Should we question our current model for encouraging innovation in the pharmaceutical sector?

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Big picture on pharma innovation

- Some good news...
  - Huge progress in treating infectious diseases, including HIV
  - Important contributions to improvements in cancer, cardiovascular disease, vision problems, etc.
  - Most recently, rapid development of effective vaccines for COVID
- And some bad news
  - Too little innovation: neglected diseases, antibiotics
  - Too much innovation: me-too drugs
  - Too expensive/unaffordable

Conditions for patents to stimulate socially-valuable innovation

- Strong link between profits and social value
  - Well-functioning product markets
    - Insurance coverage -> access
    - Prices reflect quality
    - No agency problems (physician-patient, payer-patient)
  - Well-functioning capital markets
    - Internal allocation of resources
    - External sources of funding

Do these conditions hold?

- In general, R&D effort responds to market size, need, expansion of insurance....
  - At least in the US and developed countries
- In general, R&D effort responds to patent and exclusivity extensions
  - Again, mostly in rich countries
- Growth of the biotechnology sector suggests availability of capital
  - But not everywhere or all of the time
- Less evidence is available on the social or therapeutic value of this R&D effort

Limitations of patent incentives

- "One size fits all" nature of patent law
  - Patent term is independent of therapeutic value -> distorted investment
  - Broad patents can block cumulative or follow-on innovation
- Imperfect information about quality, particularly at time of patent application or grant
  - Challenging to link patent term to quality, though other exclusivity policies can

Effectiveness of patents depends on other market characteristics

- Do prices reflect all information?
  - Clinical evidence takes time to develop and diffuse
  - -> "best" treatments may not have the highest profits
  - -> distorted investment
- Lack of insurance
  - -> low profits due to inability to pay
  - -> neglected diseases, geographic and demographic inequities
- Agency problems: patients
  - Insurance coverage may lead to overconsumption, including of ineffective treatments
  - -> distorted investment

Effectiveness of patents depends on other market characteristics

- Agency problems: physicians
  - Physicians may be influenced by marketing or payments from industry
  - -> overuse or inappropriate use
  - -> distorted investment
- Agency problems: payers
  - Private insurers may refuse coverage of treatments with long-run benefits, or non-health benefits, or unmeasured benefits
  - Monopsonistic public payers may hold up producers who have already sunk R&D costs
  - -> underinvestment

If not patents, what else?

- "Push" policies: public funding of R&D through government grants, tax breaks
- Prizes or advance market commitments
- Or some combination

Push policies depend on key conditions

- Low information costs
  - Easy to identify where innovation is needed
  - Easy to identify the most productive researchers
- Well-functioning government
  - Optimal allocation of funding across diseases
  - Optimal allocation of funding to best recipients
  - Time horizons, risk tolerance
- Technology transfer
  - From lab to product market

Do these conditions hold?

- In general, NIH funding responds to (domestic) need
- In general, NIH funding flows to productive (domestic) researchers
- In general, NIH funding yields substantial spillover benefits to the private sector
- In general, less evidence for (and lower levels of funding by) other government funding

Do these conditions hold?

- Some evidence of free-riding: when NIH increases, other funders pull back (Kyle et al., JPubEc 2019)
  - Note unmet Lisbon goal of 3%
- And NIH funding is not perfect:
  - Bias in peer review of applications
  - Efforts by politicians to direct funding to their districts
  - Lobbying by disease interest groups

Limits of push policies

- Efficient technology transfer may require push + pull
  - "Pushed" projects without an eventual market might get stuck in the valley of death
  - Can conflict with goals of access: should we restrict prices on drugs helped by government funding?
- Politics
  - Who pays, and how much?
  - What diseases get funded?
  - Who gets funded?
  - What type of research gets funded?

Prizes or AMCs also depend on key conditions

- Low information costs
  - Easy to identify where innovation is needed
- Well-functioning government(s)
  - Optimal determination of prizes across diseases
- International coordination may be even more important

Conclusion

- Patents are not perfect, but are easier than many of the alternatives
  - Pharma innovation yielded major gains in health during the 20th and 21st centuries
  - Counterfactual is hard to know, but patents are likely a contributing factor
- Opportunities for improving the effectiveness of patent incentives by "tweaking" other policies
  - Fixing information problems in health markets
  - Improved regulatory approaches to pricing
- Alternatives are challenging to implement
  - Coordination within and across countries
  - Trust in experts