

Developing Successful Topical Therapies for Dermatologic Disease

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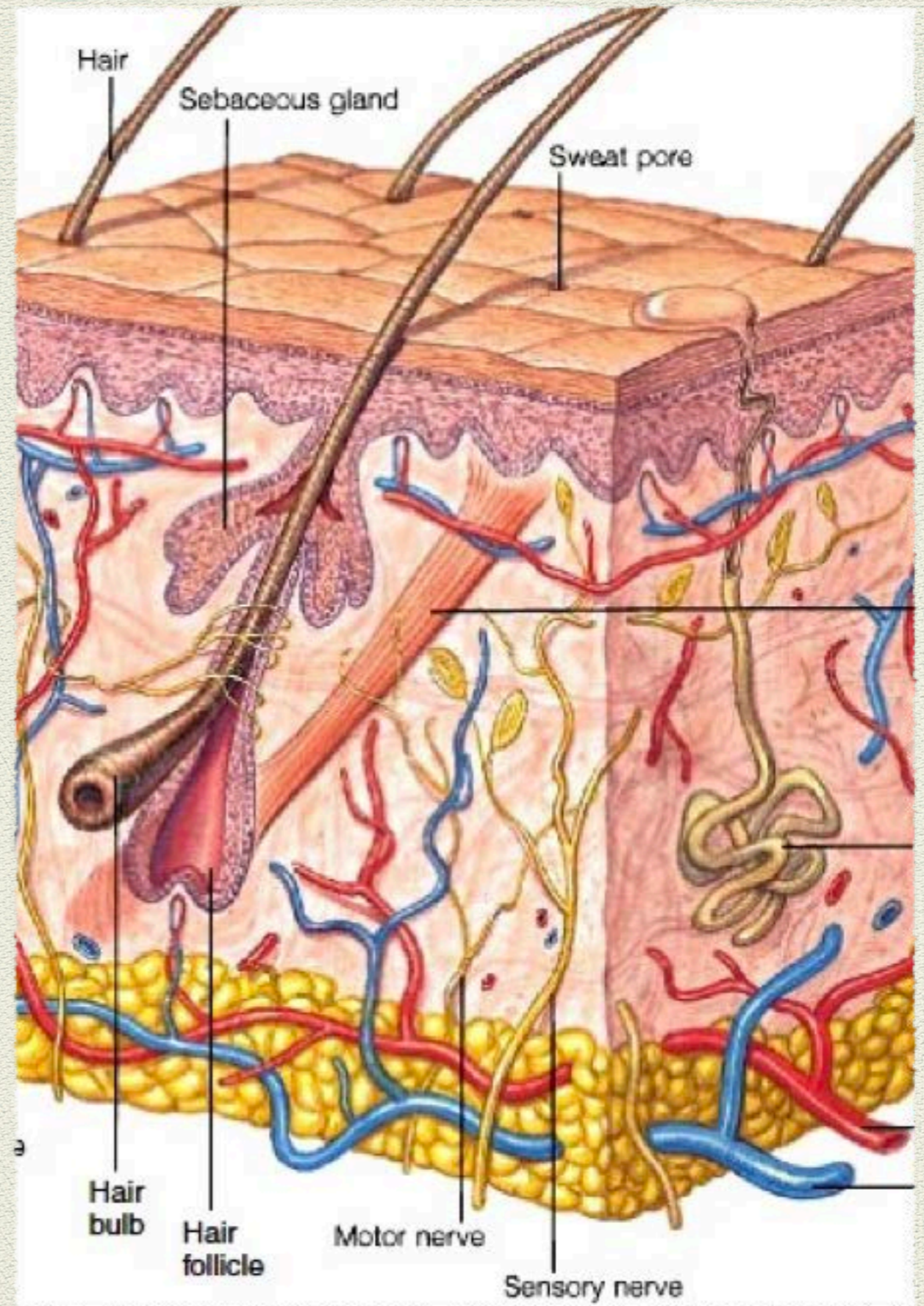
Donald S. Coffey, PhD

