

Bioscience Policy: Syllabus and Schedule

11:373:404 Sect.1
Mondays 2 to 5 PM
206 Thompson Hall

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Course Description: The world faces huge challenges today and in the near future: nearly a billion people do not have enough food, increasing food production can lead to pollution and greenhouse gas production, global warming is accelerating which is causing more flooding and drought and reducing food production. Pandemics of zoonotic diseases such as COVID-19 killed nearly a billion people. The current Avian Flu pandemic is killing millions of chickens and wild birds and making dairy cattle, humans and other animals sick.

At the same time, there have been amazing advances in the biological sciences, information technology and engineering that can contribute to increasing food production, reducing the growth of global warming and controlling disease. However, biological knowledge and technology cannot contribute to the solutions needed unless policy makers provide the money, institutions and policies that will allow government research institutes like Rutgers to do research and innovations and support for regulators like the U.S. Food and Drug Administration to protect us from the spread of dangerous new technology.

At the same time companies will not transform the biological knowledge, research tools and concepts into useful medicines, plants and biochemicals unless effective government policies are in place. These policies are the focus of this course. Companies need to make profits to survive. Governments must provide them with access to University or other government institute scientists so that they have technological opportunity to innovate a new product. Governments must ensure that there are markets for the innovations in the early stages of product developments. The firms also need assurance through patents or other policies that their new products will not be copied immediately reduce the innovative firm's market. Finally, government agencies need to provide science-based regulations to ensure the health and environmental safety of new products.

The development and spread the mRNA and DNA vaccines for COVID-19 is an example on how breakthroughs in science combine with billions of government dollars in funding for vaccine production, guaranteed demand for the product, streamlining regulations, and government marketing can save millions of lives as well as allowing companies to make profits. Additional advances in biology will be the basis of growth in health, agriculture, industry and the environment in the 21st Century. New Jersey industry and Rutgers University are among the leaders in biological sciences and biotechnology research. This course will examine the impact of government investments in science and the impact of technology policies on research and technology development by industries which are based on the biological sciences – Pharmaceuticals, Food, Agriculture, Biofuel and other biochemicals. It will also look at how

government policies shape the impact of science on these industries and on economic growth and welfare of the citizens of United States and the World.

Prerequisites: An introduction to microeconomic theory. Need to be comfortable with economic analysis using supply and demand curves and be prepared to learn the basics of cost benefit analysis.

Learning Goals:

By the end of the course students will be able to:

1. analyze and develop science policies using
 - a. Induced innovation theory
 - b. Simple cost benefit analysis
2. understand the basic structure of the industries based on biology such as the pharmaceutical industry, bio-fuel industry, food industry and agricultural biotech industry
3. be more effective in finding reliable information in libraries and on the web
4. communicate and write more effectively about science policy issues
5. work more effectively in groups

Assessment of learning goals

Goals number 1 and 2 will be assessed in an in-class midterm exam, class discussion and their two policy briefs. Goals number 3 through 5 will be assessed through the performance in their group projects. Each group of 3 students will present 3 class presentations and write 2 policy briefs of 10 to 15 pages.

Assessing students' progress:

Class discussion	15%
Midterm	30%
Presentations to class	20%
Written reports	35%

Class attendance:

People learn more when they try to put the information and ideas to work in discussions and presentations both in and outside of class. It is impossible to participate in class discussions if you do not show up. I will take attendance as one indicator of participation.

Course Ethics Policy

Students will be held to the highest standards of academic integrity, as described in the University code of academic conduct (<http://academicintegrity.rutgers.edu/academic-integrity-at-rutgers>)

Readings: Most of the readings are on the Canvas website for this class. The individual readings are in files section of the class website. Below in the syllabus I have indicated the folder by putting them in *italics* followed by a short reference the specific paper. For example, Chapter 13 in Vernon Ruttan book is shown as *Policies*: Ruttan Chapter 13.

Mariana Mazzucato. The Entrepreneurial State: Debunking Public vs. Private Sector Myths. Anthem Press. Penguin Books, 2023.

