Economics of Biotech and Medical Innovations
Economics 4290: Fall 2024

Professor: Dr. Vivek Ghosal
Website: https://faculty.rpi.edu/vivek-ghosal
Email: ghosav@rpi.edu
Office: Sage 3504. (Please email me if you have questions. We can set up meeting as needed.)
Classes: Mon, Thrs 4-5:50PM. Sage 3205.

** As we make progress during the semester, I may make some changes to this syllabus. All changes will be discussed in class and announcements posted on LMS/Blackboard.*

RPI Academic Calendar: Some key dates for Fall 2024
1. Sept 2. Monday. No class.
2. Sept 3. Tuesday. Class – Follow Monday class schedule.
3. Oct 14. Monday. No class.
4. Nov 8. Friday. Last day to drop course with W grade.
5. Nov 27-29. No class.
6. Dec 10. Tuesday. Last day of RPI classes.

* RPI's academic calendar: https://info.rpi.edu/registrar/academic-calendar

Cellphone Protocol
Please put away your cellphone during class. If you absolutely must use your cellphone, please step outside. No cellphone use during class lectures. I will remind everyone of this issue during class.

COURSE OVERVIEW

The aim of the course is to focus on biopharmaceuticals markets, within the broader context of healthcare and health insurance markets. We will examine economic theory and concepts, data, and quantitative analysis related to firms' activities in areas such as innovation, R&D expenditures, patents, pricing, mergers and acquisitions, and market competition. The course will shed light on the role played by health insurance systems in determining access and pricing of biopharmaceuticals. We will study the economic implications of regulations, such as those by the U.S. FDA, in bringing biopharmaceuticals to market, and issues related to effectiveness, pricing and access. The course will highlight the steep prices for new and innovative treatments, how these compare to older treatments, and the challenges faced by the U.S. healthcare system in paying for these therapies. Finally, the course will highlight economic and policy issues affecting the U.S. healthcare sector, along with selected comparisons to European national healthcare systems, and how they may affect innovation, pricing and access to biopharmaceuticals.

Learning Objectives

Consistent with the course materials related to biopharmaceuticals and healthcare markets, students will demonstrate understanding of advanced economic topics, and be able to communicate effectively in written and presentation forms. Via the tests and the written and oral assignments, students will be able to demonstrate proficiency in:
(a) economic concepts and theory to understand functioning of biopharmaceuticals markets;
(b) analyzing innovations in biopharmaceuticals markets;

(c) assessing data, methods and applications in biopharmaceuticals;
(d) interpretation of data and inferences; and
(e) policy issues in biopharmaceuticals markets.

IMPORTANCE OF CLASS LECTURES

The course involves a lot of reading on diverse topics and attending class will be very important to understanding the class materials. While the main readings will be posted on LMS, there will be a fair amount of materials that will be done during class on the whiteboard. The class whiteboard materials done during regular lectures are not available in document form posted on LMS. The class whiteboard materials will range from detailed discussions on various topics, solving numerical and mathematical problems, as well as various diagrams to show market equilibrium outcomes. As the materials get more complicated during the semester, it will be even more important to attend class as the in-depth discussions of the main readings will be done on the whiteboard. It is essential that you attend class and stay current with class lectures, as the context and discussions in class are going to be important for understanding the materials.
If you miss class, please connect with students in the class to get details on materials we went through during the class.

READINGS

There is **no** textbook for the course. All class materials will be based on readings. These will be sequentially posted on Blackboard as we make progress during the semester. The discussion on stock price movements will be based on class lectures only.

SEQUENCE OF MATERIALS

** I will post slides and readings on each item as we make progress during the semester.*

1. Essentials of Markets and Competition

** We will spend very little time on this section in class as much of this is introductory economics materials. I will spend some time on relevance of the concepts for markets such as pharmaceuticals and insurance. Please make sure you go through these slides in their entirety to understand the key concepts which we will use through the semester.*

- Costs of production
- Demand
- Profit maximization
- Competitive and monopoly markets
- Potential limitations of competitive and monopoly markets for studying biopharmaceuticals
- Role of health insurance

2. Models of Oligopolistic Competition

** These materials are more complex in terms of how to solve the models and their implications for pricing and will require careful understanding. Solving these models and working out pricing and profit implications will continue till the end of the semester.*

- Competition with a limited number of firms
- Firms in differentiated products markets
- Modeling biopharmaceuticals markets
- Implications for pricing and policy

3. Firms' Stock Price Movements
Class lectures on stock price movements will be incorporated throughout the discussions on biopharmaceuticals markets.

