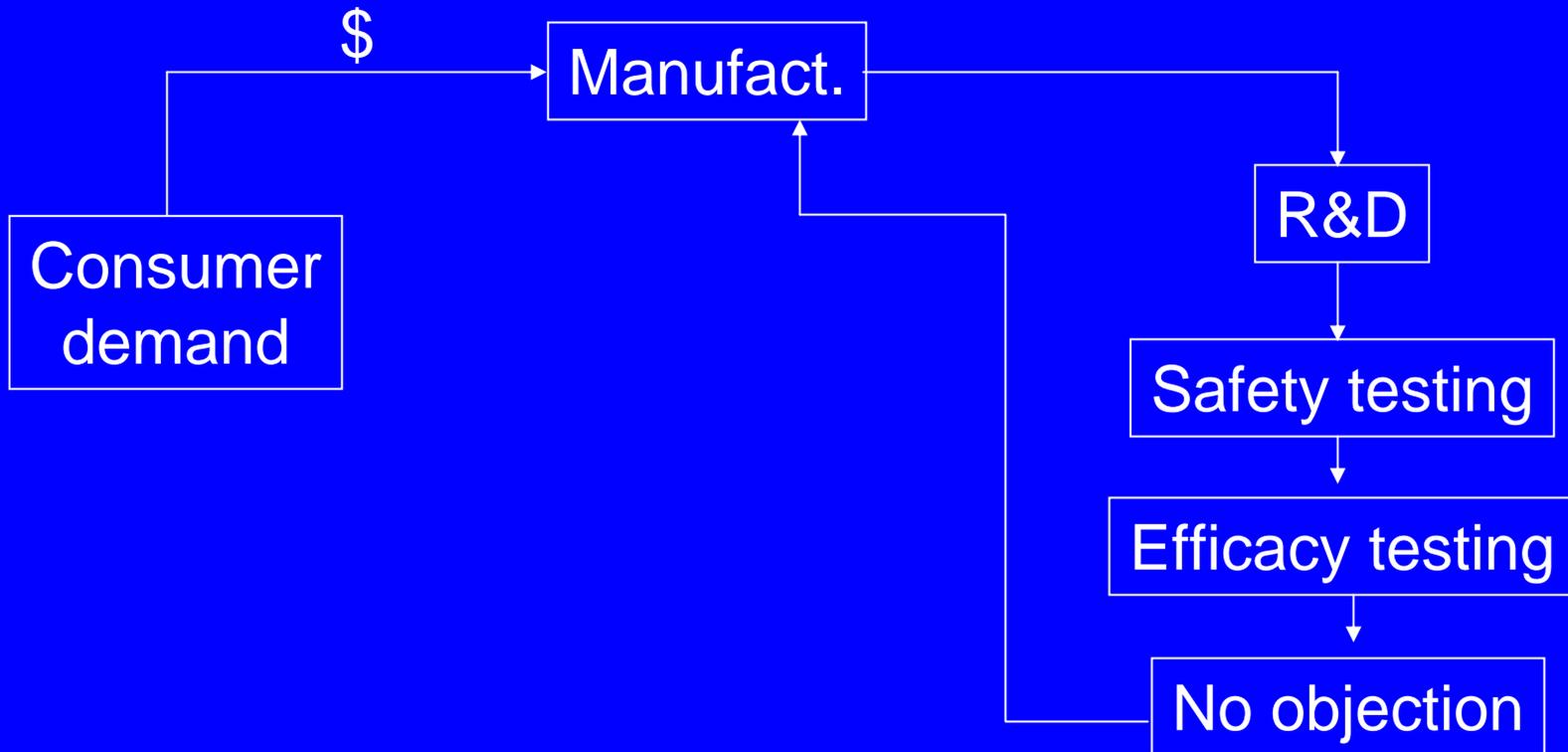
Term of Exclusive Marketing Rights

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