Vernon W. Ruttan. Technology, Growth and Development: An Induced Innovation Perspective. New York: Oxford U Press, 2001. This book is an economist's view of technical change.

Gary P Pisano. *Science Business: The Promise, The Reality, and The Future of Biotech* Boston: Harvard Business School Press 2006

Thomas E. Getzen. *Health Economics: Fundamentals and Flow of Funds*. New York: John Wiley & Sons 2004.

Daniel Charles. *Lords of the Harvest: Biotech, Big Money and the Future of Food*. Perseus Publishing: Cambridge, Massachusetts 2001.

Fran Hawthorne *Inside the FDA: The Business and Politics behind the Drugs We Take and the Food We Eat*. John Wiley & Sons: Hoboken, NJ 2005.

Projects

In response to the COVID-19 Pandemic President Trump's administration developed Operation Warp Speed and other policy measures to develop COVID-19 tests, vaccines and therapeutic drugs. The Biden administration in the US and other countries around the world developed their own set of policies for developing or importing new vaccines and drugs. The research and policies to develop new medical products have now become an important part of the US agenda to keep ahead of China in science and economic growth. The advances in biology and biotechnology in medical science and technology along with our competition with China and other countries are now spilling over into the food, agricultural and bio-based energy like biofuels and bioplastics. New biological technologies such as the gene-editing technology CRISPR-Cas9 are leading a revolution in medical, plant and animal biosciences. Recent advances in genomics, computer power and artificial intelligence now allows models to predict the structure of proteins which has been described as the innovation of the year by *Science* magazine.

Governor Murphy wants to make innovation in biobased industries one of the major components of economic growth in New Jersey. The state government support for Rutgers has been stagnant for years but there is hope that the governor will provide more support of Rutgers as part of his program. Leaders of China, Brazil, India, Malaysia, and other countries have also embraced innovation in agricultural biotechnology, biofuels, and pharmaceuticals as ways of increasing economic growth. At the same time in many countries the lack of investments in science and protective technology policies constrains the growth of food production, the availability of life saving drugs, the development of alternative fuels, and economic growth in general.

You are going to advise President Biden, Governor Murphy, or leaders of other countries on what policies, regulations and government investments they could make to support the biological sciences and the development of industries based on these sciences. Teams of students will analyze government policies that influence the use of bioscience and biotechnology in the food,

agricultural, pharmaceutical and biofuel industries. Then the teams will propose and justify policy changes in US and elsewhere in the world.

The goal of the politicians we are advising is to serve the citizens of their countries and to stay in power. They need advisors who can draw on economics and technical expertise. We will break up into teams of students focusing on either pharmaceuticals, food and agriculture, and biofuels. The teams will look at major corporations and start-up companies that are major investors developing innovation in these industries (e.g., Merck, Bristol Myers Squibb, Johnson and Johnson, Amgen, Ginkgo Biosciences, Caribou Biosciences...), food and agriculture (e.g. Bayer-Monsanto, Dow-DuPont, Advanta,) or biofuels (Exxon, BP, Petrobras, Amyris). Then they will examine how different policies influence their decisions to invest in research and the development of new technologies.

The teams will also need to decide on which countries they wish to focus on. I expect most teams will focus on the US or New Jersey but if a group of you have a special interest in biotechnology in another country that would also be possible. In pharmaceuticals the U.S. has been the leader in research and innovation but now India is changing its laws rapidly to try to build up its pharmaceutical industry. China and Brazil are also trying to develop their pharmaceutical industries. In biofuels, Brazil was the leader for a long time while in recent years the US has caught up and surpassed Brazil in biofuel production although Brazilian biofuels are still more efficient and produce much less greenhouse gas than US biofuel. In agricultural biotechnology the US has been the technology leader in the development and deployment of new technology.

The teams will write and present two short policy papers during the term. The key policies that are on the agenda of the class are:

- Increase or reduce government spending on research:
 - Examples at the national level in the US include National Institute of Health or Department of Energy research funding of their own labs and of universities like Rutgers
- Policies that would change the demand for new technology such as requiring government agencies to buy innovative products, or protecting local innovators from competition from foreign products (e.g. US taxes on Brazilian biofuel) or subsidies for US biofuel production.
- Regulatory changes to make it easier and less expensive to get new products approved and into the market.
- Policy changes to reduce or strengthen patents on genes.
- Policies to strengthen universities that produce scientists and technicians
- Policies designed to help start-up companies
 - University technology transfer offices
 - Small Business Innovation Research (SBIR) grants

- Government financed business incubators
- Tax incentives for R&D.