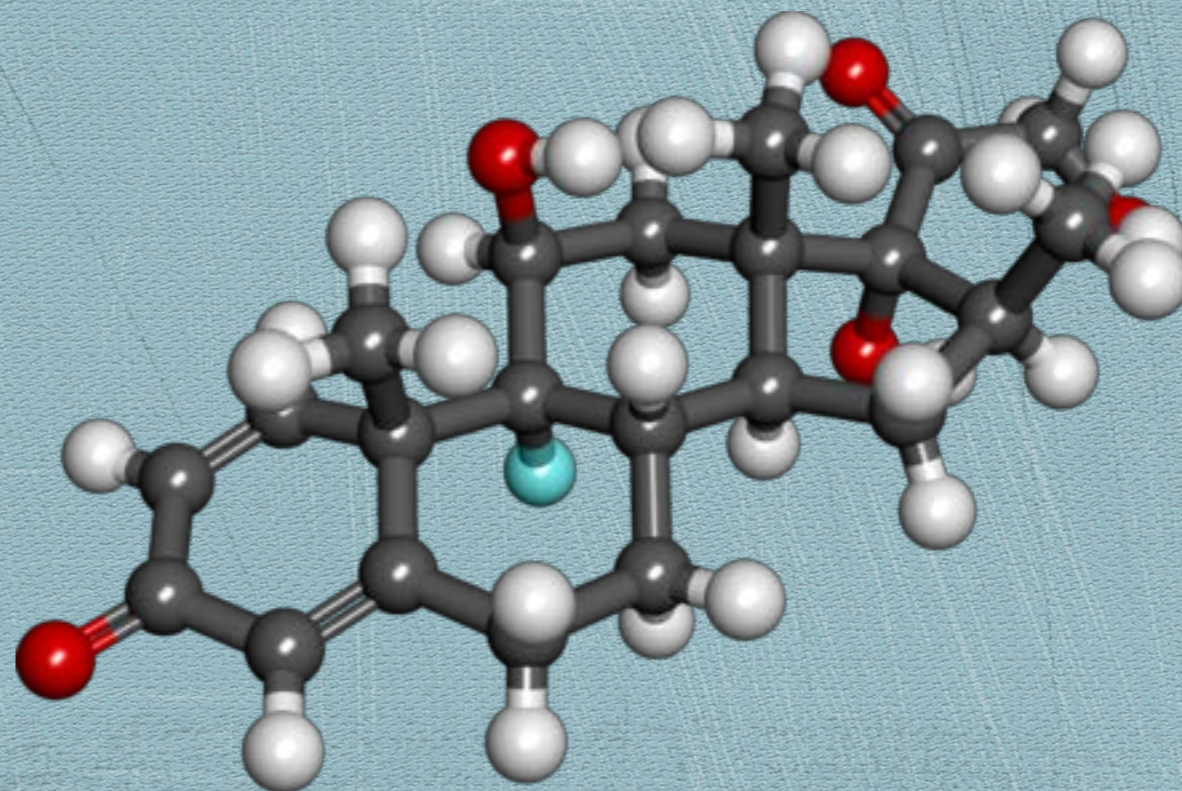
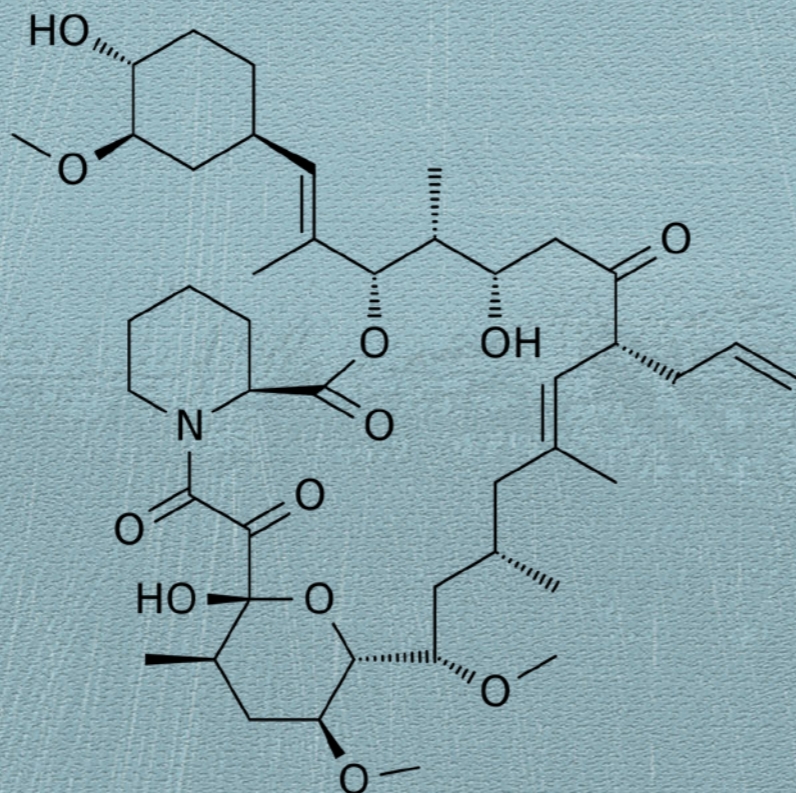
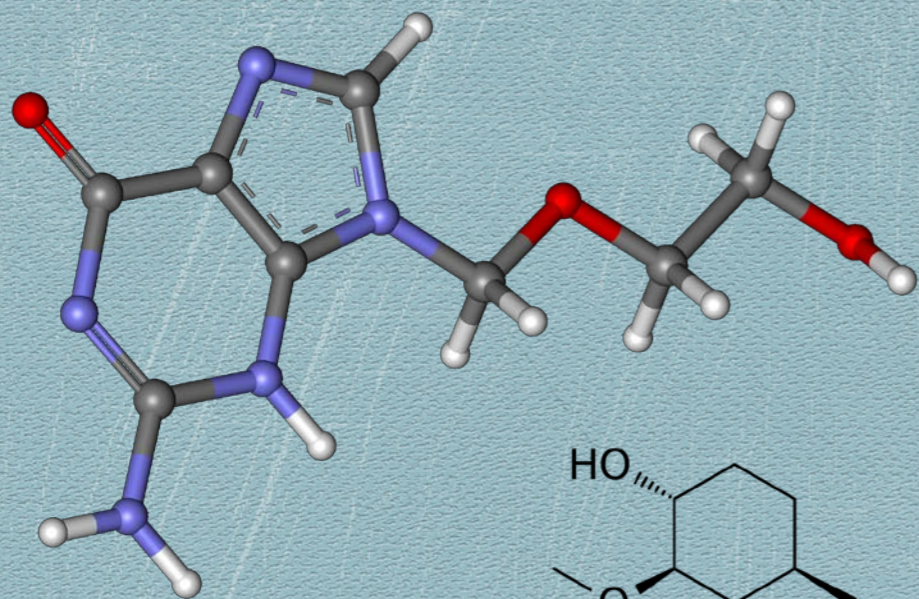