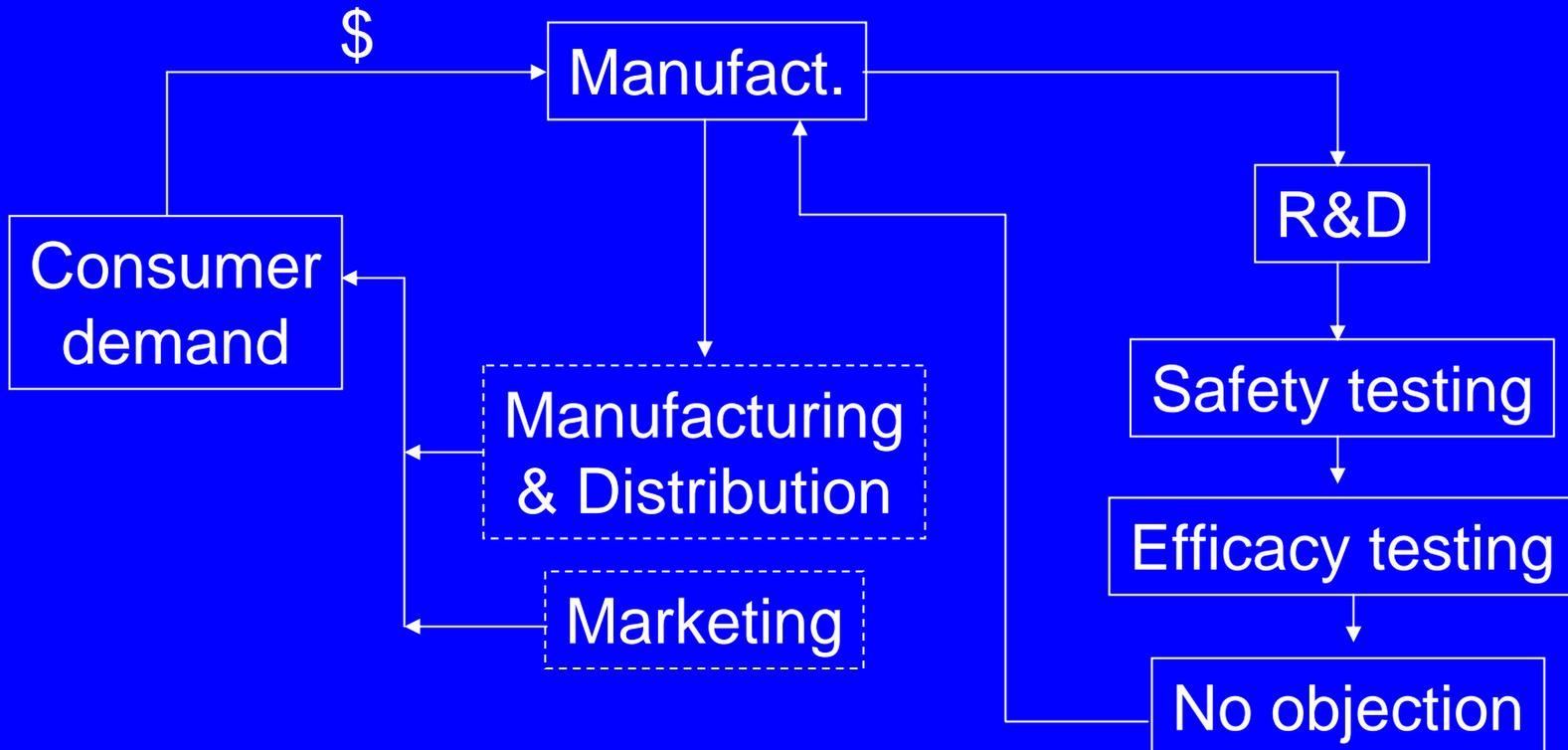
Term of Exclusivity



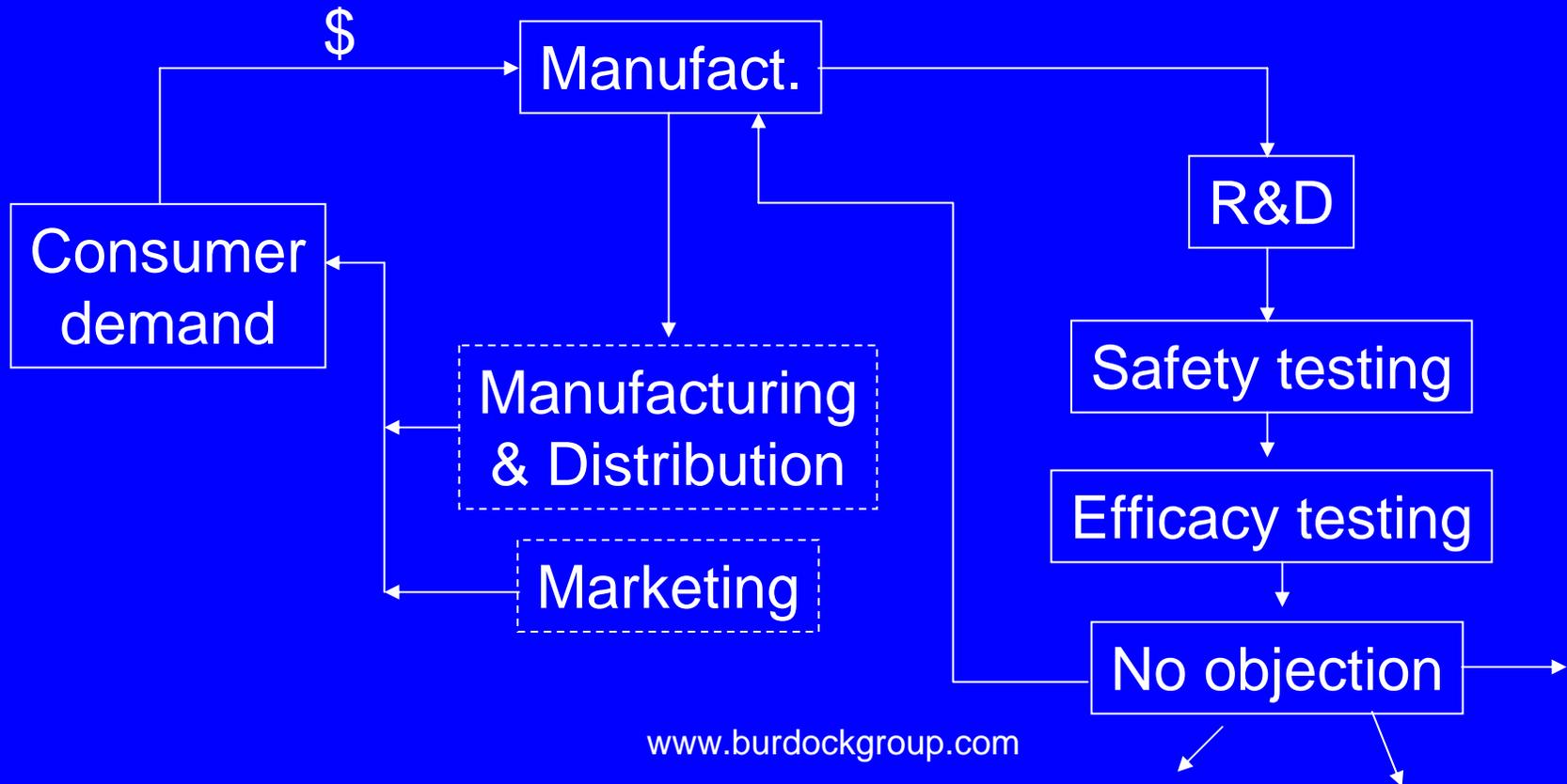
