Overcoming Regulatory Impediments to Anti-Aging Technologies

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FDA
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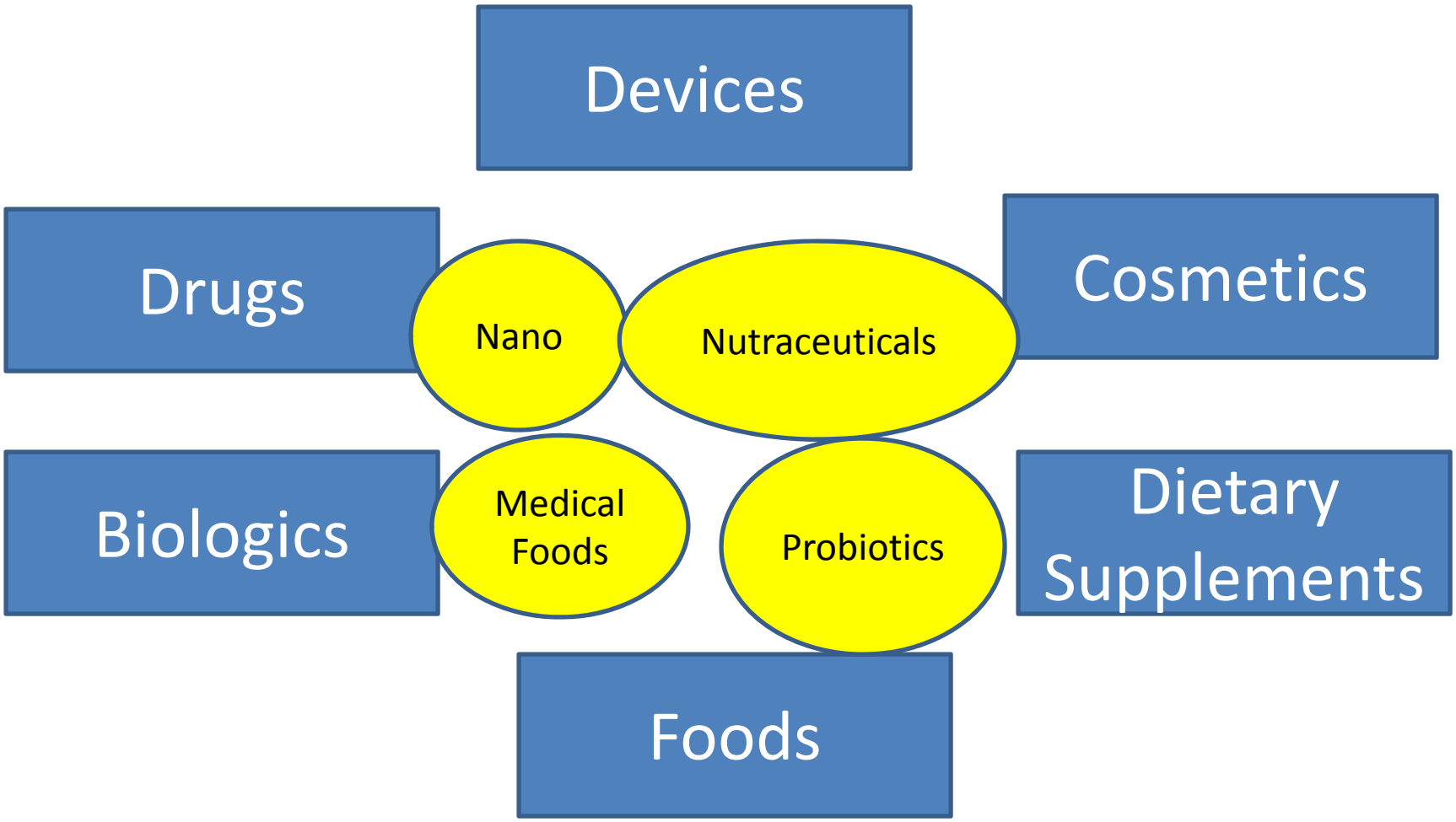
FDA Approval

- Most technologies (pharmaceuticals, gene therapy, implanted devices) potentially involved in anti-aging require FDA pre-market approval
- Under the Federal Food, Drug & Cosmetic Act, FDA must and can only consider two factors in approving such products: safety and efficacy
  - i.e., no authority to consider social, ethical or religious concerns
- Once a product such as a drug has been approved by FDA, can generally be prescribed for any purpose by a doctor