4. Markets for Healthcare
** We will be selective and focus on those items that are important to understanding the markets for biopharmaceuticals. We will discuss medical care and insurance markets in some detail as these are critical to reimbursement policies, access, and pricing.*

Medical care markets
Health insurance
Healthcare systems and policies

5. Markets for Biopharmaceuticals
** The 3 modules noted below are the key components of the course. Readings will be posted sequentially on each treatment module as we make progress.*

Modules. Treatment categories: Product (Firm).

1. Autoimmune Disorders: *Humira* (Abbvie).
2. Hepatitis C: *Sovaldi* and *Harvoni* (Gilead Sciences).

Within each module, the areas of focus will be:

Innovation, R&D, patents
Mergers and acquisitions
Structure of market, pricing, competition
Access to treatments (private insurance, Medicare, Medicaid)
Health outcomes
Policy implications

6. Role of Policy
** This policy part will be woven into the discussions throughout the semester and the different modules indicated above.*

Innovation, access, pricing
Healthcare systems
Selected comparisons to European systems and outcomes related to pricing and access

TESTS AND PAPER

1. Tests

There will be **three tests** during the semester. Tests will be in-class during the scheduled class period.

Each test will contain 4-5 short-answer questions with sub-parts. **All tests will be partially cumulative** – it is difficult to separate some of the materials in topics numbered 1-2 (above) from those that appear in 3-6. Test scores will be available about 10-12 days after the test.

Test 1: Monday, Oct 7. 50 points.
Test 2: Thursday, Nov 14. 50 points.
Test 3: Thursday, Dec 5. 50 points.
NOTE:
* I will provide more details on tests as we make progress.

* I may make changes to the test dates. If I do, I will announce it well before the test date. Since the tests are during class time, they do not pose conflicts with other classes.
* Before each test, I will post review materials and sample problems.

NO makeups tests will be administered. The **ONLY** exceptions are:

1. If you are ill. A doctor's note is required.
2. For RPI approved official activities.

Makeup tests can create fairness and other problems. Since I would exhaust the set of reasonable questions for the regularly scheduled test, writing makeups inevitably implies me searching for different questions to ask. For fairness, the policy of no makeups will be adhered to without exception irrespective of the student's personal situation. In the event there is a makeup exam due to valid reasons, the score-to-grade conversion on the makeup will be same as in the regular test.

2. Short Paper

Paper is worth 65 points. **See end of this document for details**.

The final paper is due on **Monday, December 2.** You can submit your final paper earlier. I will announce dates for submission of intermediate drafts as we make progress.

Important:

(a) If you miss the deadline for submission of final version of paper, 10 points will be deducted from the score for the paper for each team member.

(b) If you miss the deadline for intermediate draft of paper, 5 points will be deducted from the score for the paper for each team member.

(c) During assigned date for class presentations, all team members must be present. Unless there are medical or other valid reasons for absence (see criteria for makeup tests for this). If you are absent for the presentation, 5 points will be deducted from the score for the paper for the team member absent for the presentation. (All team members must be present on the day of presentation.)

3. Course Grade

Total points for the class are 215: 150 points for the three tests; and 65 points for the paper.

I will use the class mean (μ) and standard deviation (σ) of scores as "cutoffs" to convert numerical scores to letter grades.

A: ($\mu+\sigma$)	A^-: ($\mu+0.50\sigma$)	
B^+: ($\mu+0.25\sigma$)	B: (μ)	B^-: ($\mu-0.25\sigma$)
C^+: ($\mu-0.50\sigma$)	C: ($\mu-\sigma$)	D: ($\mu-1.5\sigma$)

For example, on a total of 100 points, if the class mean (μ) is 80 and standard deviation (σ) is 8, then we have the following cutoffs for letter grades. A (88); A- (84); B+ (82); B (80); B- (78); C+ (76); C (72); D (68).