Term of Exclusivity



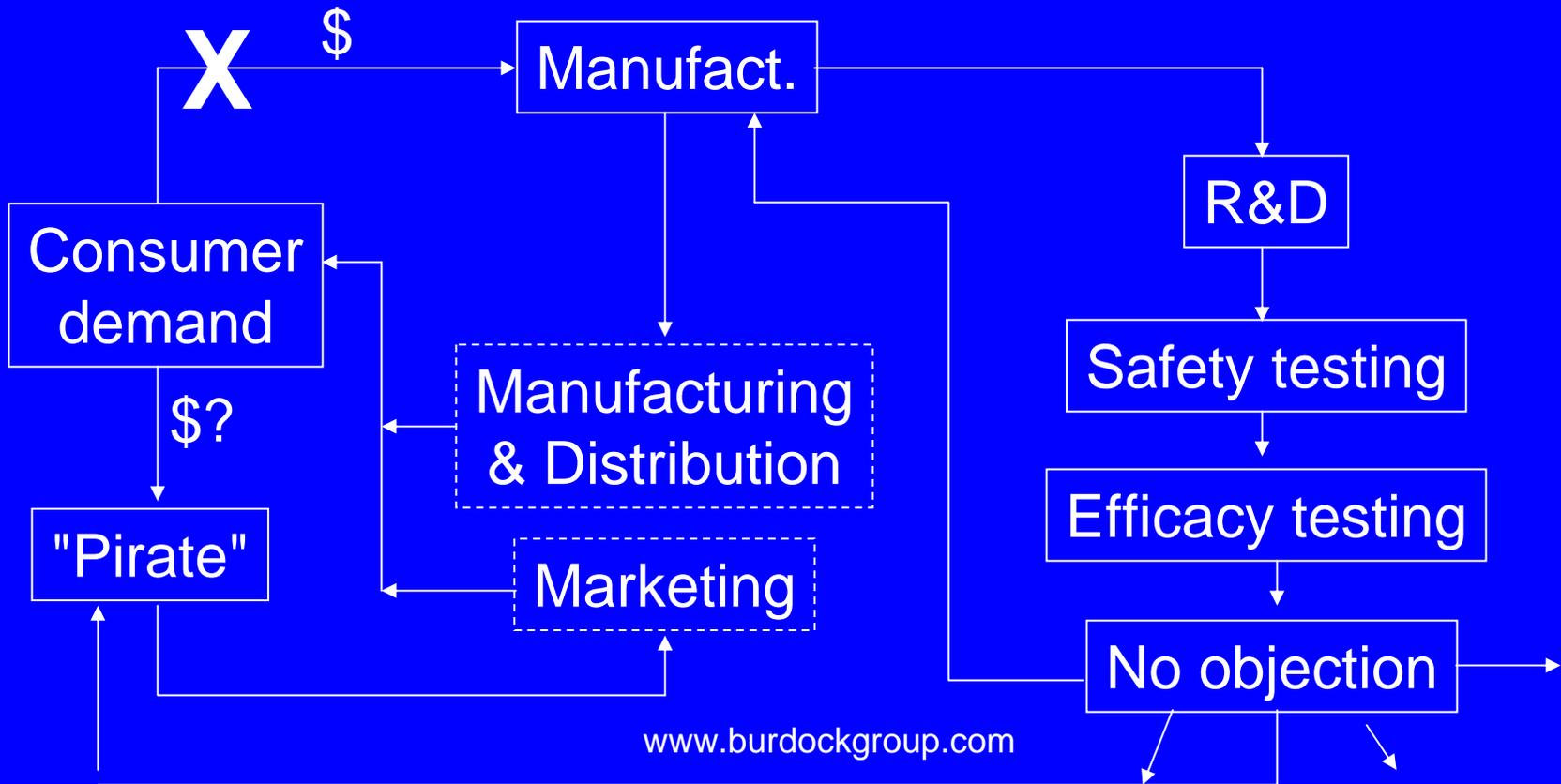
Term of Exclusivity



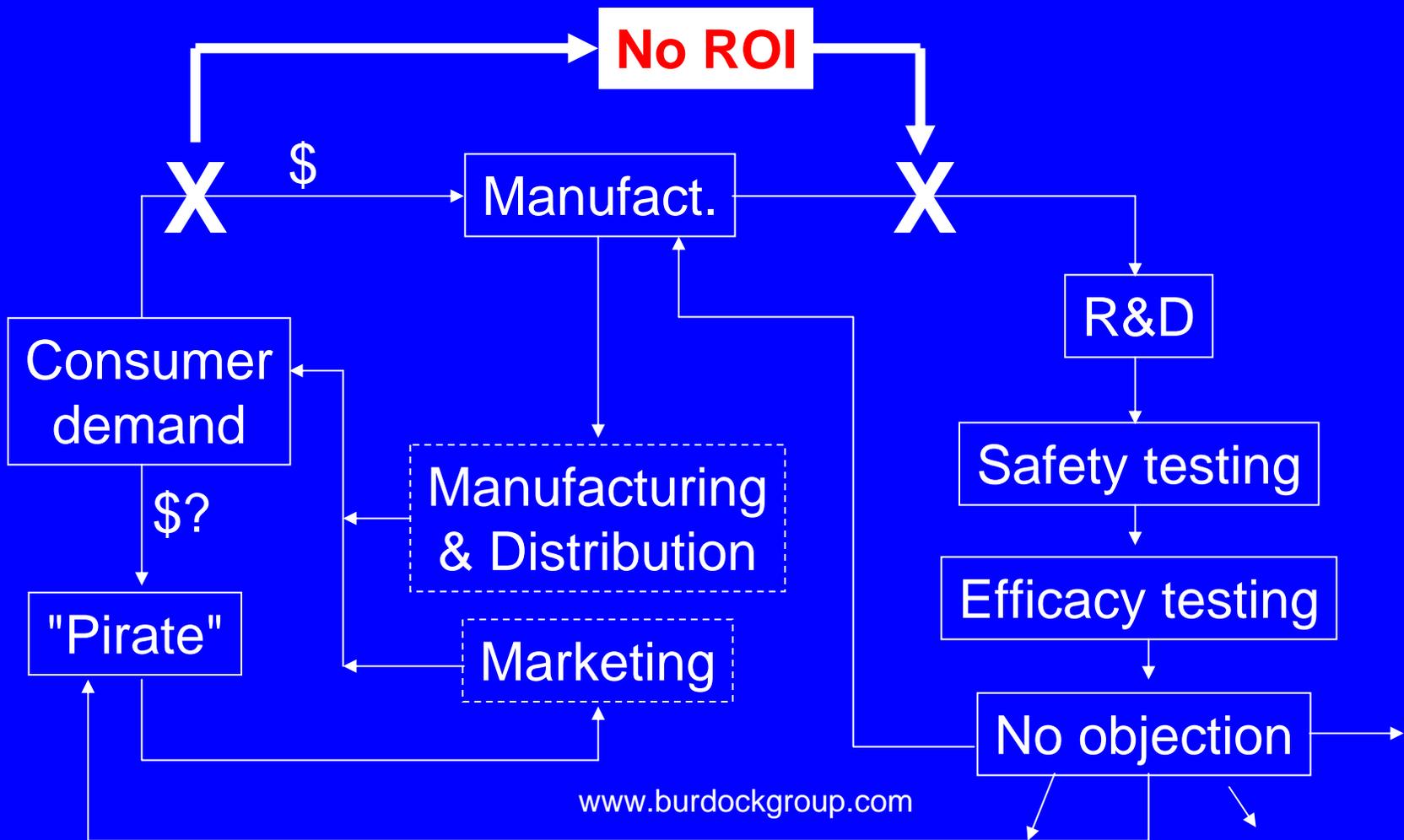
