

# Evaluating Breakthrough Technology: An FDA Perspective

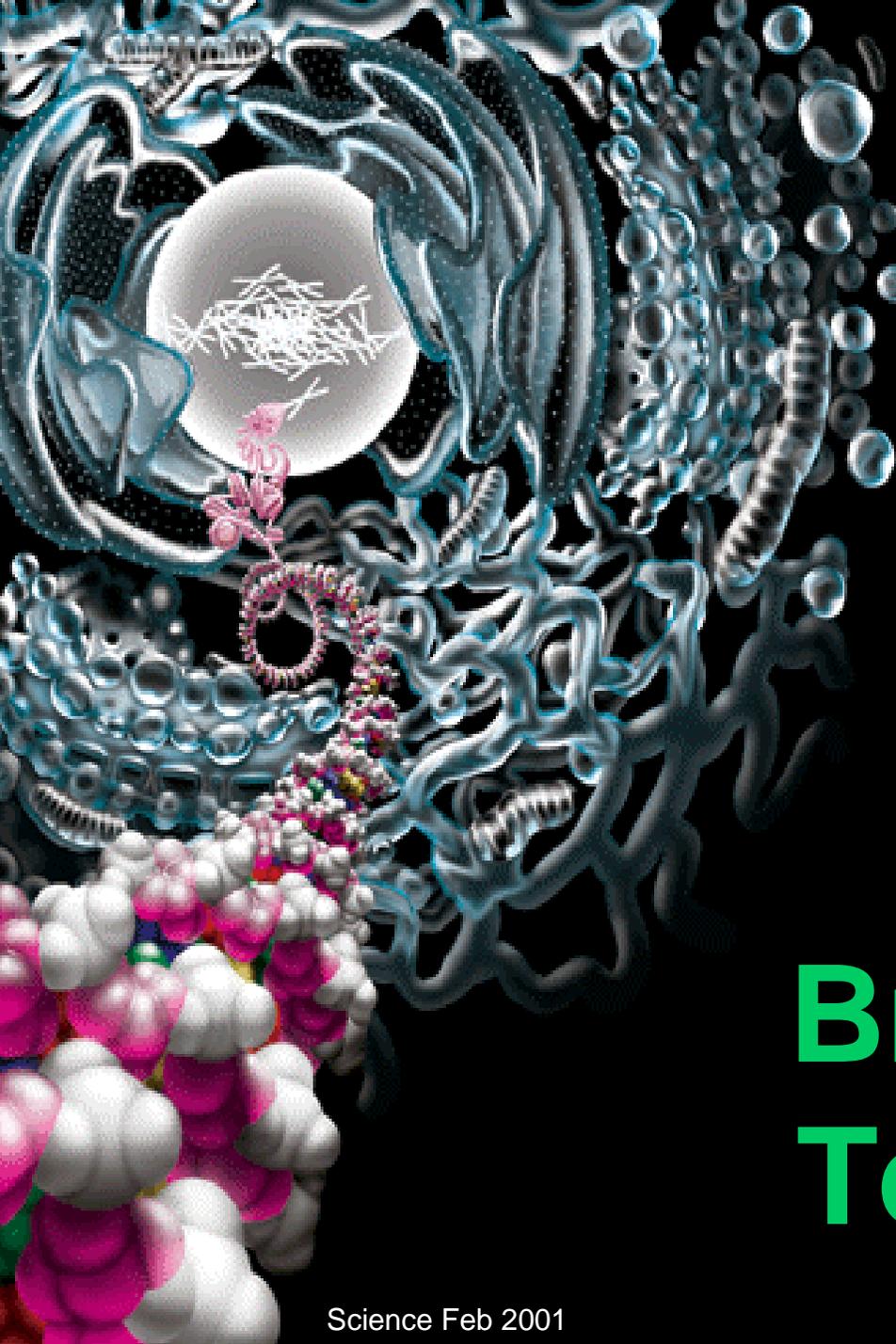
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# What are Breakthrough Technologies

# Fast Track Products

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## Food Drug & Cosmetic Act

- Amended by the FDA Modernization Act of 1997 to include section 506: Fast Track Products

## Two Qualifying Criteria:

- Intended to treat a serious or life-threatening condition
- Potential to address unmet medical needs for the condition



# Treatment of Serious Conditions:

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## Examples

- a therapy directed at serious symptoms or serious manifestations of the condition;
- a diagnostic evaluated for the impact on a serious aspect of the condition;
- a preventive intended to prevent a serious aspect;
- a product which could ameliorate serious adverse effects of other treatments.

