

Bioscience Policy: Syllabus and Schedule

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TH 9:15 to 12:15 Hickman 211

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Course Description: Advances in biology will be the basis of growth in some of key industries of 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, and Biofuel. 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.

Learning Goals:

1. Increase student's knowledge of the industries based on biology.
2. Increase student's ability to use economics to analyze government policies
3. Increase student's skills at finding reliable information in libraries and on the web.
4. Improve student's research and writing skills through writing policy briefs.
5. Develop a set of policies that will increase sustainable growth of the biotechnology industries in New Jersey and ensure the safety of consumers of biotechnology products.

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

Assessing students' progress:

| | |
|------------------------|-----|
| Class discussion | 15% |
| Midterms | 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.

Readings: Most of the readings are on the Sakai website for this class. They individual readings

are in folders. 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*.

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. If you buy just one book for this course, this is the one.

Other resource books:

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.

Food and Agriculture Organization *State of Food and Agriculture 2008: Biofuels: Prospects, Risks, and Opportunities*. Rome 2008.

Worldwatch Institute. *Biofuels for transport: Global Potential and Implications for Sustainable Energy and Agriculture*. Earthscan: London 2007.

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

Part of President Obama's economic stimulus package was investing in science and technology development to grow the U.S. economy out of its current recession. In particular there has been a lot of discussion about Green Innovation as an engine of growth. Recently, however, US funding of research has started to slow down. In New Jersey Governor Christie supported the merger of Rutgers and UMDNJ and pushed through a bond issue to support the merger. He hopes that the new university will bring more US dollars and perhaps industry dollars into the state for biotech research that will strengthen the biotech and pharmaceutical industries in New Jersey. 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 can be constraints to the growth of food production, the availability of life saving drugs, the development of alternative fuels, and economic growth in general. We are going to advise President Obama, Governor Christie, 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 teams of advisors who can draw on economics and technical expertise. We will break up into teams that consist of about three 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, Cipla....), food and agriculture (e.g. Monsanto, 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 throughout the term. The key policy changes that are on the agenda of the class are:

- Increase or reduce 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 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

Resources for teams:

1. Pharmaceutical industry and companies:

Pharmaceutical Research and Manufacturers of America www.phrma.org.

Generic Pharmaceuticals Association <http://www.gphaonline.org>

Biotechnology council of New Jersey www.biotechnj.com

Pharmaceutical and agricultural organizations using biotechnology: BIO: Biotechnology Industry Organization: www.bio.org

Merck www.merck.com

Bristol Myers Squibb www.bms.com

2. Food and Agriculture Industry, GM crops, organic crops, flavors, Wine, Nutraceuticals,

GM Crops: The Economic Research Service of the US Department of Agriculture has the following website on biotech <http://www.ers.usda.gov/briefing/Biotechnology/>

International Food Information Center www.ific.org

The BIO: Biotechnology Industry Organization: www.bio.org

Monsanto www.monsanto.com - food and biofuels

Pioneer/DuPont www.pioneer.com

Small companies – Mendel Biotech, Ceres,

Organic agriculture: The Economic Research Service of the US Department of Agriculture has the following website on <http://www.ers.usda.gov/Briefing/Organic/>

United Nations Food and Agriculture Organization on international organic agriculture <http://www.fao.org/organicag/en/>

Pamela Ronald and Raoul Adamchak. [Tomorrow's Table: Organic Farming, Genetics, and the Future of Food](#)

3. Biofuels.

The Department of Energy has good website on alternative fuels

<http://www.afdc.energy.gov/afdc/fuels/index.html>

They also have a site for the US Biofuel Action Plan

http://apps1.eere.energy.gov/news/daily.cfm/hp_news_id=137

For Ethanol there is the Renewable Fuels Association www.ethanolrfa.org

For Biodiesel the Biodiesel Development Board <http://www.biodiesel.org/>

<http://www.biodiesel.org/>

Potential impacts of biofuel <http://bio.org/ind/advbio/EconomicImpactAdvancedBiofuels.pdf>

Exxon, BP, and Petrobras

Medium and smaller – Synthetic Genomics, Amyris and DSM

4. Consumer organizations

Food safety - Center for Science for the Public Interest <http://www.cspinet.org/>

For health and food safety information a general site is Public Citizen <http://www.citizen.org/hrg/>

Many disease specific organizations which may have public policy programs i.e. the American Cancer Society www.cancer.org

5. Government and policy organizations

U.S. Research Organizations

National Science Foundation NSF

National Institute of health NIH

Agricultural Research Service, U.S. Department of Agriculture.