Term of Exclusivity



Term of Exclusivity



Term of Exclusivity



Three Steps Forward

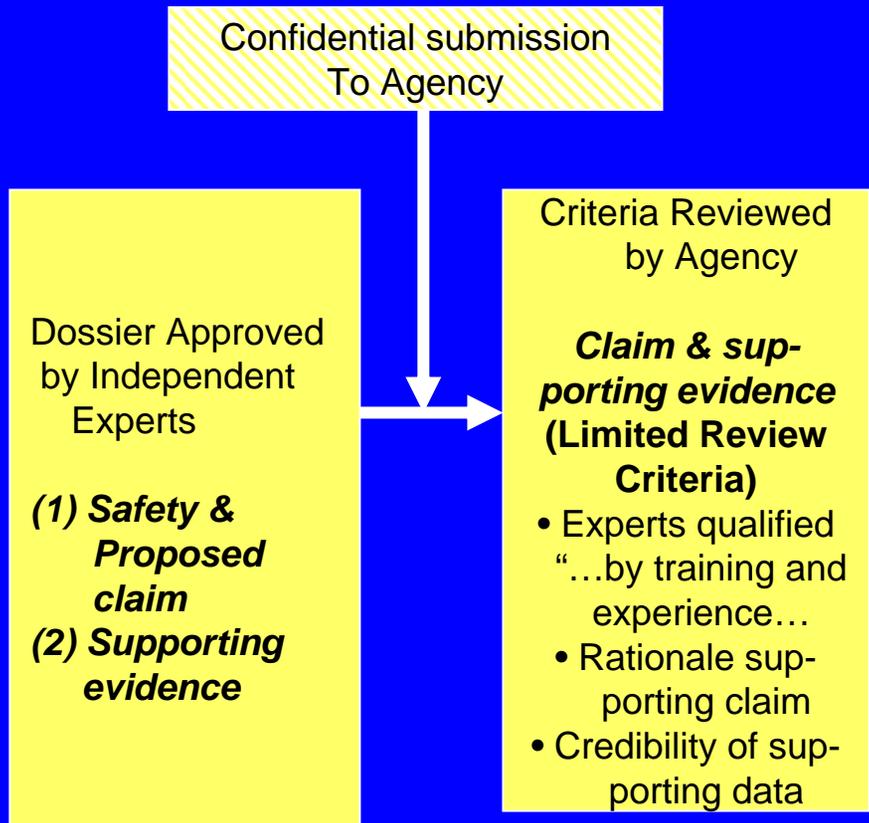
1. Promote the use of Independent Experts
2. Initiate a Notification program
3. Permit a term of exclusivity