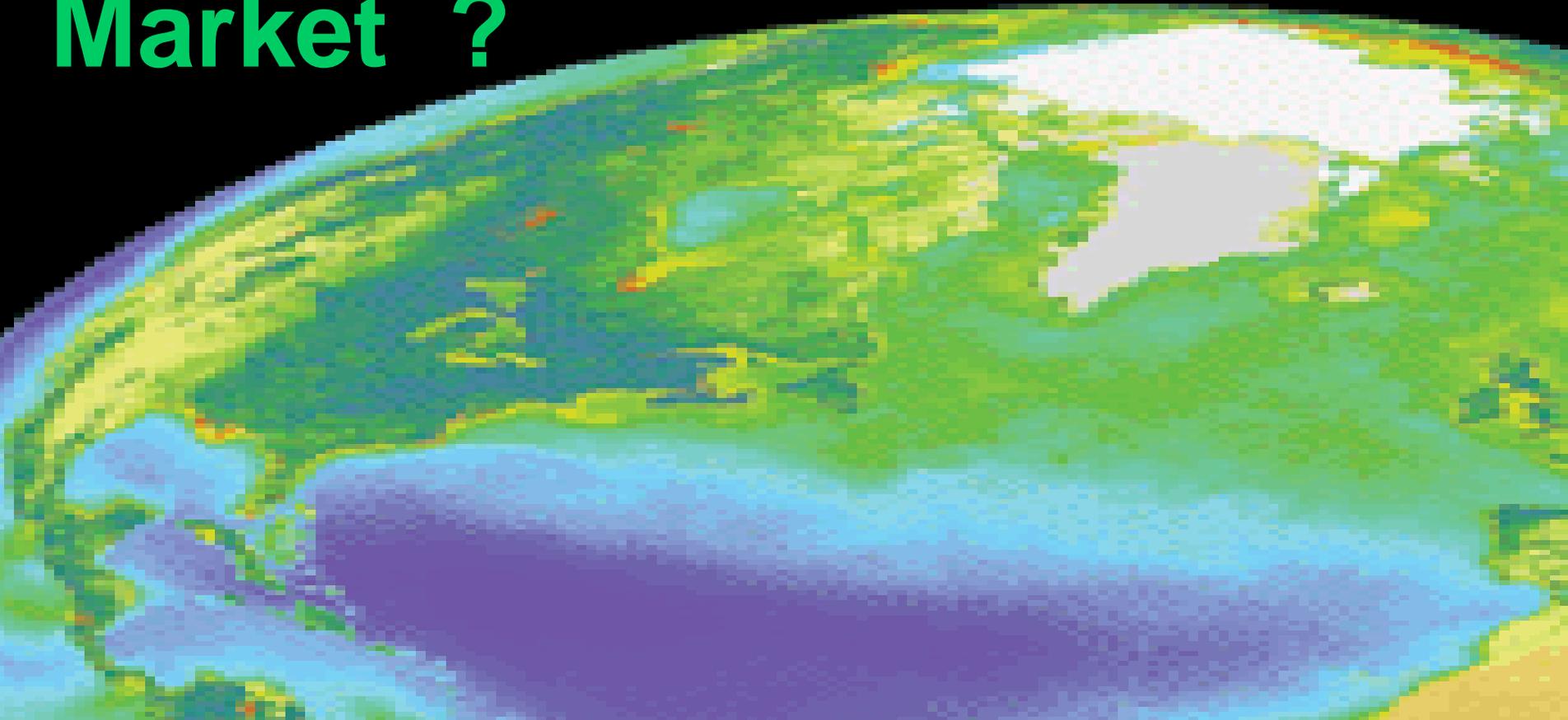
# Address Unmet Medical Needs

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## Examples

- no existing therapy
- new therapy is better
- new therapy for patients intolerant or unresponsive to existing therapy
- new therapy is less toxic
- new therapy improves compliance (which is shown to improve effects on serious conditions)