National Renewable Energy Laboratory (NREL) Biomass program <http://www.nrel.gov/biomass/>

6. Regulatory Agencies:

Food and drug administration – www.fda.gov

Environmental Protection Agency - renewable fuels standard.

<http://epa.gov/otaq/renewablefuels/>

Class Schedule and Readings

Week I. Introduction and overview of course

Some Issues

Should the US and New Jersey government invest more money in research on basic biology research or biotechnology research like the New Jersey Cancer Research Institute, stem cell research, or the Rutgers Energy Institute or should we spend less money and try to balance the budget?

Should governments prohibit patents on genes or should they strengthen patents?

Should African and Asian government restrict or encourage the use of genetically engineered crops? How should it regulate these crops?

Should the US government continue to support the development of the biofuel industry with funding for research and pilot plants as well as subsidies for biofuel production?

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?

Week II. How are new pharmaceuticals, foods and biofuels developed?

Pharmaceutical research

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

Components of research: [http://www.innovation.org/index.cfm/nonav/Inside R & D](http://www.innovation.org/index.cfm/nonav/Inside_R_&_D)

Stories of the development of specific drugs – read one or two

<http://www.innovation.org/index.cfm/StoriesofInnovation/InnovatorStories>

Agricultural biotech research

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

Components of research: <http://www.monsanto.com/products/Pages/research-development-pipeline.aspx>

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.

Week III. Why do pharmaceutical, agricultural, food, environment, and energy industries invest billions of dollars to make new products?

Economics and the structure of the health, 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 *Food Supply Chain Management: Economic, Social and Environmental Perspectives* Chapters 3 and 4

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

Biofuel Pray and Deshmukh Biofuel Research in the US

Week IV. What have the biosciences contributed to society so far?

New pharmaceuticals –

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

PhRMA “Value of Medicines: Facts and figures 2006.”

<http://www.phrma.org/files/Value%20of%20Medicine%202006.pdf>

Food and agriculture

Jorge Fernandez-Cornejo and Margriet Caswell, The First Decade of Genetically Engineered Crops in the United States Economic Information Bulletin No. (EIB-11) April 2006. <http://www.ers.usda.gov/publications/eib11/>

For further reading - <http://www.ers.usda.gov/Briefing/Biotechnology/>

Biofuel impact Worldwatch Institute Chapters 7 and 8

Week V. Why government intervention and what policies are available?

Policy Ruttan Chapter 13 Science and technology policy. 534 - 553

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....

Week VI. 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,
Medicine Merrill Goozner, *The \$800 million Pill: the Truth Behind the Cost of New Drugs*. University of California Press: Berkeley, California. 2004. Chapter 1
Biofuel: Pray Chapter 10 Biofuel Research.

Speaker from Biotech Industry about relationship between government research and private innovation

Week VII.

***Presentation 2 and policy paper Government R&D Funding on Your Industry

Week VIII.

First Quiz

Week IX. - Spring Break

Week X. Intellectual property rights

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.

Week XI. Introduction to 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
Renewable Fuel Standards Overview 2012

Additional information:

Website on the US regulatory frameworks
Pharmaceuticals <http://www.fda.gov/fdac/special/testtubetopatient/default.htm>
Agricultural and Food Biotechnology <http://usbiotechreg.nbio.gov/>
and <http://www.aphis.usda.gov/brs/usregs.html>

Environmental Protection Agency - renewable fuels standard.
<http://epa.gov/otaq/renewablefuels/>

Week XII. Industrial development policies, and business incubators (Anwar Naseem)

Readings: On business incubators look at wikipedia on the topic and
<http://www.njbin.org/> for a description of some of incubators supported by the state of New Jersey
<http://ecocomplex.rutgers.edu/> for a description of the Rutgers Ecocomplex which is part of SEBS

Week XIII. Visit EcoComplex in Burlington New Jersey

Discuss role of government based incubators
Meet start-up companies on bioenergy who are working in this incubator.

Week XIV. Government procurement and mandates

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

Week XV. *Second midterm**

*** Finish Presentations and hand in second policy paper