Independent Expert Review & FDA Notification

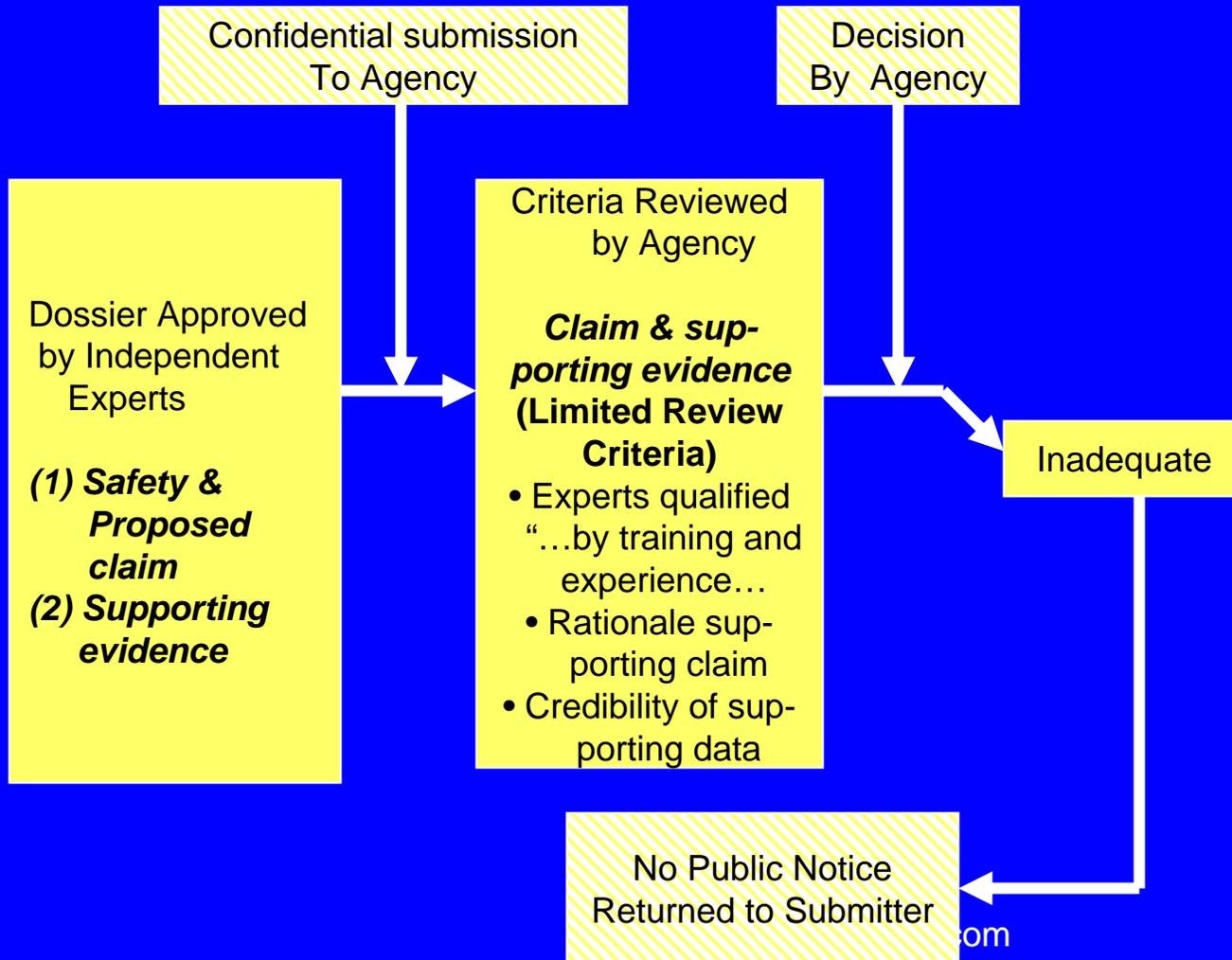
Dossier Approved
by Independent
Experts