The papers will analyze the impact of the key policies on profits and research of the firms, their impact on employment, on consumers, and the taxpayers who finance the policies.

Team Responsibilities:

1. Two policy briefs during the term which include a one page executive summary for policy makers and a few pages of analysis and background material. The analysis and background material must have references and information about websites where the information came from. Otherwise, the material will just be opinion and not be convincing to policy makers.

- a. Policy brief 1 on government funding for research
- b. Policy brief 2 on changes in patents, regulations, OR government procurement of innovations

2. Three short presentations

- a. Description of the size and structure of your industry and key innovative companies in your industry
- b. Policy 1 Government funding of research
- c. Policy 2 Changes in patents, regulations, policies to increase demand for innovations

3. Critiques of other group's presentations

Preliminary Class Schedule and Readings

Sept 9 Introduction and overview of course

Challenging global issues -

Major topics of the course

What are the economics of science and technology?

Who develops new pharmaceuticals, new foods, new plant varieties, new fuels and why?

What factors lead to research and innovation?

What is science and technology policy?

National policies

Local and regional policies

How do governments decide what policies to adopt?

How can economists help?

How are new pharmaceuticals, foods and biofuels developed?

Pharmaceutical research

Medical Gary P Pisano. *Science Business* Chapters 2, 3

Components of research:

PHRMA Case studies

Agricultural biotech research

Food and Agriculture: Daniel Charles. *Lords of the Harvest:* Chapters 1, 4, and 6.

Components of research:

Sept. 16 How are new pharmaceuticals, foods and biofuels developed part 2

Economic models of research and innovation:

Theory Ruttan. Chapter 3 The process of invention and innovation

Theory Ruttan's Chapter 4 pages 100-108. Induced technical innovation and Chapter 5

Technology adoption. Pages 147-159.

Giovanni Dosi and Richard Nelson – Chapter 3

<https://www.sciencedirect.com/science/article/pii/S0169721810010038>

Directed innovation – Acemoglu - AEA Presidential address

Innovation systems framework – Pray and Birner 2024

Sept 23 Why do pharmaceutical, agricultural, food, environment, and energy industries invest billions of dollars to make new products?

Economics and the structure of the pharmaceutical, food, and biofuel industries

Readings

Medical Gary P Pisano. *Science Business* Chapter 5

Medical Getzen. *Health Economics* Chapters 1, 2 (review of supply and demand in health economics), and 12 pp 251-258 Numbers on Pharmaceuticals

Food and Agriculture Pullman and Wu Grain supply chain Chapters 4

Biofuel. Biofuel industry Wikipedia <http://en.wikipedia.org/wiki/Biofuel>

Biofuel Pray and Deshmukh Biofuel Research in the US

What have the biosciences contributed to economic growth and welfare of society so far?

New pharmaceuticals –

Medical Economic Impact of Pharmaceuticals 2011 written by Batelle Technology Partnership Practice.

Food and agriculture

Geoffrey Barrows, Steven Sexton, and David Zilberman Agricultural Biotechnology: The Promise and Prospects of Genetically Modified Crops. *Journal of Economic Perspectives*—Volume 28, Number 1—Winter 2014—Pages 99–120

Fernandez-Cornejo, Jorge, Seth Wechsler, Mike Livingston, and Lorraine Mitchell. Genetically Engineered Crops in the United States, ERR-162 U.S. Department of Agriculture, Economic Research Service, February 2014.

New Jersey

Joseph J. Seneca, Michael L. Lahr, Will Irving Contribution of the Life Sciences Industry to the New Jersey Economy. Rutgers. The Bloustein Institute of Public Policy 2014

Also an update on NJ in 2019

file:///C:/Users/Cpray/Downloads/NJ%20Life%20Sciences%20Report_2019.pdf

Sept. 30 Why government intervention and what policies are available?