October 10, 1932 to November 10, 2017



Understand
your anatomical
target/disease





Understand your Drug(s)





Understand your vehicle/excipients

Herpes simplex 1 (Cold sores)



Psoriasis



Acne vulgaris



Rosacea



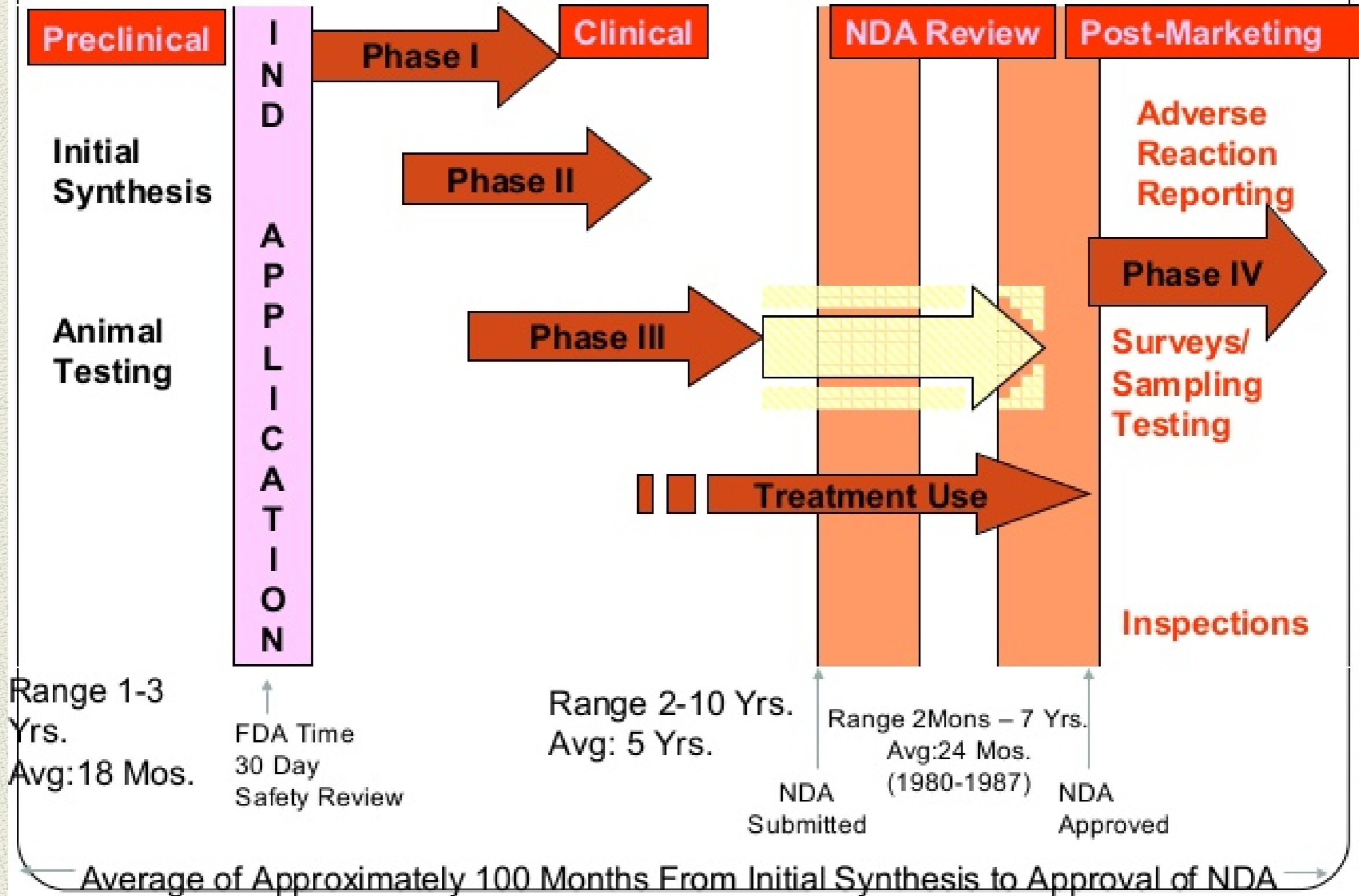


Understand What the Patient Wants



Understand the selective nature/toxicity of the therapeutic agent.