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

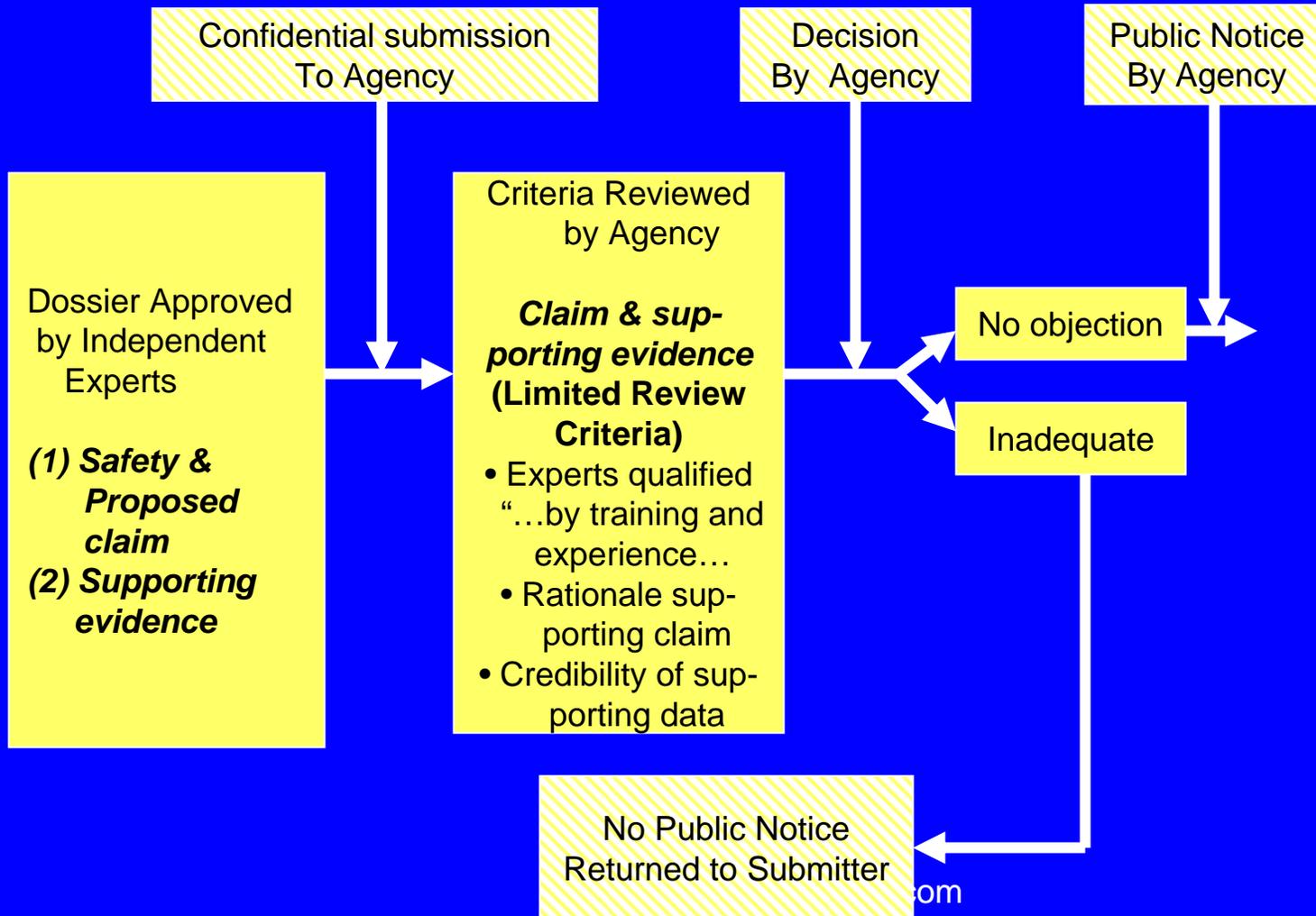
Independent Expert Review & FDA Notification