**How do  
breakthrough  
products get to  
Market ?**



# Fast Track Products

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## Food Drug & Cosmetic Act

- Amended by the FDA Modernization Act of 1997 to include section 506: Fast Track Products
- Authorizes FDA to:
  - Facilitate Development
  - Expedite Review



Premarket

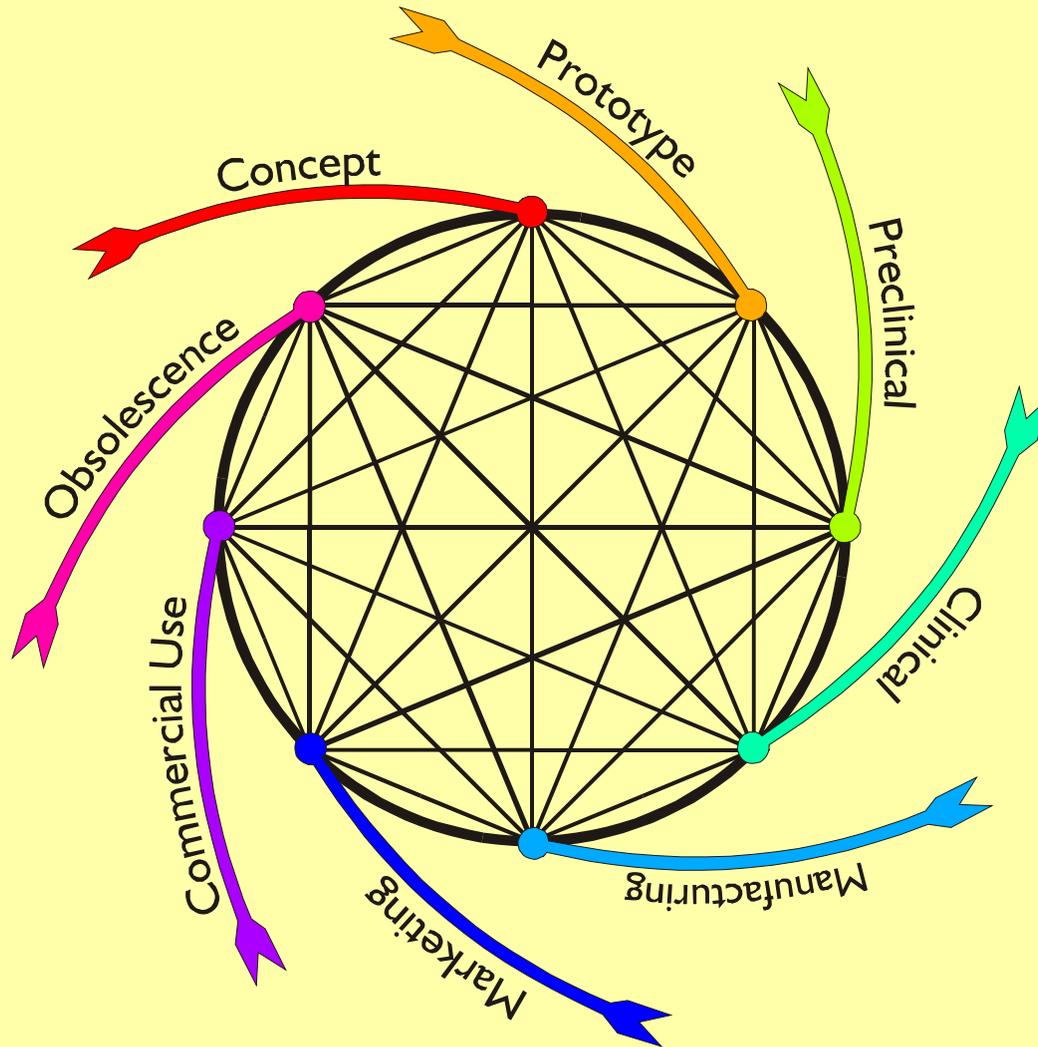
Postmarket



**Evidence**



# CDRH Vision - Total Product Life Cycle



# Engineering

## Design

Concept

Prototype

Biocompatibility

Materials Science

Toxicology