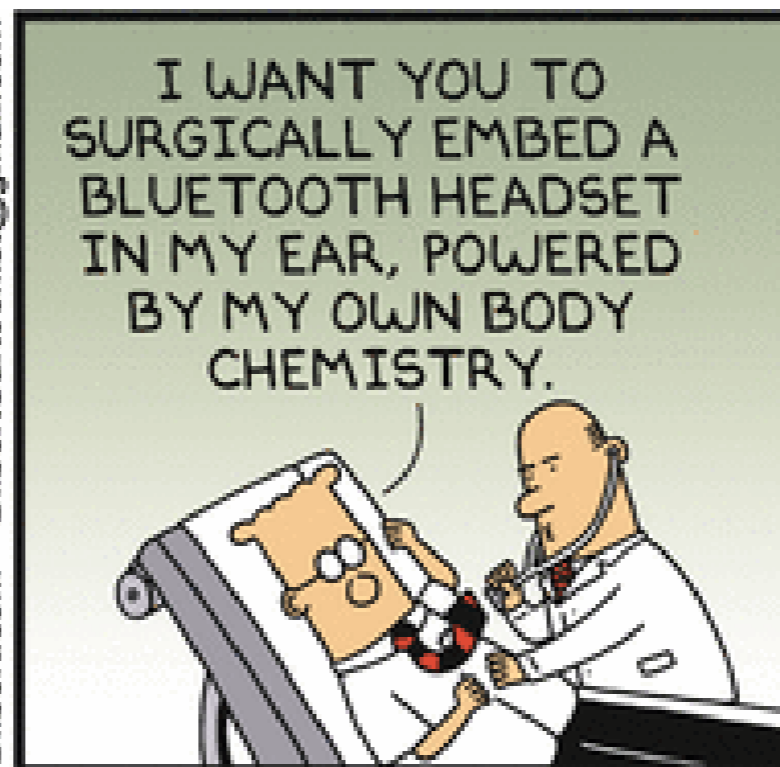
Drug Development Process



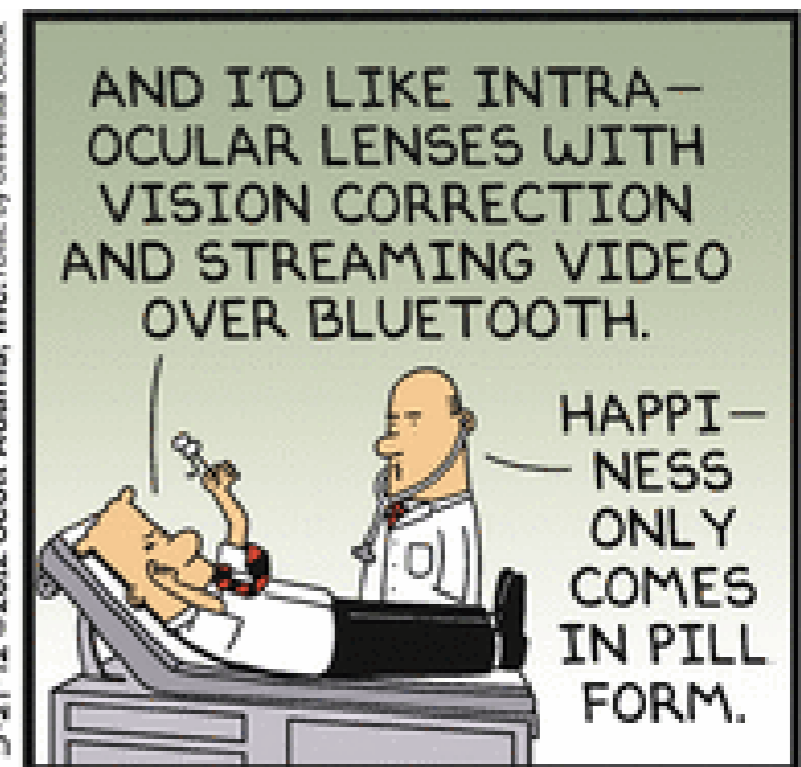
Device vs. Drug Happiness

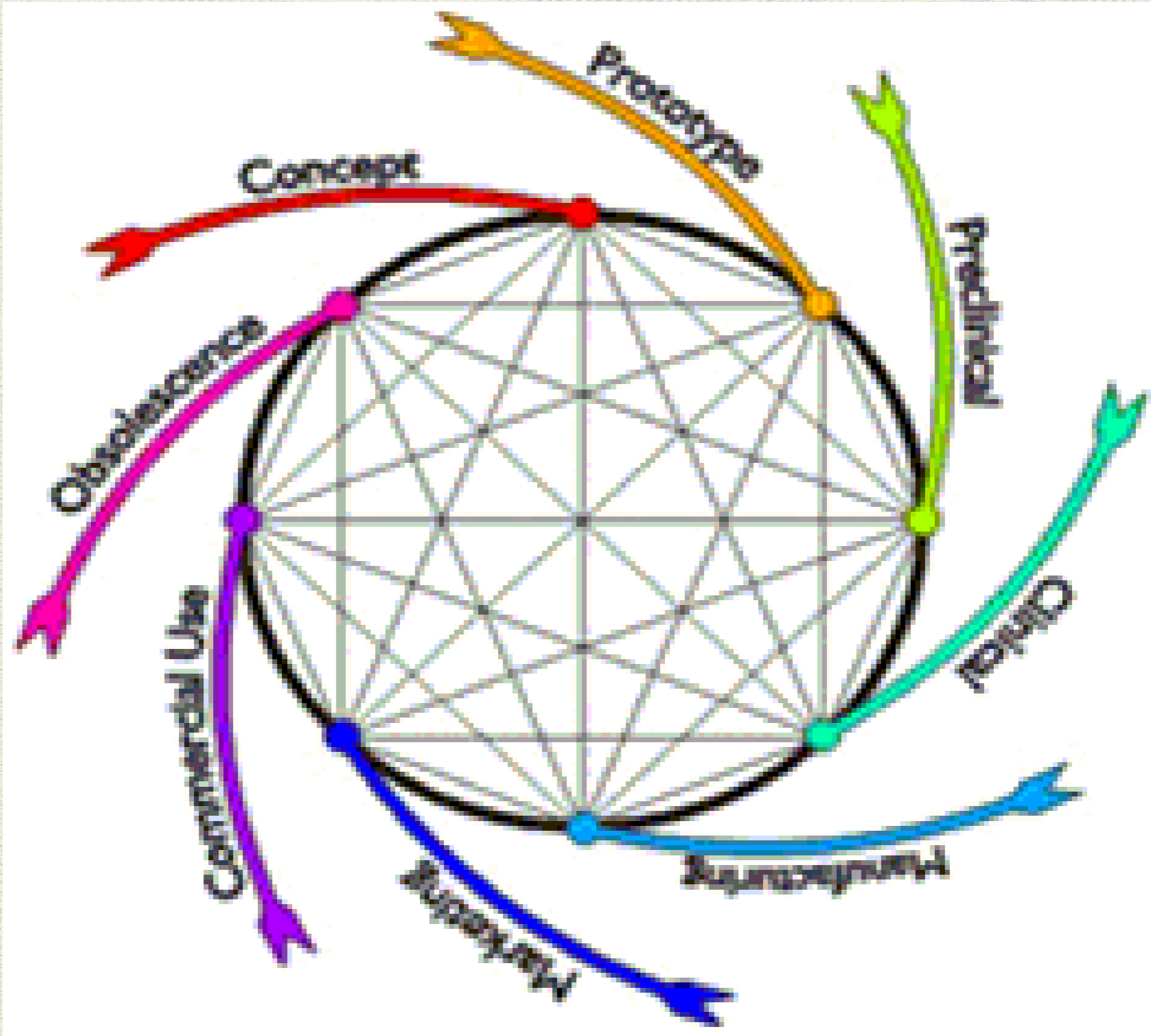


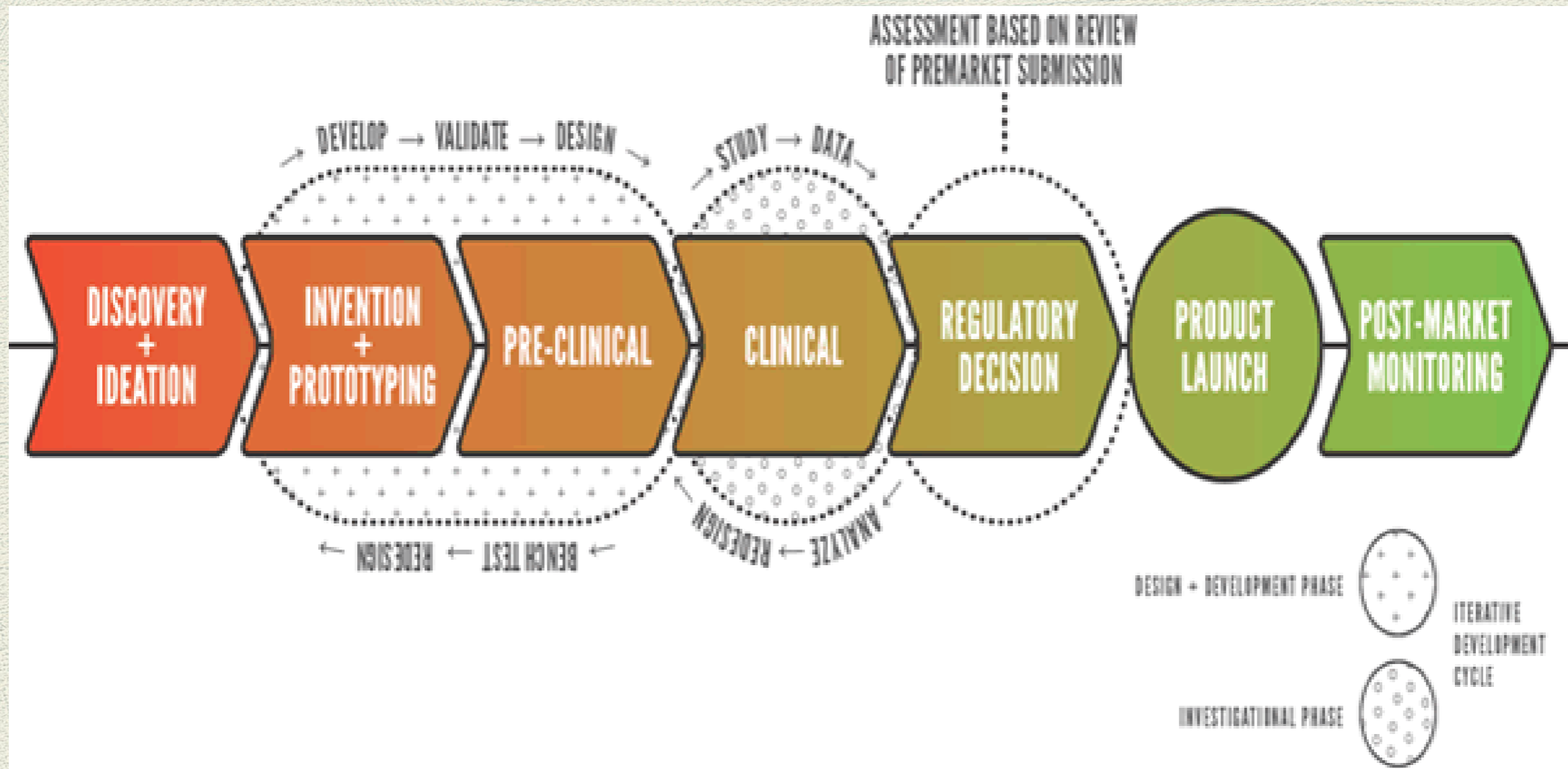
Dilbert.com DilbertCartoonist@gmail.com



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Combination Products

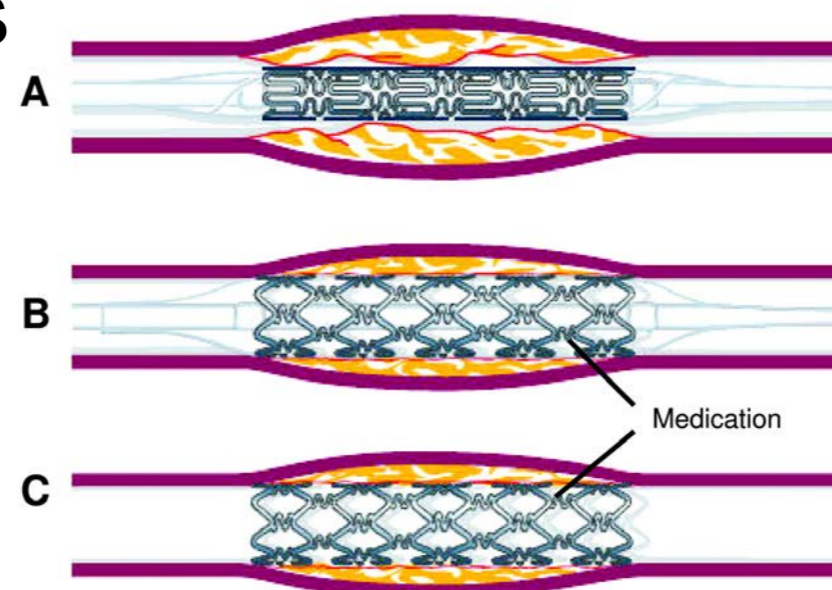
- Include device/drug and device/biologic products that are:
 - physically linked; or
 - separately packaged together (e.g., drug and device products); or
 - packaged separately but required to be used together.
- Raise unique regulatory and scientific issues



Unused auto-injector



Used auto-injector



Important Design Considerations Clinical Outcome Studies

- Selection of appropriate endpoints
- Randomization
- Masking (blinding)
- Controls for comparative clinical trials
- Placebo effect
- Subject selection
- Skill level of the investigator
- Performance criteria for non-comparative clinical outcome studies
- Time of evaluations and length of follow-up

Lonely low toxicity drug ISO an
indication...





FDA Campus





| Product | Interaction with FDA during development | Application - Study - Marketing |
|---------------------|--|---------------------------------------|
| Devices | Q-sub Pre-IDE 513(g) | IDE 510(k) de novo PMA |
| New Drugs/Biologics | pre-IND SPA | IND NDA BLA |
| Generic Drugs | Pre-ANDA (product development) Controlled Correspondence | ANDA |