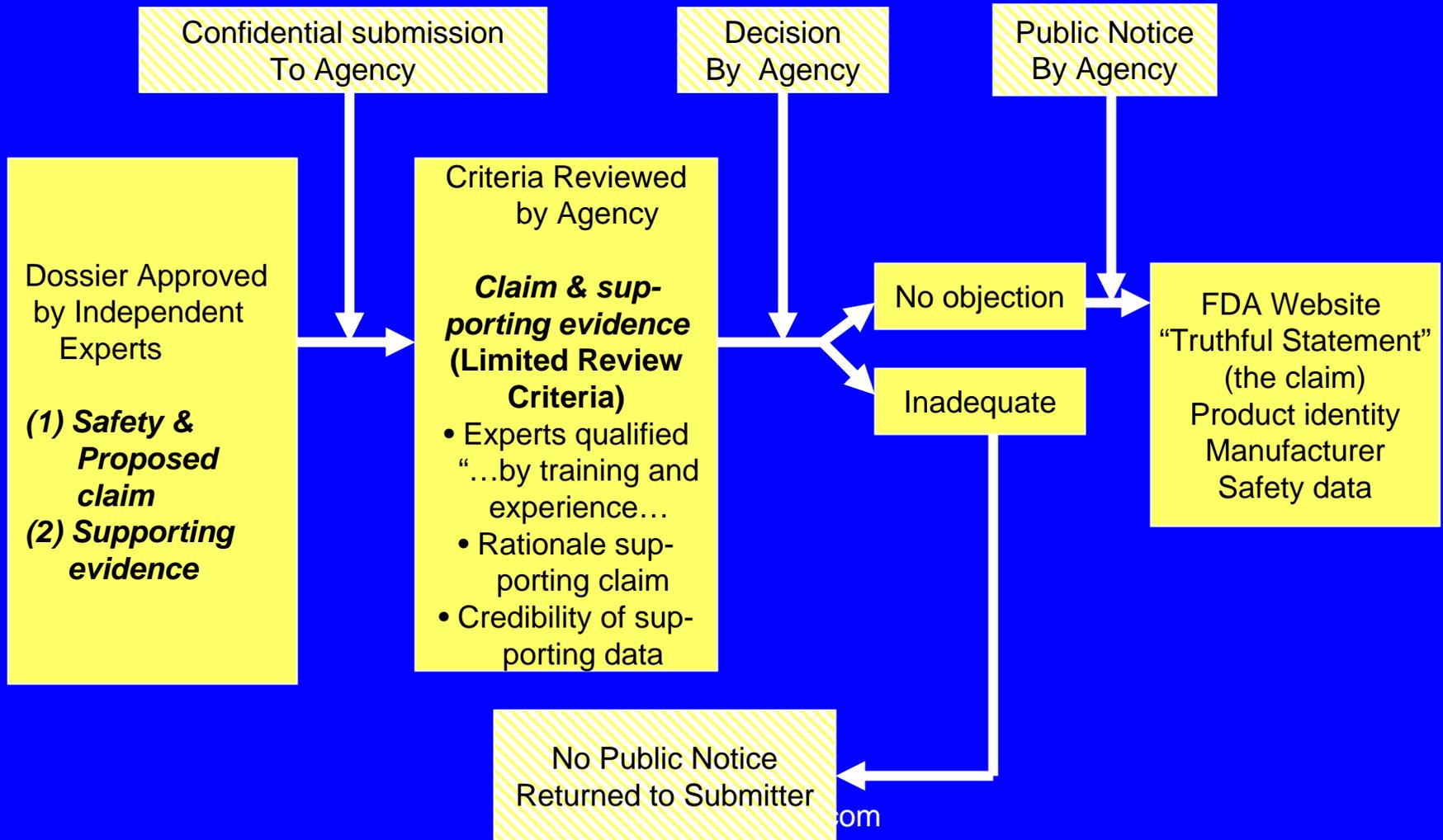
Independent Expert Review & FDA Notification



Independent Expert Review & FDA Notification



Independent Expert Review & FDA Notification



Term of Exclusivity

Public Release
(immediate)

- Safety information
- Claim
- Product name & manufacturer

Sequestered Info.
(~5 years)

- Supporting evidence for claim

Independent Expert Review & FDA Notification

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

Term of Exclusivity

Ensure ROI

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

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)

Dietary Supplements Public Meeting

November 15, 2004

George A. Burdock, Ph.D.

Diplomate, American Board of Toxicology

Fellow, American College of Nutrition

Gburdock@burdockgroup.com

www.burdockgroup.com