Please note that the distribution after any one test is imperfect due to small sample. Once the test scores add up, the distribution based on the cumulative scores (a larger sample) makes more sense. In other words, you will get a better idea of course letter grade after Test 2. If you have any questions about your grades, please email me and we can set up a time to discuss as needed.

Important: For those taking S/U option, to get a "Satisfactory" or "Pass" grade in this course you will need to maintain **at least a C**. A grade of C minus or less is Unsatisfactory or Fail. There will be no exceptions to this rule.

ACADEMIC INTEGRITY

Student-teacher relationships are built on mutual respect and trust. Students must be able to trust that their teachers have made responsible decisions about the structure and content of the course and that they are conscientiously making their best effort to help students learn. Teachers must be able to trust that students do their work conscientiously and honestly, making their best effort to learn. Acts that violate this mutual respect and trust undermine the educational process. The Rensselaer Handbook of Students Rights and Responsibilities defines various forms of Academic Dishonesty and you should make yourself familiar with these. In this class, all assignments that are turned in for a grade must represent the student's own work (or in teams as agreed upon up front). The required research paper should reflect an equivalent amount of effort by each group member.

POLICY ON COLLABORATION, CHEATING, PLAGIARISM

As per current RPI expectations, cheating or plagiarism will be reported to the Dean of Students. In addition, a score of zero will be given on the first assignment or Test where cheating or plagiarism is detected. If there is a subsequent infraction the student will receive a grade of F for the course. If a student has any question concerning this policy before submitting an assignment, please ask the course instructor for clarification.

Definition of plagiarize (https://www.merriam-webster.com/dictionary/plagiarize)
"transitive verb
: to steal and pass off (the ideas or words of another) as one's own: use (another's production) without crediting the source"

In the context of the course, you **may not** copy and paste materials (sentences, paragraphs, and other items) from the readings, or any other materials elsewhere (e.g., papers and readings online), to write your paper, and any other class written component. Any materials used from the readings or from online sources must be fully cited. If plagiarism is detected, I will deduct points as noted above, with a warning. The second violation will be reported to the Dean of Students. Please make sure you understand this policy carefully and avoid any violation.

ELECTRONIC WARNING SYSTEM (EWS) POLICY

RPI's Electronic Warning System (EWS) helps instructors, academic advisors, ALAC staff, and others to alert each other to a student showing possible problems so services can be coordinated as needed. RPI's broad policy is stated as:

> "When an instructor or academic advisor notices that a student has problems in a particular class or with academic progress in general, filing an EWS message shares that information with others so that services can be coordinated to help the student. Reported concerns might include irregular attendance, assignments not handed in, poor test or quiz performance, poor math skills, poor communication skills, failing a course, missing an advisor meeting, slow rate of progress, or other issues. Once an EWS message is submitted, an email describing the problem(s) or concern(s) is sent to the student (in all but "other" cases), plus the instructor, academic advisor, advising Hub representative, Student Success Office, and ALAC. The instructor and/or academic advisor is expected to contact and meet with the student to resolve the concerns. If a student has multiple warnings or the concern goes beyond academic matters, support offices such as the Counseling Center, Student Success Office and/or ALAC are asked to intervene."

Consistent with this, I will report on related issues via EWS.

See next page for details on paper and template …

SHORT PAPER DETAILS

1. Objective is to write a short paper highlighting a specific innovation in biopharmaceuticals or medical devices. The innovation you study needs to be cutting-edge, clearly defined, and represent a marked improvement over existing technology and treatment benefits.

2. Total points=65.

3. Paper will be written in teams of 2-3 students. There will be no single-student papers.

4. Length of paper: about 15 pages double-spaced. (It can be slightly more if needed to make your paper complete.) This includes the main paper content, plus figures, tables, and references. Formatting: 12-point font and 1" margins.