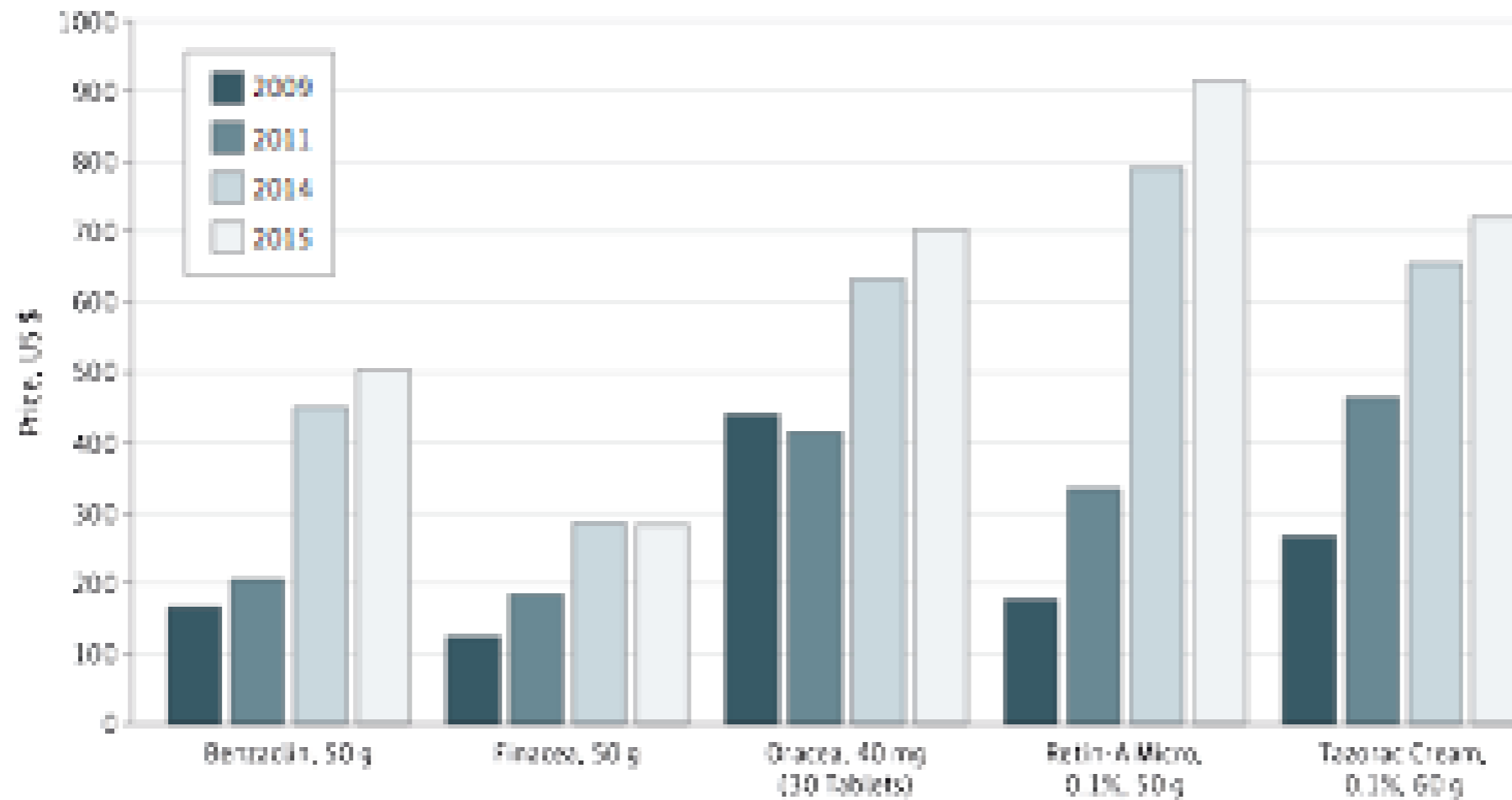
The U.S. Dermatology Marketplace

| | 2015 dollars estimate |
|---|---------------------------------|
| Devices Therapeutic | ~8 billion* |
| Drugs (all specialties) | ~22 billion# (424 billion**) |
| Cosmetics (all cosmetics, including oral) | ~64 billion** (80 billion) |

*BCC Research LLC. #Freedonia Focus Reports. **Statista

Increasing Drug Cost

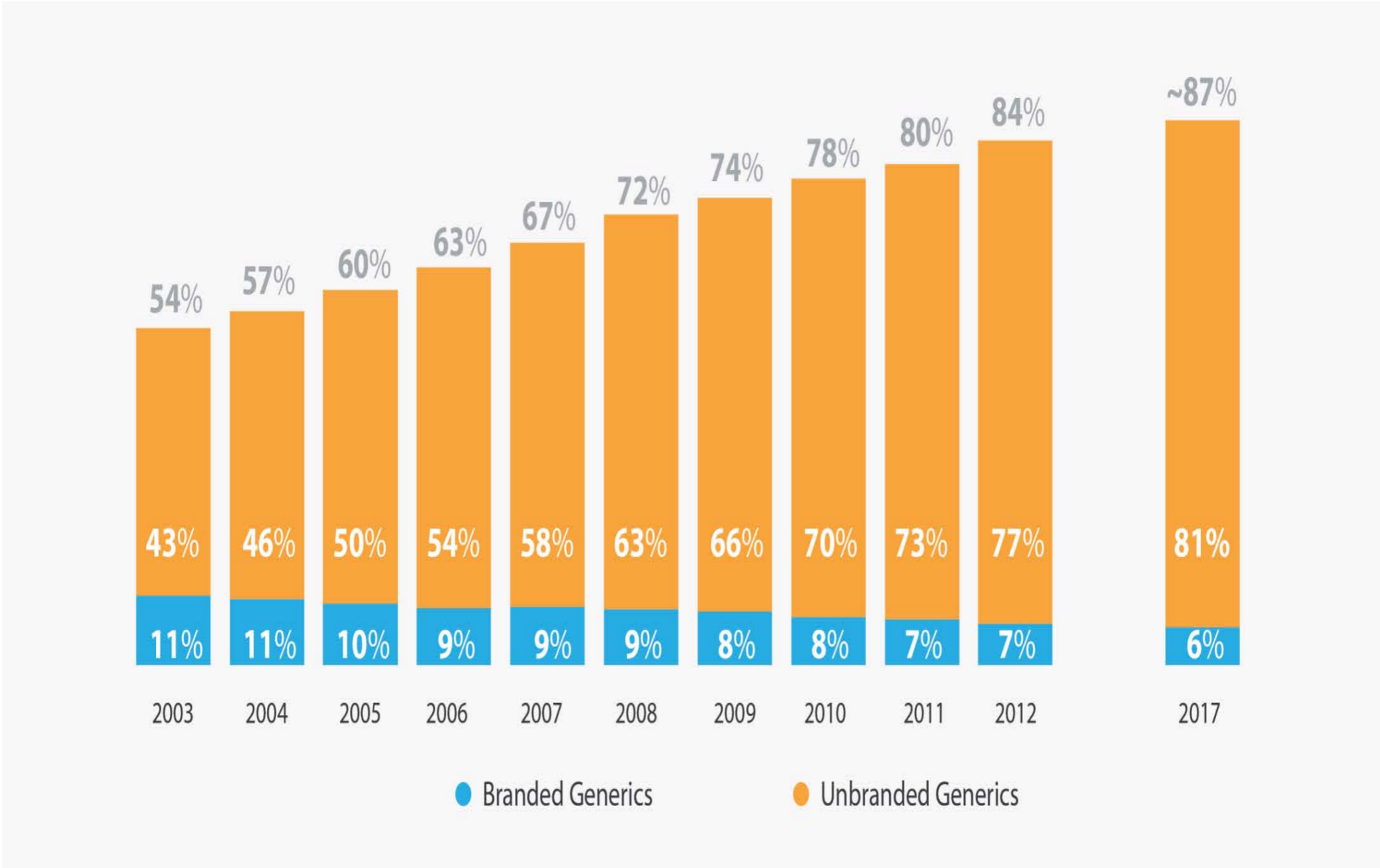
Figure 2. Mean Prices of Acne and Rosacea Drugs



The mean price across the 4 surveyed national pharmacy chains (Costco, CVS, Sam's Club, and Walgreens) of Benzacilin, Finacea, Oracea, Retin-A Micro, 0.1%, and Tazorac cream, 0.1%, in 2009, 2011, 2014, and 2015. The prices of these drugs more than doubled; the price of Retin-A Micro more than quadrupled between 2009 and 2015.

