

Drug Innovation Out of Order

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Microbiota

- Communities of microorganisms in your body
- Dysbiosis linked to poor health
- Possibility of treating recurrent *Clostridium difficile* infections with stool from a healthy person
- *C difficile* causes inflammation & severe diarrhea
- Can be fatal very quickly



Not the Usual R&D Paradigm



Ancient texts

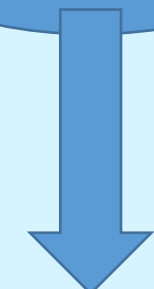
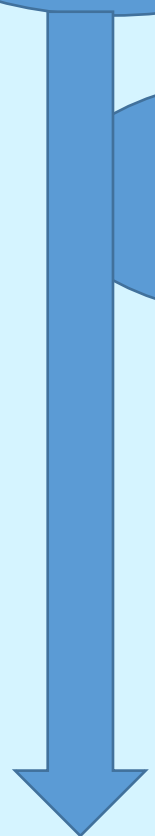
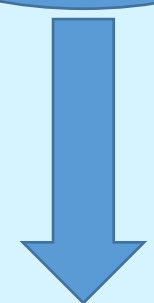
Academic
clinicians start
to use and test

Initial Results
Staggering

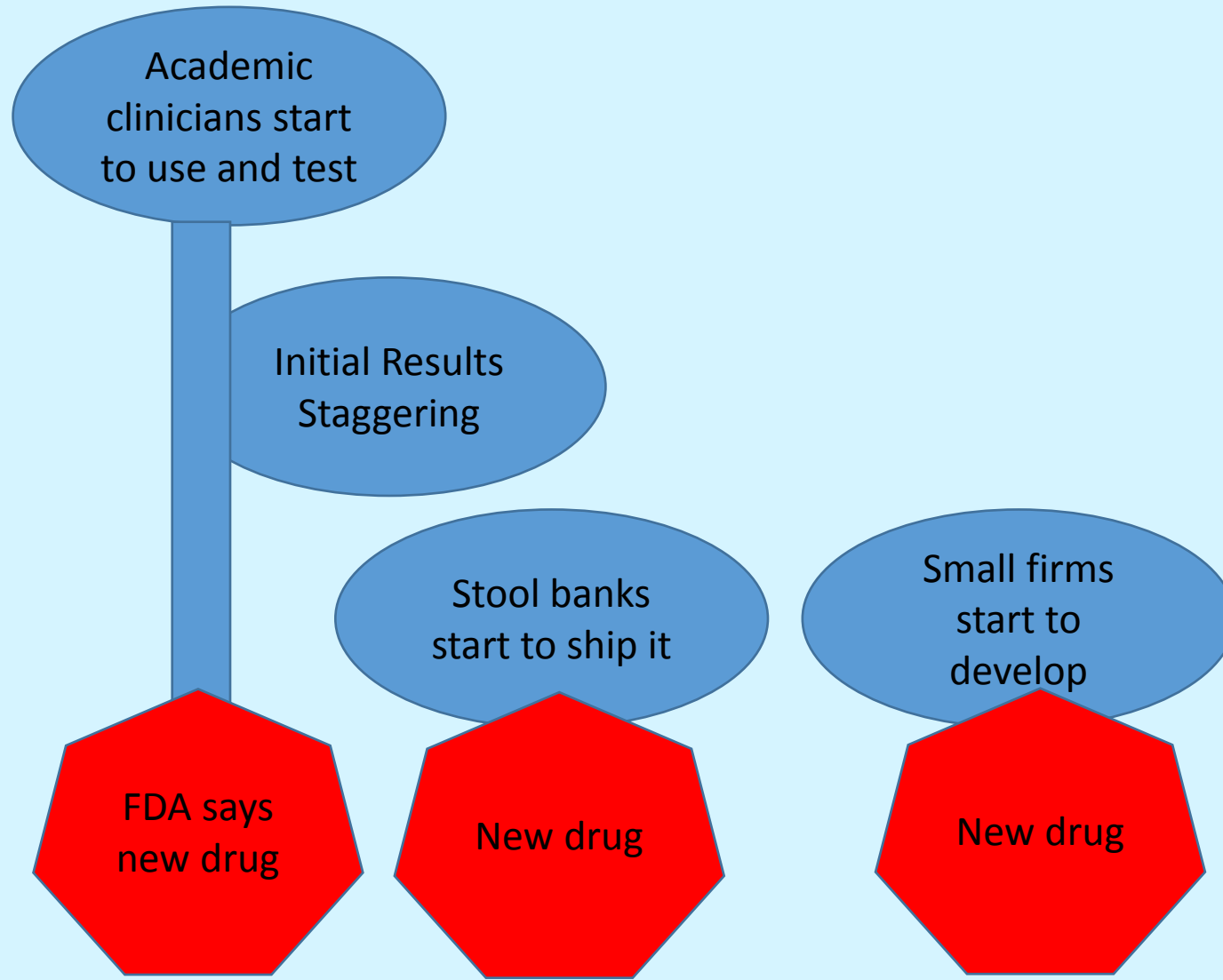
Stool banks
start to ship it

Small firms
start to develop

 YouTube



Regulatory Analysis



FDA's Approach

Academic
clinicians start
to use and test

Initial Results
Staggering

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Debate in Literature

- Debate about suitable regulatory framework really complaints about economic implications of new drug authority
- Data exclusivity has pricing and access implications
- But lack of exclusivity has incentive implications

Key Points

- Policy dilemma from out-of-order innovation is not unique to fecal microbiota
- These scenarios allow us to see premarket testing as distinct desirable behavior

Other Out-of-Order Scenarios:

Unapproved prescription drugs

Compounded drugs

New uses for approved drugs

Dietary substances

Other microbiota-based therapies

Cannabis

What To Do?

- Test commitment to premarket evidentiary requirements in the regulatory paradigm
- But if commitment is firm, then exclusivity must follow (no enforcement discretion, in other words)
- Accept the price differential and fight rhetoric about price gouging
- But test acceptance of price differential: does it mean we need to revisit commitment to premarket paradigm?

Why it Matters **Now**

- The out-of-order sequence is hard for us to stomach
- Exacerbated by longstanding periods of enforcement discretion
- Many more “treatments” likely to follow this out-of-order paradigm in the years to come
- FDA needs to avoid falling into this trap again