Mode of Action

Preclinical

Hazard Analysis

Clinical Sciences

Study Design

Statistics

Review Sciences

Environment

EMC  
Shock  
Vibration

End of Life

Risk Analysis

Obsolescence

Commercial Use

Post-Marketing Surveillance

Human Factors

Adverse Event Reporting

Forensic Engineering

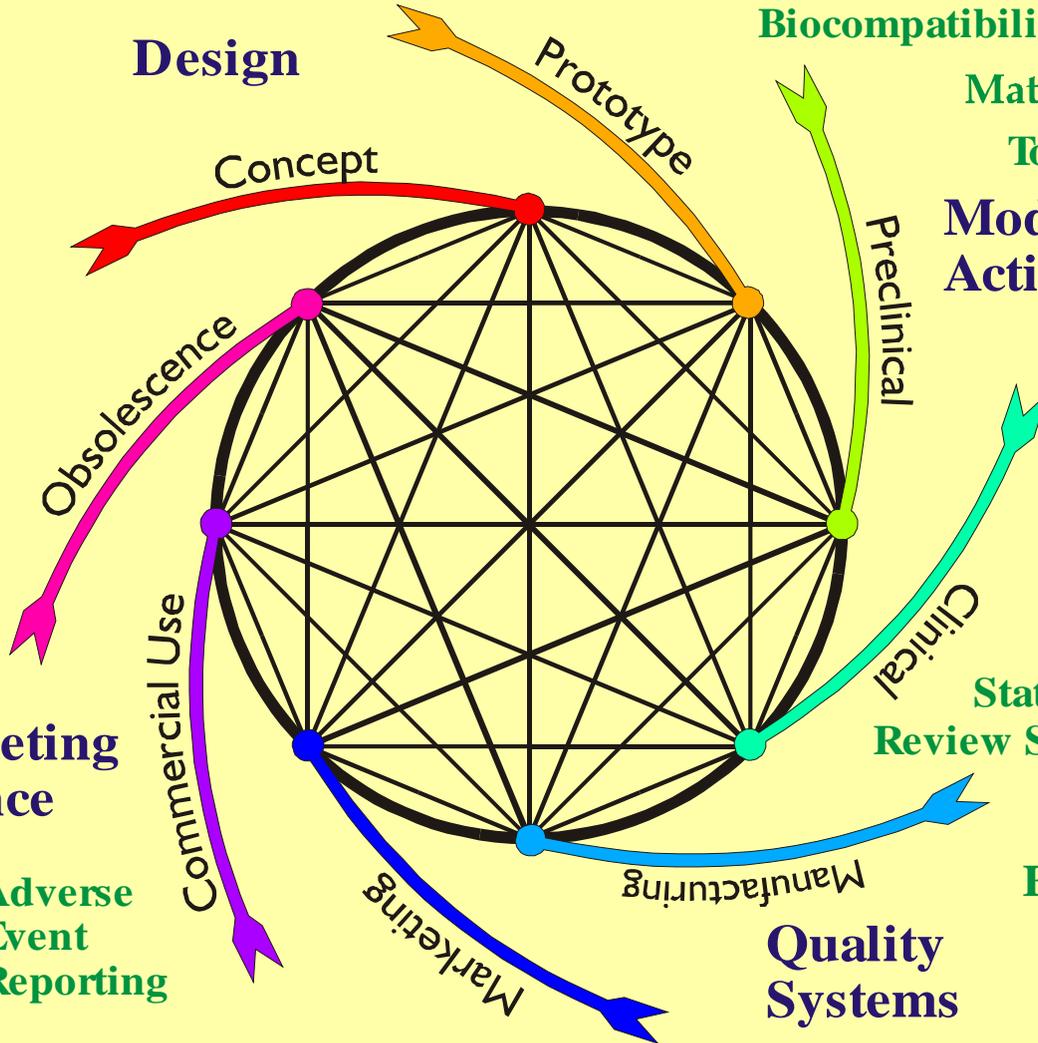
Epidemiology

Manufacturing

Quality Systems

Reuse

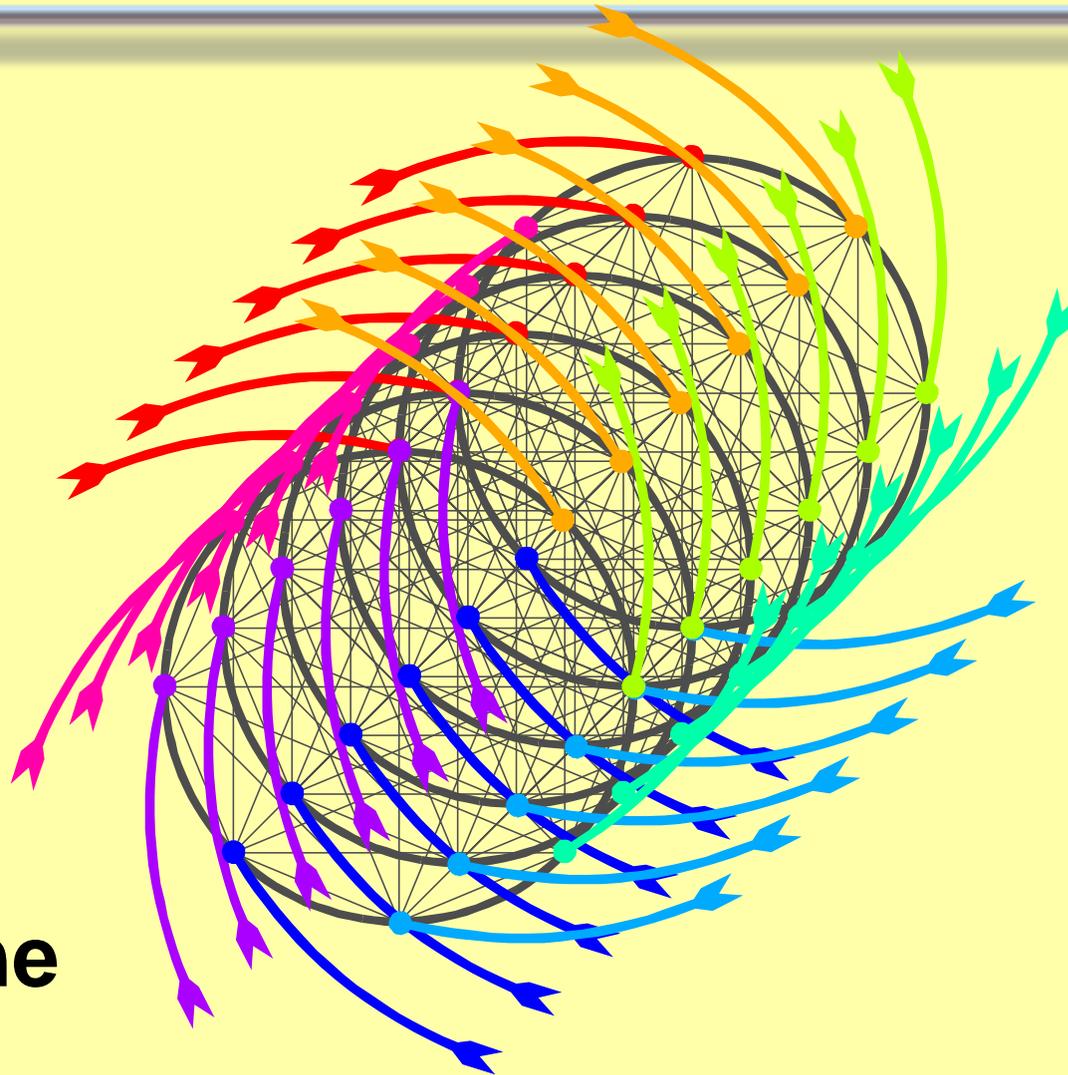
Sterility





# CDRH Vision - Total Product Life Cycle

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**The Pipeline**

# New Technologies

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## Issues

- Regulatory Path:
  - Drug ?
  - Biological ?
  - Device ?
- Combination Products
  - Which Center Leads ?
- How to accelerate development ?



# Acceleration: Options

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Intensify

Telescope

Combine

Shorten

Simplify

Skip

Postpone



# Acceleration: Options

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Intensify

Telescope

Combine

Shorten

Simplify

Skip

Postpone

*Lower Standards?*

