INNOVATION POLICY IN HEALTH CARE

Course Syllabus

This course examines the policy framework for innovation in health care and the life sciences, including funding of research and development, protection of intellectual property, FDA market authorization, insurance coverage and pricing, and equity in access.

Instructor

James Robinson

Contact information
james.robinson@berkeley.edu

James Robinson is Leonard D. Schaeffer Professor of Health Economics and Director of the Berkeley Center for Health Technology (BCHT) at the University of California Berkeley. Professor Robinson's research focuses on the biotechnology, medical device, insurance, and health care delivery sectors. He has published three books and over 150 papers in peer-reviewed journals such as the New England Journal of Medicine, JAMA, and Health Affairs.

Course Learning Objectives

- **Financing of Research and Development**: Compare alternative mechanisms for stimulating R&D investments in the life sciences, including research grants, commercialization grants, tax credits, patent-protected pricing, innovation prizes, and advanced market commitments.
    - Class discussion: apply learnings through a proposal of incentives for development of new antibiotics for drug resistant infections
- **Equity and Access to Innovation**: Be able to introduce policy debates on the ethical considerations concerning patient access, including tradeoffs between paying for today's drugs versus investing in tomorrow's, rare orphan conditions versus prevalent population health challenges, targeting access initiatives at historically underserved communities versus broad national distribution, etc.
    - Class discussion: should R&D investment be focused on rare diseases (e.g., pediatric orphan conditions) or more prevalent public health conditions (e.g., heart disease)?
- **Regulation of Market Authorization**: Be able to analyze FDA processes for market authorization for drugs and medical devices.

    - Class discussion: FDA has moved to reduce evidentiary demands on drug firms, to reduce the cost and delay of regulation. But accelerated review increases the risks that patients will be exposed to unsafe medications and insurers will pay for ineffective treatments. Should the review and authorization process be accelerated or slowed down?
- **Coverage & Access**: Describe the principles of intellectual property policy (patent and regulatory exclusivity) and the methods of health technology assessment (HTA).
    - Class discussion: European nations have formal HTA bodies that support their drug price payment processes with clinical and cost effectiveness studies. The US has a non-governmental entity in the Institute for Clinical and Economic Review (ICER). Should the US create a formal governmental HTA entity?
- **Drug pricing and Investment.** Understand the determinants of drug pricing, including the distinction between list and net prices, and the process of negotiations between payers and manufacturers
    - Class discussion: The US is preparing for formal Medicare negotiations with pharmaceutical manufacturers over the prices of drugs that have been on the market 7-11 years but still are able to charge high prices and account for a meaningful share of total spending. Is price regulation desirable or will it unduly impede investments in R&D and the subsequent innovations?
- **Investment and Access to Innovation in the Global Environment**. Understand the position of the life sciences in global competition for economic, political, and military leadership. Be able to identify features of innovation policies that have proven effective in different nations. Be able to distinguish nationalist and globalist strategies for investment in and access to innovation, respectively.
    - Class discussion. Should the US government actively support US-based drug, device, and diagnostic firms in competition with firms based in other nations? Should the US government give priority to its citizens in access to US-funded innovation or adopt a globalist policy?

Course Schedule

Session #	Date	Topic
1		Financing Innovation: public and private sector roles
2		FDA regulation: drugs, devices, digital therapies, diagnostics
3		Intellectual property, market exclusivity, generics & biosimilars
4		Technology assessment, insurance coverage, and provider payment
5		Drug pricing and price negotiations
6		Investment in and Access to Innovation in a Global Context