5. Structure of paper: see sample template presented below.

6. Sample papers from previous semesters will be posted on the class blackboard site.

7. The final version of the paper should be emailed to me as a **Word file** by the end of day (midnight) on **Monday, December 2**. There will be no extension of the final paper deadline.

8. I will announce dates for submission of intermediate drafts of the paper.
(a) First draft will be to get started with names of team members, topic, and brief motivation.
(b) Second draft will contain details on innovation and some data on pricing and overall costs.
I will provide comments on the second draft to help you iterate towards the final version.

9. I will schedule a presentation of papers. These will be discussion-based presentations designed to highlight key aspects of the paper, with details on innovation, pricing, and overall benefits and costs. I will announce more details in class as we make progress. Comments provided during presentations will also help you make progress towards completing the paper.

Template for Paper

Below is a rough template for the paper. I am listing the potential sections in a sequence. Please note that the specifics of your paper will vary based on your choice of topic and particular innovation you study. We will discuss details in class.

You should choose a topic (biopharma or medical device innovation) that is relatively recent. If it is too old, then data and information are often hard to find. Further, the innovation studied needs to be distinct – this will also provide you with more information. We will discuss this in class.

Items your paper should include (sequence of items below can be thought of a sections of the paper)

1. Topic and motivation.

2. Medical condition being treated.

3. Specific treatment advancement. Be specific about biopharma or device. For example:
(a) Biopharma - CAR-T cell therapy:

https://www.cancer.gov/about-cancer/treatment/research/car-t-cells
(b) Medical devices (listing some recent innovations/FDA approvals):
https://www.fda.gov/medical-devices/recently-approved-devices/2022-device-approvals

4. Specific details about innovation in the treatment
How innovative is it compared to previous treatment? (Once you identify what you may want to study, the treatments or devices have extensive information on the web, FDA site, biopharma or manufacturer site, etc.) Describe health benefits of new treatment. Compare to previous treatment(s).

5. FDA trials information
Approval date plus some key highlights.
Once you identify a specific biopharma or device, you can go to the FDA website and enter that item for trials information. Or do a Google search by that biopharma or device name and clinical trials. This will give you the information you need.

6. Information about price of treatment
Compare to previous treatment.
For example, Kymriah is a CAR-T cell therapy, with new competition.
https://www.fiercepharma.com/pharma/bristol-myers-squibb-breyanzi-gilead-yescarta-lock-horns-car-t-therapy-earlier-lymphoma
https://www.primetherapeutics.com/news/real-world-car-t-treatment-costs-can-range-from-700000-to-1-million-2/
https://www.healio.com/news/hematology-oncology/20190529/car-tcell-therapy-total-cost-can-exceed-15-million-per-treatment
(For some treatments it may be hard to get price information. Do search for this information. If actual data or estimate is not available, then mention it and skip this detail.)

7. Posted sticker price versus what patients actually pay. Role of insurance (private, Medicare. Medicaid). Manufacturer patient copy discounts.

8. Competition for the treatment
If yes, highlight one or two competitors. Similarities, differences. Search for this information – if competitors are in market, this information is available. For example, for the CAR-T cell therapy, there are now options:
https://clarivate.com/lp/car-t-cell-therapy-pipeline-and-forecast-snapshot/?lid=d

9. Information about patients' access to the treatment: via private insurance, Medicare, Medicaid.

10. Information about costs to the overall healthcare system

11. Wrap-up and policy implications
Briefly comment on benefits and costs of specific treatment or device. How expensive it is compared to benefits it may offer? Policy implications: e.g., cost to healthcare system of the treatment.
For example, for CAR-T cell therapy noted above – some items:
https://www.statnews.com/2021/09/22/medicare-part-b-payment-caps-limit-outpatient-access-to-car-t/
https://www.medicare.org/articles/does-medicare-cover-car-t-therapy/
https://www.ashclinicalnews.org/spotlight/drawing-first-blood/car-t-cell-therapies-worth-costs/

https://www.healthleadersmedia.com/clinical-care/medicare-cover-costly-car-t-cell-cancer-therapy-nationwide
https://www.healthcarefinancenews.com/news/medicare-cover-expensive-car-t-cell-cancer-therapy-questions-remain-full-cost-hospitals