Rosenberg, et al, JAMA Dermatol. 2016;152(2):158-163.

Share of Prescriptions for Generic Drugs



IMS Report: Declining Medicine Use and Costs: For Better or Worse? May 2013

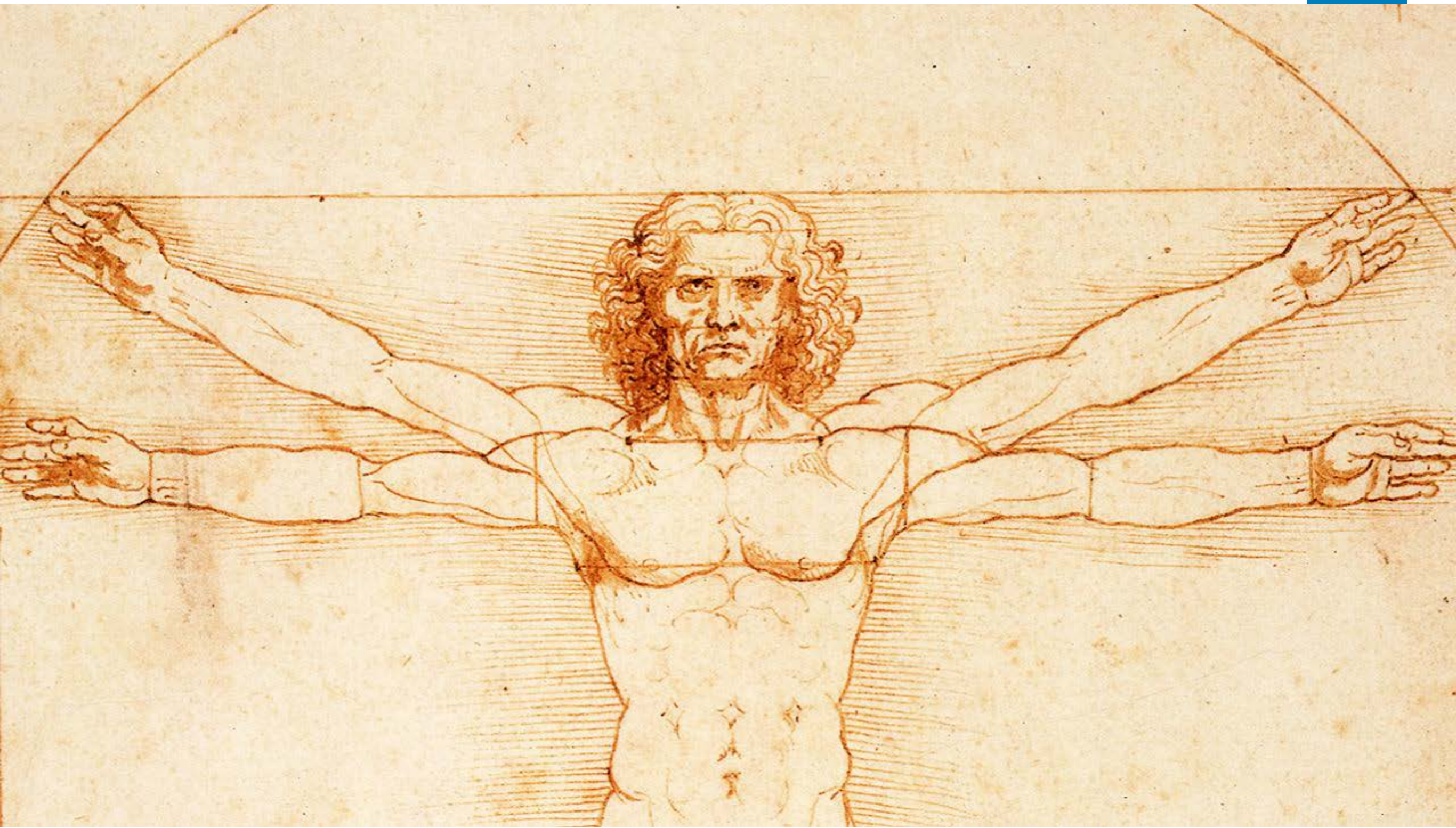
Complex Products under GDUFA II

- Complex active ingredients
 - Complex mixtures of APIs, polymeric compounds, peptides
- Complex formulations
 - Liposomes, suspensions, emulsions, gels
- Complex routes of delivery
 - Locally acting such as dermatological and inhalational drugs
- Complex dosage forms
 - Long acting injectables and implantables, transdermals, MDIs
- Complex drug-device combinations

Topical dermatological drugs are Complex Drug Products.

Topical Dermatologic Products

- Generally are locally acting.
- Some have action deeper in the tissue or may have systemic action (beneficial or toxic).
- Generally a way to deliver therapy with greater specificity for certain target tissue.
- A growing marketplace for treating a prominent, visible, organ afflicted by diseases that may be age-related, immune-function related, infectious disease related, genetic.





Questions?

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