Comments on:

Starving (or Fattening) the Golden Goose? Generic Entry and the Incentives for Early-Stage Pharmaceutical Innovation

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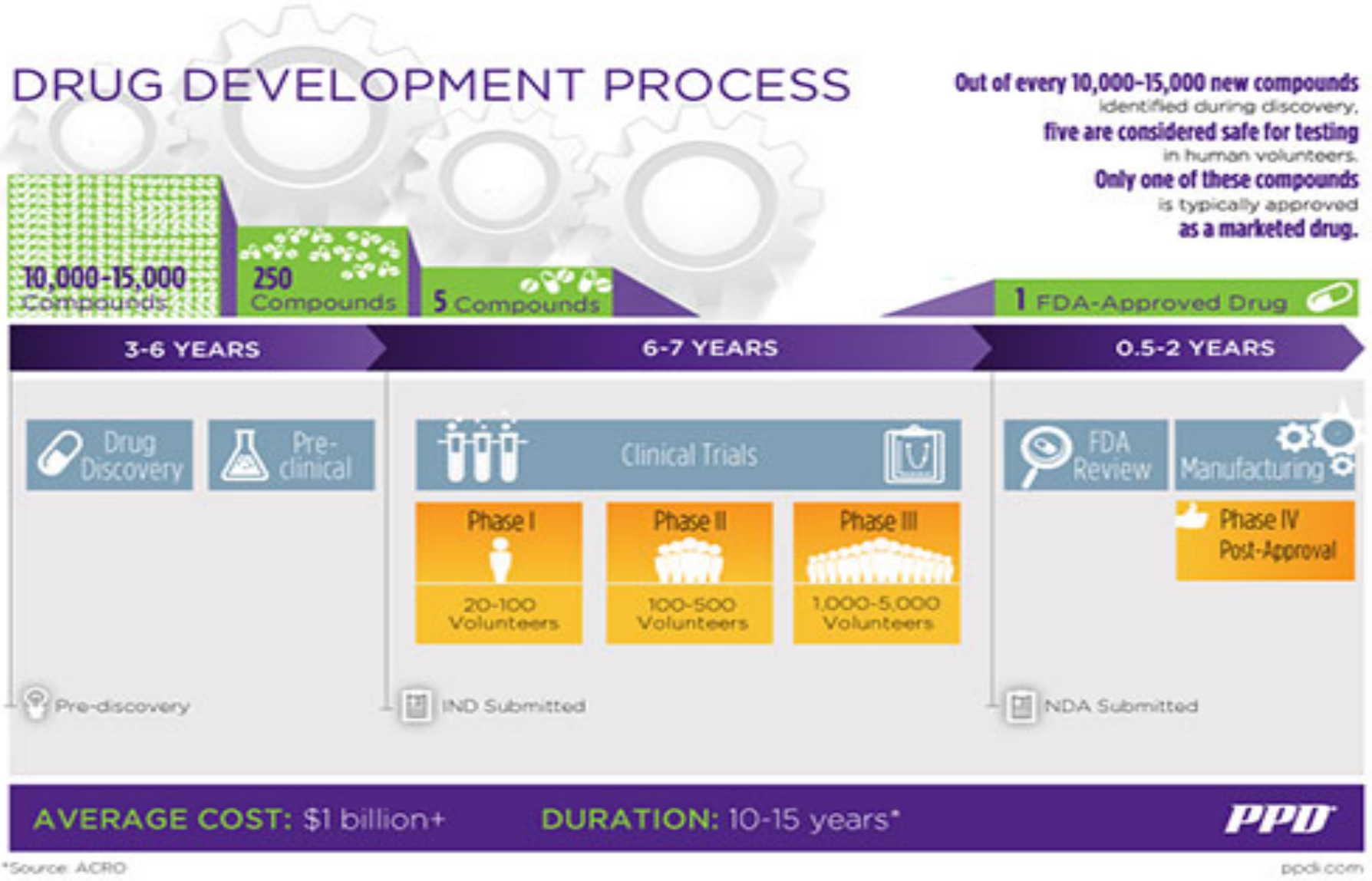
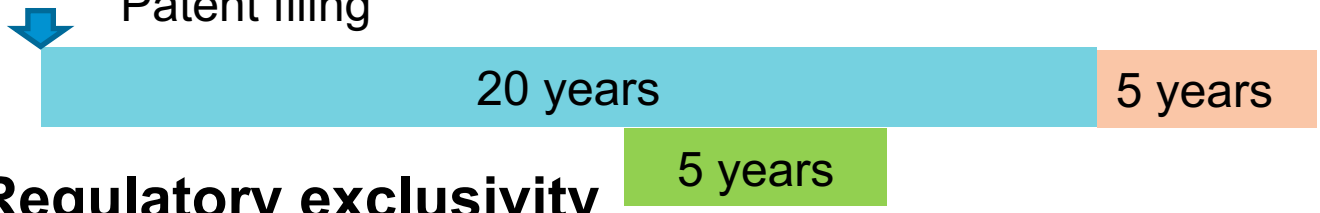
Time of Pharmaceutical Drug Discovery



US Drug Exclusivities: Regulatory and Patent

Patent exclusivity

- ~ 20 years from filing
- Plus patent term extension of 1 patent (up to 5 years) (Hatch-Waxman)



Regulatory exclusivity

- **Small molecules:** 5 years after NDA approval (Hatch-Waxman)
- Generics can file for approval at 4 years after approval (ANDA)
- If no patent issues, then generic can be approved 5 years after approval
- If patents are in force, generics seek approval after expiration (Para III), or challenge validity/infringement of patents (Para IV). Patent litigation begins.
- 30 month stay of generic approval after Para IV certification for litigation.

Regulatory exclusivity for biologics

- **Biologics:** 12 years total from BLA approval (new law enacted as part of AHCA).
- Biosimilars can file for approval at 4 years from approval (aBLA).
- FDA does not stay approval pending litigation. Can approve biosimilar 12 years after approval.

Comments on Paper

- **Impact of generic entry on early innovation? Sounds reasonable.**
  - Innovator small molecule revenues drop sharply when generics enter market.
  - Pharma now more selective in research.
  - Less revenue means less new research investments.
  - Rationale to increase US regulatory exclusivity for small molecules? Would improve value of developing old molecules for new uses.

- **Move to other therapeutic areas driven by generic entry? Not sure.**
  - Generic entry could be in one disease category, but other diseases could still present therapeutic opportunities.
  - For example, many statins for cholesterol reduction are generic. But pharma have later pursued treatments for atrial fibrillation, congestive heart failure.

- **Move to biologics driven by generic entry? Not sure.**
  - Other factors could play a role in asset valuation: technical advances in developing biologic therapeutics, especially antibodies, have made biologics competitive vs. small molecules and incentivized the shift by pharma.
  - 7 of top 10 selling drug products in 2016 are biologics; 5 are antibodies. There's more to valuing therapeutic opportunities in addition to generic entry.