FDA Regulation:
Category Based Approach

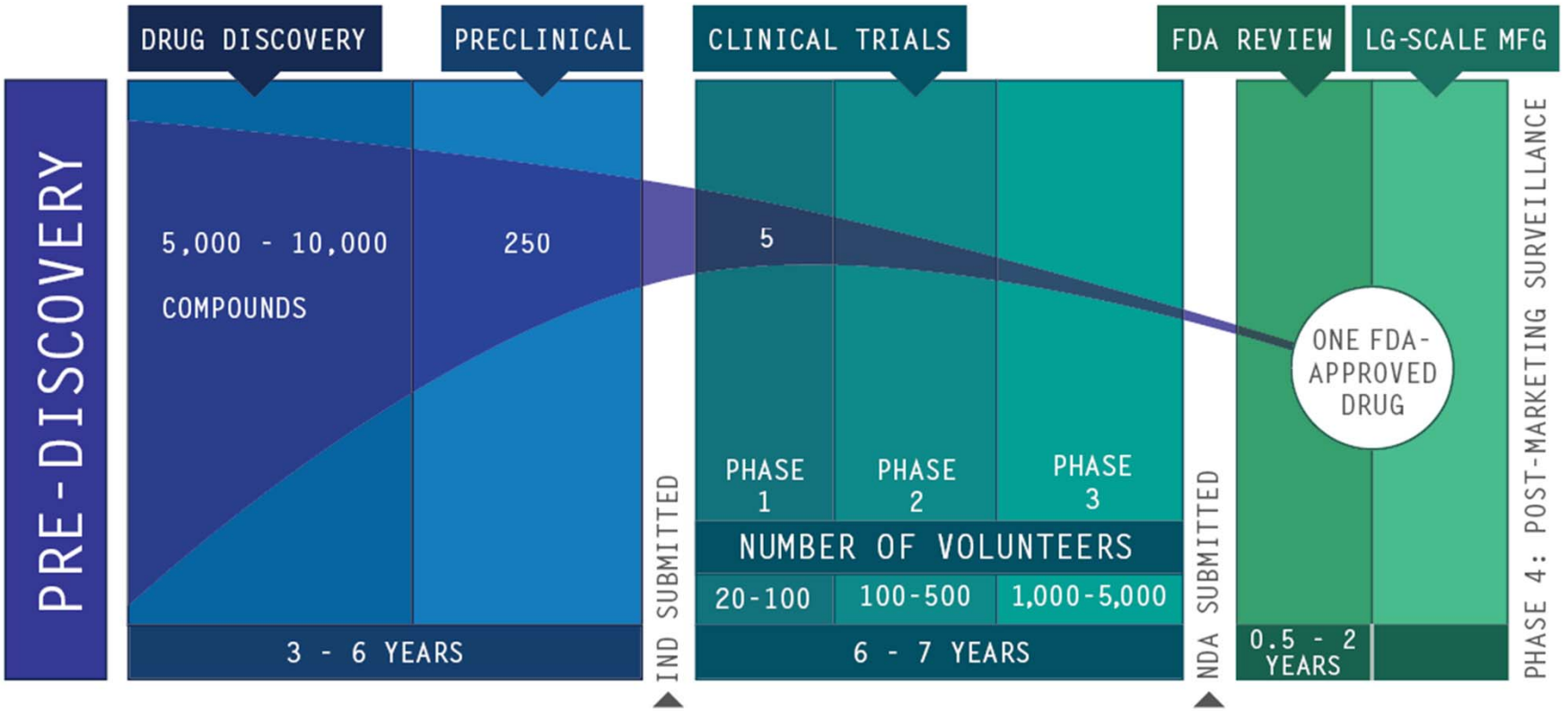


FDA Definition of “Drug”

- The term "drug" means:
  - articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals (by chemical action); or
  - articles (other than food) intended to affect the structure or any function of the body of man or other animals (also by chemical action).

YOU ARE WHAT YOU CLAIM!

Drug Approval Process



Source: Innovation.org

Problem with FDA Approval of Anti-Aging Drugs

- To prove efficacy of an ant-aging drug, would need to produce two Phase 3 studies showing statistically significant increase in longevity
- Problem – it would take at least a decade of follow-up (and likely longer) to demonstrate increased lifespan
- Cost would be >>>>billions

Option 1: Focus on Anti-Aging Symptoms

- Company could try to define anti-aging endpoint as symptomatic relief
  - What are symptoms of aging?
  - What qualifies as symptomatic relief?
  - How do deal with subjective aspect of many symptoms?
  - How can FDA ensure results reflect changes to actual process of aging vs. agent that just makes patient feel better (e.g., marijuana)
- No good precedents

Option 2: Approve Drug for Specific Disease or Condition

- Rather than seeking approval of drug for anti-aging benefits, demonstrate that drug helps to treat or extend life for a specific disease or condition
- Once approved by FDA for a specific disease or condition, doctors can prescribe drug off-label for any purpose (e.g., anti-aging)
- But:
  - Manufacturers cannot promote drug as anti-aging
  - Insurers may not cover drug for anti-aging purposes
  - Doctors may face increased malpractice risk for off-label use

Option 3: Approve Product as Dietary Supplement

- Dietary Supplements are regulated under 1994 *Dietary Supplement Health and Education Act* (DSHEA)
- No pre-market requirement to demonstrate safety or efficacy; products are often promoted with little or no evidence of effectiveness or safety
- Burden is on the FDA to show that products are not safe or effective
- Only apply if oral administration

Dietary Supplements: Labelling

- *Health claims:*
  - refer to prevention or treatment of a specific disease
  - must be approved by FDA as part of drug approval
- *Structure and function claims*
  - allowed without FDA approval
  - must include disclaimer that not approved by FDA

Example of structure and function claim

Structure and function claim

disclaimer

Source: Jim Lund

Option 4: Enhancement

- Some view anti-aging treatments as enhancement rather than therapeutic
- FDA has no approval pathway for enhancement products

Conclusion

- Current FDA approach does not provide efficient/feasible pathway for approval of anti-aging treatments
- With recent progress in anti-aging treatments, urgent need for new regulatory pathway for anti-aging treatments
  - May be part of a transition from a disease-focused model to a health-focused model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