New reading???

How do we decide if government should make an investment or adopt a new policy?

Required Readings:

Medical Getzen Chapter 3 Cost-benefits and cost effectiveness analysis.

Food and Agriculture: Fuglie and Heisey “Economic Returns to Public Agricultural Research”

***Student presentation 1 on size of industry, specific firms such as Merck, Petrobras, Exxon, Monsanto or other companies, controversies....

October 7. Public sector research: the US Government and Rutgers University

United States Government investments in basic science research and in applied research

Readings: *Medicine* Congressional Budget Office *Research and Development in the Pharmaceutical Industry* October 2006 Whole paper but focus on pp 27 -35.

Food and Agriculture Pardey,

Role of University in Economic Development:

Feeding the World: Innovation, Land Grants and University Research Parks
<http://expansionsonline.advanced-pub.com/Vizion5/viewer.aspx?issueID=12&pageID=83> pages 80 through 84.

A New Paradigm for Economic Development: How Higher Education Institutions are working to Revitalize their Regional and State Economies
http://www.rockinst.org/pdf/education/2010-03-18-A_New_Paradigm.pdf

October 14. *Midterm*****

October 21. Intellectual property rights: Introduction to Patents

Scotchmer *chapter 3 “A Primer for Non-Lawyers on Intellectual Property”*
Pharmaceuticals Vogel chapter 4

Problems – Adam B. Jaffe & Josh Lerner. *Innovation and Its Discontents: How our Broken Patent System Is Endangering Innovation and Progress, and What to Do About It*, by

Princeton University Press. 2004. Introduction, pages 1 - 17; Chapter 2: The Dark Side of Patents.

Compulsory licensing.....(TRIPS waiver.....)

<https://endpts.com/a-watered-down-covid-19-vaccine-ip-waiver-nears-the-finish-line-will-it-actually-expand-supplies/>

October 28. Regulations

Required readings:

Vogel chapter 3

Fran Hawthorne Chapter 3 FDA the first 100 years.

Chapter 4 Focuses on regulation of food

U.S. Regulation of Ag Biotechnology 2000

Regulation on genome editing? CRISPR babies

Additional information:

FDA overview <https://www.fda.gov/about-fda/fda-basics/what-does-fda-regulate>

Pharmaceuticals <https://www.fda.gov/drugs/development-approval-process-drugs>

Agricultural and Food Biotechnology

<https://www.fda.gov/food/agricultural-biotechnology/how-gmos-are-regulated-food-and-plant-safety-united-states>

November 4. Class presentations # 2

November 11. Government price controls, procurement and other policies that increase demand for technology

Hand in first policy brief April 7th

Price controls and their impact

Vernon, Pharma price controls

<https://www.cato.org/sites/cato.org/files/serials/files/regulation/2002/12/v25n4-7.pdf>

Recent summary https://bfi.uchicago.edu/wp-content/uploads/2021/09/BFI_WP_2021-108.pdf

Harvard Business Review <https://hbr.org/2021/10/the-u-s-can-lower-drug-prices-without-sacrificing-innovation>

Operation Warp Speed – procurement guarantees and procurement contracts....

GAO <https://www.gao.gov/assets/gao-21-319.pdf>

CRS cost <https://crsreports.congress.gov/product/pdf/IN/IN11560>

Lesson from Warp Speed [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00503-1/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00503-1/fulltext)

November 18. Role of Rutgers in supporting new companies

Guest speaker – Deb Pires, Rutgers technology transfer offices

<https://research.rutgers.edu/researcher-support/innovate>

November 25 China vs. US science and technology policy.

Library of Congress: Bioindustry support – China appendix

Bioeconomy <https://crsreports.congress.gov/product/pdf/R/R46881>

Chinese policy as of 2019 <https://www.uscc.gov/sites/default/files/Research/US-China%20Biotech%20Report.pdf>

Dec 2 *Presentation 3 Policies Changes in patents, regulations, or demand for innovations**

Dec. 9. Last day of Classes

Hand in second policy paper December 20 ???